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Presidential Determination No. 2022–04 of November 12, 2021

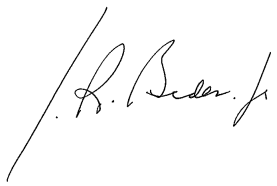
Presidential Determination Pursuant to Section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012

Memorandum for the Secretary of State[,] the Secretary of the Treasury[, and] the Secretary of Energy

By the authority vested in me as President by the Constitution and the laws of the United States, after carefully considering the reports submitted to the Congress by the Energy Information Administration, including the report submitted in August 2021, and other relevant factors, including global economic conditions, the level of spare capacity, and the availability of strategic reserves, I determine, pursuant to section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012, Public Law 112–81, and consistent with prior determinations, that there is a sufficient supply of petroleum and petroleum products from countries other than Iran to permit a significant reduction in the volume of petroleum and petroleum products purchased from Iran by or through foreign financial institutions.

I will continue to monitor this situation closely.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, November 12, 2021

[FR Doc. 2021–25436
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Presidential Documents

Proclamation 10309 of November 16, 2021

Suspension of Entry as Immigrants and Nonimmigrants of Persons Responsible for Policies or Actions That Threaten Democracy in Nicaragua

By the President of the United States of America

A Proclamation

In light of the importance to the United States of fostering democratic processes and institutions in Nicaragua to help the Nicaraguan people achieve their aspirations for democracy, and given the suppression of human rights and democracy in Nicaragua, I have determined that it is in the interest of the United States to restrict and suspend the entry into the United States, as immigrants and nonimmigrants, of members of the Government of Nicaragua, led by President Daniel Ortega, including his spouse and Vice President Rosario Murillo, and others described in this proclamation who formulate, implement, or benefit from policies or actions that undermine or injure democratic institutions or impede the return to democracy in Nicaragua.

The repressive and abusive acts of the Ortega government and those who support it compel the United States to act. The Ortega government's crackdown on opposition leaders, civil society leaders, and journalists in preparation for the November 2021 Nicaraguan presidential and legislative elections harms the institutions and processes essential to a functioning democracy. The Ortega government's undemocratic, authoritarian actions have crippled the electoral process and stripped away the right of Nicaraguan citizens to choose their leaders in free and fair elections.

The Ortega government's detention of and denial of fair trial guarantees to peaceful protesters, civil society leaders, private sector leaders, student leaders, political leaders, journalists, and presidential candidates in Nicaragua stifles political discourse and the democratic process. Police and prison authorities contribute to the repressive climate the Ortega government promotes by carrying out politically motivated arrests and detentions of individuals exercising their human rights and holding political prisoners incommunicado, without access to lawyers, family members, and needed medical care. Family members and the media have reported that some prisoners have lost significant weight in detention, cannot walk unassisted, have been held in solitary confinement, and are subjected to frequent, extensive interrogations. The physical and psychological abuse of political prisoners at the hands of police and prison authorities is intolerable and cannot stand.

The Ortega government controls multiple security services, including non-uniformed, armed, and masked parapolice, who abuse persons to further the Ortega government's authoritarian agenda, including by harassing, threatening, and committing violence against those opposed to the government. Members of the Nicaraguan National Police (NNP), along with violent mobs of pro-government supporters also controlled by government actors, have attacked religious institutions in retaliation for their support for political and religious leaders.

Municipal officials, acting on direct orders from the Ortega government, have directed violence against pro-democracy protesters in their communities and other local actors opposed to the government. For example, mayors

and mayors' offices loyal to the Ortega government have organized and channeled state funds to parapolice groups engaged in violent repression. These municipal officials wield enormous political power and discretionary budget authority, conferred upon them from the highest levels of the Ortega government. The climate of fear established and perpetuated by these municipal officials has diminished the possibility of free and fair elections and undermined democracy in Nicaragua.

The judiciary has failed the Nicaraguan people by aiding and abetting the Ortega government's use of politically motivated charges to lock up political prisoners. By stacking the judiciary with government-controlled judges and prosecutors, the Ortega government has abused the justice system to silence critics. Authorities have held many political prisoners incommunicado for months, without access to their lawyers, and with no knowledge of the spurious charges presented against them.

The widespread impunity for crimes committed against opposition actors; the persistent corruption practiced by Nicaraguan government officials in the performance of public functions that has eroded democratic institutions; and the continued failure of President Daniel Ortega, Vice President Rosario Murillo, Nicaraguan government officials, and others to support the rule of law, human rights, and other principles of high priority to the United States demand a forceful response.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, including sections 212(f) and 215(a) of the Immigration and Nationality Act (8 U.S.C. 1182(f) and 1185(a)) and section 301 of title 3, United States Code, hereby find that the unrestricted immigrant and nonimmigrant entry into the United States of persons described in section 1 of this proclamation would, except as provided for in section 4 of this proclamation, be detrimental to the interests of the United States, and that their entry should be subject to certain restrictions, limitations, and exceptions. I therefore hereby proclaim the following:

Section 1. *Suspension and Limitation on Entry*. The entry into the United States, as immigrants or nonimmigrants, of the following persons is hereby suspended:

(a) Members of the Government of Nicaragua, including elected officials and their staff members;

(b) Mayors, vice mayors, or political secretaries who planned, ordered, assisted, aided and abetted, committed, or otherwise participated in, including through command responsibility, serious abuses or violations of human rights to punish peaceful protestors or deny Nicaraguans fundamental freedoms, or who attempted or conspired to do so;

(c) Officials of Nicaragua's security services, including the Nicaraguan Military, NNP, Directorate of Special Police Operations, parapolice groups, and paramilitary groups;

(d) Officials of the Nicaraguan penitentiary administration;

(e) Senior members of the Nicaraguan judiciary, Public Prosecutors Office, and Ministry of the Interior;

(f) Members of Nicaraguan government ministries, regulatory agencies, parastatal companies, higher education administrators and faculty, and elected officials who undertake actions, including human rights abuses, to deny services to those who make peaceful efforts to demand the return to democracy in Nicaragua;

(g) Non-government persons who serve as agents of or act at the behest of those described in subsections (a)–(f) of this section to facilitate or derive financial benefit from policies or actions, including electoral fraud, human rights abuses, or corruption, that undermine or injure democratic institutions or impede the return to democracy in Nicaragua; and

(h) The spouses, sons, and daughters of persons described in subsections (a)–(g) of this section.

Sec. 2. *Authority of the Secretary of State to Identify Covered Individuals.* Persons covered by section 1 of this proclamation shall be identified by the Secretary of State, or the Secretary of State's designee, in the Secretary of State's sole discretion, pursuant to such procedures as the Secretary of State may establish.

Sec. 3. *Implementation of Suspension and Limitation on Entry.* The Secretary of State shall implement this proclamation as it applies to visas pursuant to such procedures as the Secretary of State, in consultation with the Secretary of Homeland Security, may establish. The Secretary of Homeland Security shall implement this proclamation as it applies to the entry of noncitizens pursuant to such procedures as the Secretary of Homeland Security, in consultation with the Secretary of State, may establish.

Sec. 4. *Scope of Suspension and Limitation on Entry.* Section 1 of this proclamation shall not apply to:

(a) Any lawful permanent resident of the United States;

(b) Any individual who has been granted asylum by the United States, any refugee who has already been admitted to the United States, or any individual granted withholding of removal or protection under the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, and nothing in this proclamation shall be construed to affect any individual's eligibility for asylum, refugee status, withholding of removal, or protection under the Convention Against Torture, consistent with the laws and regulations of the United States;

(c) Any person otherwise covered by section 1 of this proclamation, upon determination by the Secretary of State that the person has ceased actions that undermine democratic institutions and taken concrete steps to help restore democracy in Nicaragua; or

(d) Any person otherwise covered by section 1 of this proclamation, upon determination by the Secretary of State that the person's entry would not be contrary to the interests of the United States, including when the Secretary of State so determines, based on a recommendation of the Attorney General, that the person's entry would further important United States law enforcement objectives. In exercising this responsibility, the Secretary of State shall consult the Secretary of Homeland Security on matters related to admissibility or inadmissibility within the authority of the Secretary of Homeland Security.

Sec. 5. *Termination.* This proclamation shall remain in effect until terminated by the President. The Secretary of State shall, as circumstances warrant, recommend whether the President should continue, modify, or terminate this proclamation.

Sec. 6. *General Provisions.* (a) Nothing in this proclamation shall be construed to impair or otherwise affect:

(i) United States Government obligations under applicable international agreements;

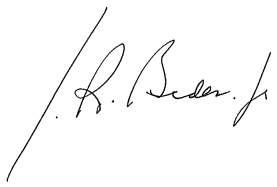
(ii) the authority granted by law to an executive department or agency, or the head thereof; or

(iii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This proclamation shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This proclamation is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

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



[FR Doc. 2021–25418
Filed 11–18–21; 8:45 am]
Billing code 3395–F2–P

Rules and Regulations

Federal Register
Vol. 86, No. 221
Friday, November 19, 2021

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

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1029; Project Identifier MCAI–2020–01126–T; Amendment 39–21777; AD 2021–22–04]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2019–21–10, which applied to all Airbus SAS Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2019–21–10 required a one-time eddy current conductivity measurement of certain structural parts of the outer flaps to determine if the incorrect alloy was used, and replacement if necessary. This AD continues to require a one-time eddy current conductivity measurement of certain structural parts of the outer flaps to determine if the incorrect alloy was used, and replacement if necessary; and also requires a new one-time eddy current conductivity measurement of certain other structural parts of the outer flaps to determine if the parts were properly heat treated, and replacement if necessary; and includes additional affected airplanes; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD was prompted by a quality control review, which determined that the wrong aluminum alloy was used to manufacture several structural parts and by the issuance of an updated list of suspected parts, including those that may have been improperly heat treated. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 27, 2021.

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

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1029.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1029; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3223; email: *sanjay.ralhan@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0174, dated August 5, 2020 (EASA AD 2020–0174) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –215, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2019–21–10, Amendment 39–19776 (84 FR 63794, November 19, 2019) (AD 2019–21–10). AD 2019–21–10 applied to all Airbus SAS Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The NPRM published in the **Federal Register** on November 20, 2020 (85 FR 74299). The NPRM was prompted by a quality control review, which determined that the wrong aluminum alloy was used to manufacture several structural parts and by the issuance of an updated list of suspected parts, including those that may have been improperly heat treated. The NPRM proposed to continue to require a one-time eddy current conductivity measurement of certain structural parts of the outer flaps to determine if the incorrect alloy was used, and replacement if necessary, as specified in EASA AD 2019–0012, dated January 24, 2019 (which corresponds to FAA AD 2019–21–10). The NPRM also proposed to require a new one-time eddy current conductivity measurement of certain other structural parts of the outer flaps to determine if the parts were properly heat treated, and replacement if necessary, and to include additional affected airplanes, as specified in EASA AD 2020–0174.

The FAA is issuing this AD to address structural parts that may not meet the certified life limit, which could result in failure of the flap trailing edge and reduced controllability of the airplane. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Include All Required Airplanes in the SUMMARY of the NPRM

Bradley Schrock requested the FAA include the additional required Airbus Model airplanes in the **SUMMARY** section of the NPRM. The commenter pointed out that the additional models could easily be overlooked if the reader were to only read the **SUMMARY** of the NPRM.

The FAA does not agree to revise the **SUMMARY** of this final rule. Operators are required to follow the applicability of the AD, which is specified in paragraph (c) of this AD. While the **SUMMARY** of this final rule doesn't specify all airplanes affected by this AD, it does specify that the FAA is adding airplanes to the applicability. Additionally, in the Background section of this final rule, the FAA has included all airplane models that are affected by this AD. Further, the **SUMMARY** section is a preamble requirement for all documents published in the **Federal Register** and must follow drafting requirements prescribed by the Office of the Federal Register (OFR). The **SUMMARY** section briefly provides context for the document within the **Federal Register**/CFR publication system; it does not summarize the content of the document. Adding the requested airplane models does not follow the OFR's requirements for the **SUMMARY** section. The FAA has not changed this final rule in this regard.

Request To Revise Compliance Statement in Paragraph (f) of the Proposed AD for Model A321 Airplanes

Delta Air Lines (DAL) requested that the FAA revise the compliance statement in paragraph (f) of the proposed AD for Model A321 airplanes. DAL suggested that paragraph (f) of the NPRM be revised to read: ''Comply with this AD within the compliance times specified, unless already done. For A321 operators, the earliest date that compliance may have occurred is 29MAY2020 (the issuance date of [EASA] PAD 19–100R1).'' DAL pointed out that the suspected parts are line replaceable units (LRUs) with off-wing Instructions for Continued Airworthiness, and that these parts comprise a pool of rotable parts. DAL then specified that no revision of the service information referenced in EASA AD 2020–0174 has included the serial numbers of outer flap tabs. DAL stated that EASA AD 2020–0174 allows the use of any revision of the service information for the determination of these suspected parts. Further, DAL argued that, for Model A321 operators, the use of any service information revision for determination of suspected part applicability is inadequate for the identification of suspected outer flap tabs. DAL asserted that before May 29, 2020, comparison with the outer flap serial number lists within the service information referenced in EASA AD 2020–0174 could allow inadvertent exclusion of an outer flap tab that is included in the quality escape population.

The FAA does not agree to revise the compliance statement in paragraph (f) of this AD. As stated previously, EASA AD 2020–0174 takes precedence over the service information referenced therein and this AD requires using EASA AD 2020–0174 for determining suspected parts. EASA AD 2020–0174 specifies using the service information only for accomplishing the required inspections and not for identifying the suspected parts. The FAA has determined EASA AD 2020–0174 addresses the unsafe condition on the universe of suspected parts. Further, the FAA has determined that the information provided by EASA and the manufacturer is adequate information for accomplishing the required actions. The FAA has not changed this AD regarding this issue.

Request To Add Exception To Clarify the Definition of Suspected Improperly Heat Treated (IHT) Parts

DAL requested that the FAA revise the NPRM to include an exception to EASA AD 2020–0174 to clarify the definition of suspected IHT parts for Model A321 airplanes. DAL specified that, for Model A321 airplanes, the suspected IHT parts are constituent parts of the outer flap tabs, not the outer flaps as defined in EASA AD 2020–0174. DAL mentioned that if not clarified, the definition could introduce confusion for operators of Model A321 airplanes.

The FAA does not agree to include an exception to EASA AD 2020–0174. Appendix 2 of EASA AD 2020–0174 refers to the airplane manufacturer serial numbers, flap serial numbers, and the flap tab part numbers, based on the airplane configuration at the time of delivery to the first operator. Therefore, the FAA has determined that, even though the definition specified in EASA AD 2020–0174 does not explicitly state that, for Model A321 airplanes the suspected IHT parts are constituent to the outer flap tabs, the information necessary to make that determination is already included in Appendix 2 of EASA AD 2020–0174, which the definition references. The FAA has not changed this AD regarding this issue.

Request To Include Additional Service Information for Determining Affected Parts

DAL requested that the FAA revise the NPRM to include Airbus In-Service Information (ISI) Document 57.50.00022, which DAL stated includes outer flap and outer flap tab part number definitions for the serial numbers defined in Appendix 1 and Appendix 2 of EASA AD 2020–0174. DAL pointed out that Appendix 1 and Appendix 2 of EASA AD 2020–0174 do not contain any outer flap or outer flap tab (Model A321) part numbers, instead specifying the suspected part population by LRU serial number. DAL also mentioned that Airbus does not consider the Model A321 flap tab serial numbers to be Aircraft Inspection Report (AIR) recordable within each airplane's delivery records. DAL implied that most operators would have difficulty tracing outer flap tab serial numbers to specific airplane manufacturer serial numbers. DAL also stated that there has been enough operator demand for clarification from the manufacturer that Airbus released ISI 57.50.00022. DAL noted that ISI 57.50.00022 is not referenced in the service information specified by EASA AD 2020–0174.

The FAA disagrees with the request. This AD is based on EASA AD 2020–0174, which is based on the configuration of the airplane at the time of delivery (as indicated in Notes 2 and 3 of EASA AD 2020–0174). It is not possible for the FAA to know all of the operator-specific part numbers and serial numbers installed on all of the airplanes affected by this AD or EASA AD 2020–0174. Therefore, it is the operator's responsibility to track these parts, so that they can identify discrepant parts as defined in the EASA AD and apply appropriate corrective actions. If an operator's fleet configuration, including part tracking system, does not allow compliance with the requirements of this AD, then that operator must present a customized plan for AD compliance for the applicable airplane with a request for an alternative method of compliance (AMOC) under the provisions of paragraph (i)(1) of this AD. It is impractical for the FAA to customize an AD in a way that meets operator's specific requirements for compliance. The FAA has not changed this AD regarding this issue.

Request To Include an Exception to the Method of Compliance

DAL requested that the FAA add an exception to include a statement that,

for demonstration of compliance with Paragraph (5) of EASA AD 2020–0174, the part serial number does not need to be positively identified, provided that it can be determined that the part is serviceable using the definition provided in EASA AD 2020–0174. DAL mentioned that the service information specified in EASA AD 2020–0174 does not contain part numbers for suspected parts, and instead the only part numbers within the service information appendices are the part numbers of potentially discrepant structural parts, which on Model A321 airplanes are not serialized. DAL pointed out that verbatim application of the service information might cause improper evaluation of parts for applicability of the suspected part definition. DAL continued to point out that the service information conflicts with EASA AD 2020–0174, and that EASA AD 2020–0174 bounds the suspected outer flap tab population by outer flap tab serial number in Appendix 2 of EASA AD 2020–0174. DAL then pointed out that verbatim application of the service information on Model A321 airplanes could introduce the possibility that the inspection of an outer flap tab with potentially discrepant internal structure is not completed.

The FAA does not agree to include the requested exception. This AD requires EASA AD 2020–0174, which is based on the configuration of an airplane at the time of delivery. As specified in EASA AD 2020–0174, if a serial number cannot be identified, then that part is defined as a suspected part. EASA AD 2020–0174 takes precedence over any instructions specified in the service information it references. Therefore, operators can comply with the requirements of this AD. However, once this AD is published, any person may present sufficient data and rationale and request approval of an AMOC under the provisions of paragraph (i)(1) of this AD. The FAA has not changed this AD regarding this issue.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

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

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0174 describes procedures for a one-time eddy current conductivity measurement of certain structural parts of the outer flaps to determine if the incorrect alloy was used, and replacement if necessary; and a one-time eddy current conductivity measurement of certain other structural parts of the outer flaps to determine if the parts were properly heat treated, and replacement if necessary. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 63 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2019-21-10	6 work-hours × $85 per hour = $510	$0	$510	$32,130
New actions	5 work-hours × $85 per hour = $425	0	425	26,775

* Table does not include estimated costs for reporting.

The FAA estimates that it takes about 1 work-hour per product to comply with the reporting requirement in this AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be $5,355, or $85 per product.

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

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

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2019–21–10, Amendment 39–19776 (84 FR 63794, November 19, 2019); and

■ b. Adding the following new AD:

2021–22–04 Airbus SAS: Amendment 39–21777; Docket No. FAA–2020–1029; Project Identifier MCAI–2020–01126–T.

(a) Effective Date

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

(b) Affected ADs

This AD replaces AD 2019–21–10, Amendment 39–19776 (84 FR 63794, November 19, 2019) (AD 2019–21–10).

(c) Applicability

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

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

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

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

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

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by a quality control review, which determined that the wrong aluminum alloy was used to manufacture several structural parts and by the issuance of an updated list of suspected parts, including those that may have been improperly heat treated. The FAA is issuing this AD to address structural parts that may not meet the certified life limit, which could result in failure of the flap trailing edge and reduced controllability of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0174, dated August 5, 2020 (EASA AD 2020–0174).

(h) Exceptions to EASA AD 2020–0174

(1) Where EASA AD 2020–0174 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2020–0174 does not apply to this AD.

(3) Where paragraphs (7) and (8) of EASA AD 2020–0174 mandate a parts installation limitation, this AD requires the following parts installation limitation: From the effective date of this AD, only serviceable parts as defined in EASA AD 2020–0174 are allowed to be installed on any airplane.

(4) Where any service information referenced in EASA AD 2020–0174 specifies reporting, this AD requires reporting all inspection results at the applicable time specified in paragraph (h)(4)(i) or (ii) of this AD. If operators have reported findings as part of obtaining any corrective actions approved by Airbus SAS's EASA Design Organization Approval (DOA), operators are not required to report those findings as specified in this paragraph.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

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

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(3) *Required for Compliance (RC):* Except as required by paragraphs (h)(4) and (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

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

(j) Related Information

For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3223; email: *sanjay.ralhan@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2020–0174, dated August 5, 2020.

(ii) [Reserved]

(3) For EASA AD 2020–0174, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu*; internet: *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1029.

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

Issued on October 13, 2021.

Gaetano A. Sciortino,

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

[FR Doc. 2021–25201 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0508; Project Identifier MCAI–2021–00070–T; Amendment 39–21747; AD 2021–20–09]

RIN 2120–AA64

Airworthiness Directives; ATR–GIE Avions de Transport Régional Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–03–03, which applied to certain ATR–GIE Avions de Transport Régional Model ATR72 airplanes. AD 2021–03–03 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2021–03–03, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 27, 2021.

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

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of March 31, 2021 (86 FR 11103, February 24, 2021).

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0508.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0508; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220; email *shahram.daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0020, dated January 15, 2021 (EASA AD 2021–0020) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all ATR–GIE Avions de Transport Régional Model ATR72 airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–03–03, Amendment 39–21406 (86 FR 11103, February 24, 2021) (AD 2021–03–03). AD 2021–03–03 applied to certain ATR–GIE Avions de Transport Régional Model ATR72 airplanes. The NPRM published in the **Federal Register** on July 20, 2021 (86 FR 38239). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in EASA AD 2021–0020.

The FAA is issuing this AD to address fatigue cracking and damage in principal structural elements, which could result in reduced structural integrity of the airplane. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0020 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires EASA AD 2020–0173, dated August 5, 2020, which the Director of the Federal Register approved for incorporation by reference as of March 31, 2021 (86 FR 11103, February 24, 2021). This material is reasonably available because the interested parties have access to it through their normal course of business

or by the means identified in the **ADDRESSES** section.

Costs of Compliance

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

The FAA estimates the total cost per operator for the retained actions from AD 2021–03–03 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2021–03–03, Amendment 39–21406 (86 FR 11103, February 24, 2021); and

■ b. Adding the following new AD:

2021–20–09 ATR–GIE Avions de Transport Régional: Amendment 39–21747; Docket No. FAA–2021–0508; Project Identifier MCAI–2021–00070–T.

(a) Effective Date

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

(b) Affected ADs

This AD replaces AD 2021–03–03, Amendment 39–21406 (86 FR 11103, February 24, 2021) (AD 2021–03–03).

(c) Applicability

This AD applies to ATR–GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before October 9, 2020.

(d) Subject

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

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking and damage in principal structural elements, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Maintenance or Inspection Program Revision, With No Changes

This paragraph restates the requirements of paragraph (k) of AD 2021–03–03, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before December 12, 2019, except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0173, dated August 5, 2020 (EASA AD 2020–0173). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2020–0173, With Revised Exceptions

This paragraph restates the requirements of paragraph (l) of AD 2021–03–03, with revised exceptions.

(1) Where EASA AD 2020–0173 refers to its effective date, this AD requires using March 31, 2021 (the effective date of AD 2021–03–03).

(2) The requirements specified in paragraphs (1) and (3) of EASA AD 2020–0173 do not apply to this AD.

(3) Paragraph (4) of EASA AD 2020–0173 specifies revising ''the approved AMP [aircraft maintenance program]'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, to incorporate the ''limitations, tasks and associated thresholds and intervals'' specified in paragraph (4) of EASA AD 2020–0173 within 90 days after March 31, 2021 (the effective date of AD 2021–03–03).

(4) Except as provided by paragraph (2) of EASA AD 2020–0173, the initial compliance time for doing the tasks specified in paragraph (4) of EASA AD 2020–0173 is at the applicable ''associated thresholds'' specified in paragraph (4) of EASA AD 2020–0173, or within 90 days after March 31, 2021 (the effective date of AD 2021–03–03), whichever occurs later.

(5) The provisions specified in paragraphs (5) and (6) of EASA AD 2020–0173 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2020–0173 does not apply to this AD.

(i) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (m) of AD 2021–03–03, with a new exception. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals, are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2020–0173.

(j) New Maintenance Program Revision

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0020,

dated January 15, 2021 (EASA AD 2021–0020). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2021–0020

(1) Where EASA AD 2021–0020 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2021–0020 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2021–0020 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) Except as provided by Note 1 of EASA AD 2021–0020, the initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2021–0020 is at the applicable ''thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2021–0020, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraphs (4) and (5) of EASA AD 2021–0020 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2021–0020 does not apply to this AD.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0020.

(m) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(n) Related Information

For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220; email *shahram.daneshmandi@faa.gov.*

(o) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on December 27, 2021.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0020, dated January 15, 2021.

(ii) [Reserved]

(4) The following service information was approved for IBR on March 31, 2021 (86 FR 11103, February 24, 2021).

(i) European Union Aviation Safety Agency (EASA) AD 2020–0173, dated August 5, 2020.

(ii) [Reserved]

(5) For EASA AD 2021–0020 and AD 2020–0173, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

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

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

Issued on November 14, 2021.

Ross Landes,

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

[FR Doc. 2021–25203 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0880; Project Identifier MCAI–2021–00685–T; Amendment 39–21779; AD 2021–22–06]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 747–400F series airplanes. This AD was prompted by the determination that more restrictive tasks and limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate more restrictive tasks and limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective December 6, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 6, 2021.

The FAA must receive comments on this AD by January 3, 2022.

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

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

For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section,

Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* under Docket No. FAA–2021–0880.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* under Docket No. FAA–2021–0880; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0880; Project Identifier MCAI–2021–00685–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0138, dated June 9, 2021 (EASA AD 2021–0138) (also referred to as the MCAI), to correct an unsafe condition for certain The Boeing Company Model 747–400F series airplanes.

This AD was prompted by the determination that more restrictive tasks and limitations are necessary.

EASA approved supplemental type certificate (STC) 10068342, dated January 16, 2019, which installs a dual non-activated global navigation satellite system (GNSS) unit and antenna on The Boeing Company Model 747–400F series airplanes. EASA STC 10068342 was validated by the FAA as STC ST04393NY, dated September 3, 2019. After EASA approved the original STC, Fokker Services published an updated Instructions for Continued Airworthiness (ICA) supplement that introduced more restrictive tasks. The STC was later amended and approved by EASA as STC 10068342, Revision 1, dated March 8, 2021, and validated by the FAA as STC ST04393NY, Revision 1, dated May 3, 2021. The amended STC incorporates the updated ICA supplement. As a result, operation of an affected airplane with the original STC but without the ICA supplement could result in cracks around the antenna/unit installation.

The FAA is issuing this AD to address cracks around the antenna/unit installation, which, if unchecked, could lead to rapid decompression of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0138 describes more restrictive tasks and limitations associated with the GNSS unit and antenna. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Requirements of This AD

This AD requires accomplishing the actions specified in EASA AD 2021–0138 described previously, except for any differences identified as exceptions in the regulatory text of this AD, and except as discussed under ''Differences Between this AD and the MCAI.''

This AD requires revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (j)(1) of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2021–0138 is incorporated by reference in this AD. This AD requires compliance with EASA AD 2021–0138 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the

heading of a particular section in EASA AD 2021–0138 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0138. Service information required by EASA AD 2021–0138 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0880 after this AD is published.

Difference Between This AD and the MCAI

Whereas EASA AD 2021–0138 applies to airplanes with EASA STC 10068342 embodied, this AD applies to airplanes with U.S. STC ST04393NY embodied. As stated previously, EASA STC 10068342 has been validated by the FAA as STC ST04393NY.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) and intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

FAA's Justification and Determination of the Effective Date

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

There are currently no domestic operators of these products. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Regulatory Flexibility Act (RFA)

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

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. For any affected airplane that may be imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD.

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the FAA recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleets, the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the FAA estimates the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–22–06 The Boeing Company: Amendment 39–21779; Docket No. FAA–2021–0880; Project Identifier MCAI–2021–00685–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 6, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–400F series airplanes, certificated in any category, equipped with a dual non-activated global navigation satellite system (GNSS) unit and antenna installed in accordance with supplemental type certificate (STC) ST04393NY, dated September 3, 2019.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by the determination that more restrictive tasks and limitations are necessary. The FAA is issuing this AD to address cracks around the antenna/unit installation, which, if unchecked, could lead to rapid decompression of the aircraft.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0138, dated June 9, 2021.

(h) Exceptions to EASA AD 2021–0138

(1) Where EASA AD 2021–0138 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2021–0138 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2021–0138 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2021–0138 is at the applicable ''thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2021–0138, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraph (4) of EASA AD 2021–0138 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2021–0138 does not apply to this AD.

(i) Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0138.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(k) Related Information

For more information about this AD, contact Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2021–0138, dated June 9, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0138, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

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

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

Issued on October 13, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–25200 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0781; Project Identifier AD–2021–00775–E; Amendment 39–21831; AD 2021–24–10]

RIN 2120–AA64

Airworthiness Directives; Austro Engine GmbH Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–09–04 for all Austro Engine GmbH E4 and E4P model diesel piston engines. AD 2021–09–04 required replacing a certain oil pump as well as the oil filter and engine oil. This AD was prompted by reports of an oil pump blockage on E4 model diesel piston engines. This AD requires replacing a certain oil pump as well as the oil filter and engine oil. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 27, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of May 10, 2021 (86 FR 21637, April 23, 2021).

ADDRESSES: For service information identified in this final rule, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, 2700 Weiner Neustadt, Austria; phone: +43 2622 23000; website: *www.austroengine.at.* You may view this service information at the Airworthiness Products Section, Operational Safety Branch, FAA, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0781.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0781; or in person at Docket Operations between 9 a.m. and 5 p.m.,

Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Wego Wang, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7134; fax: (781) 238–7199; email: *wego.wang@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–09–04, Amendment 39–21517 (86 FR 21637, April 23, 2021), (AD 2021–09–04). AD 2021–09–04 applied to all Austro Engine GmbH E4 and E4P model diesel piston engines. The NPRM published in the **Federal Register** on September 14, 2021 (86 FR 51026). The NPRM was prompted by reports of an oil pump blockage on E4 model diesel piston engines caused by oil contamination with casting sand from the production process of oil pump part number (P/N) E4A–50–000–BHY. The root cause was found to be an improperly performed sand casted oil pump housing cleaning process. In the NPRM, the FAA proposed to continue to require replacement of an affected oil pump, identified by P/N and serial number (S/N) in Austro Engine GmbH Mandatory Service Bulletin No. MSB–E4–030/4, Revision No. 4, dated March 30, 2021. In the NPRM, the FAA also proposed to require replacement of the oil filter and engine oil.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

The FAA reviewed the relevant data and determined that air safety requires adoption of the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Austro Engine GmbH Mandatory Service Bulletin No. MSB–E4–030/4, Revision No. 4, dated March 30, 2021 (the MSB). This service information specifies procedures for replacing the affected oil pumps installed on E4 and E4P model diesel piston engines. This service information also specifies procedures for replacing the oil filter and engine oil installed on these engines. In addition, this service information identifies the applicable S/Ns of affected E4 and E4P model diesel piston engines, the affected oil pumps requiring replacement, and an additional oil pump replacement option. The Director of the Federal Register previously approved the MSB for incorporation by reference on May 10, 2021 (86 FR 21637, April 23, 2021). This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 55 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove and replace the oil pump, oil filter, and engine oil.	16 work-hours × $85 per hour = $1,360	$1,488	$2,848	$156,640

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2021–09–04, Amendment 39–21517 (86 FR 21637, April 23, 2021); and
■ b. Adding the following new airworthiness directive:

2021–24–10 Austro Engine GmbH: Amendment 39–21831; Docket No. FAA–2021–0781; Project Identifier AD–2021–00775–E.

(a) Effective Date

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

(b) Affected ADs

This AD replaces AD 2021–09–04, Amendment 39–21517 (86 FR 21637, April 23, 2021).

(c) Applicability

This AD applies to all Austro Engine GmbH E4 and E4P model diesel piston engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 8550, Reciprocating Engine Oil System.

(e) Unsafe Condition

This AD was prompted by reports of an oil pump blockage on the E4 model diesel piston engines. The FAA is issuing this AD to prevent failure of the engine lubrication system. The unsafe condition, if not addressed, could result in failure of the engine, in-flight shutdown, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

For Austro Engine GmbH E4 and E4P model diesel piston engines having an oil pump, part number (P/N) E4A–50–000–BHY, with a serial number (S/N) listed in paragraph 1.2., Engines Affected, of Austro Engine GmbH Mandatory Service Bulletin No. MSB–E4–030/4, Revision No. 4, dated March 30, 2021 (the MSB), within the compliance time specified in Table 1 to paragraph (g) of this AD or before further flight, whichever occurs later:

(1) Remove the oil pump, P/N E4A–50–000–BHY, from service and replace with a part eligible for installation using the Accomplishment/Instructions, paragraph 2.2.1 or paragraph 2.2.2, of the MSB, as applicable.

(2) Replace the oil filter and engine oil using the Accomplishment/Instructions, paragraph 2.2.1 or paragraph 2.2.2, of the MSB, as applicable.

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Table 1 to Paragraph (g) – Replacement of the Oil Pump, Oil Filter, and Engine Oil

Engine Group	Engine Flight Hours (FHs) Since New as of May 10, 2021 (the effective date of AD 2021-09-04)	Compliance Time (after May 10, 2021, the effective date of AD 2021-09-04)
Group 1 engines and Group 2 engines	10 FHs or less	Within 30 days or before accumulating 10 FHs, or during the next scheduled maintenance, whichever occurs first
Group 1 engines	More than 10 FHs, but less than 50 FHs	Within 3 months or before accumulating 70 FHs since new, or during the next scheduled maintenance, whichever occurs first
Group 1 engines	50 FHs or more	Within 3 months or 20 FHs, or during the next scheduled maintenance, whichever occurs first
Group 2 engines	More than 10 FHs	Within 3 months or 100 FHs, or during the next scheduled maintenance, whichever occurs first

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(h) No Reporting Requirements

The reporting requirements in the Accomplishment/Instructions, paragraph 2.2., of the MSB, are not required by this AD.

(i) Installation Prohibition

After the effective date of this AD, do not install onto any engine an oil pump, P/N

E4A–50–000–BHY, with an S/N listed in paragraph 1.2., Engines Affected, of the MSB.

(j) Definitions

For the purpose of this AD:

(1) Group 1 engines are E4 model diesel piston engines in configuration ''-A'' that are installed on single-engine airplanes.

(2) Group 2 engines are E4 model diesel piston engines in configuration ''-B'' or ''-C'' and E4P model diesel piston engines that are installed on twin-engine airplanes.

(3) A ''part eligible for installation'' is an oil pump with a P/N and S/N that is not listed in paragraph 1.2., Engines Affected, of the MSB.

(k) Credit for Previous Actions

You may take credit for replacing the oil pump, oil filter, and engine oil required by paragraph (g) of this AD if you performed these replacements before the effective date of this AD using the Accomplishment/Instructions, paragraph 2.2., of Austro Engine GmbH MSB No. MSB–E4–030, Original Issue, dated February 18, 2021; Revision No. 1, dated February 23, 2021; Revision No. 2, dated March 3, 2021; or Revision No. 3, dated March 18, 2021.

(l) Alternative Methods of Compliance (AMOCs)

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

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

(m) Related Information

For more information about this AD, contact Wego Wang, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7134; fax: (781) 238–7199; email: *wego.wang@faa.gov.*

(n) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on May 10, 2021 (86 FR 21637, April 23, 2021).

(i) Austro Engine GmbH Mandatory Service Bulletin No. MSB–E4–030/4, Revision No. 4, dated March 30, 2021.

(ii) [Reserved]

(4) For service information identified in this AD, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, 2700 Weiner Neustadt, Austria; phone: +43 2622 23000; website: *www.austroengine.at.*

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

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

Issued on November 15, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–25259 Filed 11–18–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0695; Project Identifier MCAI–2021–00096–R; Amendment 39–21783; AD 2021–22–10]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model A109E helicopters. This AD was prompted by reports that certain tail rotor gearbox assemblies were installed on Model A109E helicopters and those parts are not approved for installation on that helicopter model. Because those assemblies are not part of the type design for Model A109E helicopters, there are no overhaul or life limits included in the applicable maintenance manuals. This AD requires replacement of each affected tail rotor gearbox assembly with a serviceable part, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 27, 2021.

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

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N 321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0695.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0695; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the EASA AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0031, dated January 22, 2021 (EASA AD 2021–0031) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for Leonardo S.p.A., formerly Finmeccanica S.p.A., AgustaWestland S.p.A., and Agusta S.p.A., Model A109E helicopters, all serial numbers up to 11160 inclusive.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Leonardo S.p.a. Model A109E helicopters. The NPRM published in the **Federal Register** on August 25, 2021 (86 FR 47427). The NPRM was prompted by reports that certain tail rotor gearbox assemblies were installed on Model A109E helicopters and those parts are not approved for installation on that

helicopter model. During revisions to the Model A109E technical publications it was noted that the 90-degree tail rotor gearbox assembly, part number (P/N) 109–0440–01–115, is included in the illustrated parts catalog (IPC) for helicopters with serial numbers (S/N) up to and including S/N 11160. The IPC incorrectly identifies this part number as a replacement part for P/N 109–0440–01–119 or P/N 109–0440–01–121. The NPRM proposed to require replacement of each affected tail rotor gearbox assembly with a serviceable part, as specified in EASA AD 2021–0031.

The FAA is issuing this AD to address installation of tail rotor gearbox assembly P/N 109–0440–01–115 that is not approved for installation on Model A109E helicopters. Because P/N 109–0440–01–115 is not part of the type design for Model A109E helicopters, there are no overhaul or life limits included in the applicable maintenance manuals. If a tail rotor gearbox is not properly maintained it could fail, resulting in reduced control of the helicopter. See EASA AD 2021–0031 for additional background information.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0031 requires replacement of a tail rotor gearbox assembly P/N 109–0440–01–115 with a serviceable part. EASA AD 2021–0031 also prohibits installation of tail rotor gearbox assembly P/N 109–0440–01–115 on any Leonardo S.p.A. Model A109E helicopter.

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

Costs of Compliance

The FAA estimates that this AD affects 70 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement	12 work-hours × $85 per hour = $1,020	$82,500	$83,520	$5,846,400

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–22–10 Leonardo S.p.a.: Amendment 39–21783; Docket No. FAA–2021–0695; Project Identifier MCAI–2021–00096–R.

(a) Effective Date

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

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model A109E helicopters, certificated in any category, with an affected part as identified in European Union Aviation Safety Agency (EASA) AD 2021–0031, dated January 22, 2021 (EASA AD 2021–0031) installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6520, Tail Rotor Gearbox.

(e) Unsafe Condition

This AD was prompted by reports that certain tail rotor gearbox assemblies were installed on Model A109E helicopters and those parts are not approved for installation on that helicopter model. Because tail rotor gearbox assembly part number (P/N) 109–0440–01–115 is not part of the type design for Model A109E helicopters, there are no overhaul or life limits included in the applicable maintenance manuals. The FAA is issuing this AD to address installation of tail

rotor gearbox assembly P/N 109–0440–01–115 on Model A109E helicopters that do not have overhaul or life limits for that part. If a tail rotor gearbox is not properly maintained it could fail, resulting in reduced control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0031.

(h) Exceptions to EASA AD 2021–0031

(1) Where EASA AD 2021–0031 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2021–0031 refers to its effective date, this AD requires using the effective date of this AD.

(3) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2021–0031.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2021–0031 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

For more information about this AD, contact Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2021–0031, dated January 22, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0031, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0695.

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

Issued on October 14, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–25215 Filed 11–18–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0687; Project Identifier 2019–SW–029–AD; Amendment 39–21782; AD 2021–22–09]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model AW189 helicopters. This AD was prompted by a report that a number of fairleads that support the engine combustion chamber D1 drain hose showed evidence of heat damage. This AD requires modifying the helicopter by installing a certain engine combustion chamber D1 drain assembly, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 27, 2021.

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

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0687.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0687; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0039, dated February 20, 2019 (EASA AD 2019–0039) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Leonardo S.p.A. Model AW189 helicopters.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Leonardo S.p.a. Model AW189 helicopters. The NPRM published in the **Federal Register** on August 23, 2021 (86 FR 47033). The

NPRM was prompted by a report that a number of fairleads that support the engine combustion chamber D1 drain hose showed evidence of heat damage. The NPRM proposed to require modifying the helicopter by installing a certain engine combustion chamber D1 drain assembly, as specified in an EASA AD.

The FAA is issuing this AD to address heat damage of the engine combustion chamber D1 drain hose, which in a case where the right-hand engine is operated in the one engine inoperative (OEI) rating, the D1 drain pipe could transfer so much heat to the nearby fuel system vent pipe that its internal surface temperature could exceed the auto-ignition temperature for fuel. The unsafe condition, if not addressed, could result in undetected fire ignition in the fuel tank bay with consequent loss of the helicopter. See the MCAI for additional background information.

Comments

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

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

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

Related Service Information Under 1 CFR Part 51

EASA AD 2019–0039 requires modifying the helicopter by installing the engine combustion chamber D1 drain assembly, part number 8G7170P00111.

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

Costs of Compliance

The FAA estimates that this AD affects 4 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification	4 work-hours × $85 per hour = $340	$2,557	$2,897	$11,588

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–22–09 Leonardo S.p.a.: Amendment 39–21782; Docket No. FAA–2021–0687; Project Identifier 2019–SW–029–AD.

(a) Effective Date

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

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AW189 helicopters, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2019–0039, dated February 20, 2019 (EASA AD 2019–0039).

(d) Subject

Joint Aircraft Service Component (JASC) Code: 7170, Engine Drains.

(e) Unsafe Condition

This AD was prompted by a report that a number of fairleads that support the engine combustion chamber D1 drain hose showed evidence of heat damage. The FAA is issuing this AD to address such heat damage, which in a case where the right-hand engine is operated in the one engine inoperative (OEI) rating, the D1 drain pipe could transfer so much heat to the nearby fuel system vent pipe that its internal surface temperature could exceed the auto-ignition temperature for fuel. The unsafe condition, if not addressed, could result in undetected fire ignition in the fuel tank bay with consequent loss of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2019–0039.

(h) Exceptions to EASA AD 2019–0039

(1) Where EASA AD 2019–0039 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2019–0039 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where the service information required by EASA AD 2019–0039 specifies discarding parts, this AD requires removing those parts from service.

(4) This AD does not require the ''Remarks'' section of EASA AD 2019–0039.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2019–0039 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the airplane to a location where the helicopter can be modified, provided the OEI rating is prohibited on the right-hand engine.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Related Information

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

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2019–0039, dated February 20, 2019.

(ii) [Reserved]

(3) For EASA AD 2019–0039, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0687.

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

Issued on October 14, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–25213 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2021–0332]

RIN 1625–AA09

Drawbridge Operation Regulation; Indiana Harbor Canal, East Chicago, IN

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

ACTION: Final rule.

SUMMARY: The Coast Guard is altering the operating schedule that governs the Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal at East Chicago, Indiana. Indiana Department of Transportation, the owner and operator of the bridge, has requested to stop continual drawtender service to the bridge due to a lack of openings.

DATES: This rule is effective December 20, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type USCG–2021–0332 in the ''SEARCH'' box and click ''SEARCH.'' In the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email: Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email *Lee.D.Soule@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
IGLD85 International Great Lakes Datum of 1985
INDOT Indiana Department of Transportation
LWD Low Water Datum based on IGLD85
OMB Office of Management and Budget
NPRM Notice of proposed rulemaking
§ Section
USACE United States Army Corps of Engineers
U.S.C. United States Code
USEPA United States Environmental Protection Agency

II. Background Information and Regulatory History

On July 28, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled ''Drawbridge Operation Regulation; Indiana Harbor Canal, East Chicago, IN,'' in the **Federal Register** (86 FR 40388). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this regulatory change. During the comment period that ended on September 27, 2021, we did not receive any comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499.

The Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal is a double leaf bascule bridge that provides a horizontal clearance of 68-feet and a vertical clearance of 12-feet in the closed position with an unlimited vertical clearance in the open position based on low water datum (LWD). The Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal is required to open on signal, and there are no previous rulemakings for this bridge to discuss. The Indiana Harbor Canal is a 3-mile long commercial waterway that serves several industries near the City of East Chicago, Indiana, including the largest integrated steelmaking facility in North America and the 1,400 acre Whiting Refinery that includes the site of the former 1889 Standard Oil of

Indiana refinery at the head of navigation. The Indianapolis Boulevard Bridge, mile 2.59, over the Indiana Harbor Canal is the last drawbridge before the head of navigation. Once the 1889 Standard Oil of Indiana refinery was torn down the bridge lost its purpose for regular openings, and the waterway silted in around the bridge preventing vessels from approaching. Approximately thirty years after the removal of the refinery, the U.S. Environmental Protection Agency (EPA) and the U.S. Army Corps of Engineers (USACE) partnered to remove polluted sediments form the waterway and established a contaminated dredge spoils area above the bridge. The EPA and USACE contracted dredging company is working a few weeks each season and is the only commercial vessel requesting the bridge to open. There are no records of recreational vessels using the Indiana Harbor Canal.

IV. Discussion of Comments, Changes and the Final Rule

The Coast Guard provided a comment period of 60 days and no comments were received.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the ability that vessels can still transit the bridge given advanced notice.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.400, add paragraph (c) to read as follows:

§ 117.400 Indiana Harbor Canal.

* * * * *

(c) The Indianapolis Boulevard Bridge, mile 2.59, at East Chicago, shall open on signal if at least twelve hours' notice is given.

M.J. Johnston.

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2021–25268 Filed 11–18–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2482–F2]

RIN 0938–AT82

Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States

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

ACTION: Final rule.

SUMMARY: This final rule will delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to a value based purchasing (VBP) arrangement, of the final rule entitled, ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'', published in the December 31, 2020 **Federal Register** to July 1, 2022. This final rule will also delay for 9 months the April 1, 2022 effective date of inclusion (hereinafter referred to as the inclusion date) of the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) in the amended regulatory definitions of ''States'' and ''United States'' for purposes of the Medicaid Drug Rebate Program (MDRP), adopted in the interim final rule with comment period entitled, ''Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States'', published in the November 25, 2019 **Federal Register** to January 1, 2023. We requested public comment on the proposed delays of the applicable effective date and inclusion date and discuss the comments received in this final rule.

DATES: These regulations are effective on December 20, 2021.

FOR FURTHER INFORMATION CONTACT: Christine Hinds, (410) 786–4578.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of Proposed Delays in Effective and Inclusion Dates of Certain Regulation Provisions

In the ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements: Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States'' proposed rule that published in the May 28, 2021 **Federal Register** (86 FR 28742) (hereinafter referred to as the proposed rule), CMS made two proposals. First, CMS proposed to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the final rule entitled, ''Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' (85 FR 87000) (hereinafter referred to as the December 31, 2020 final rule), for 6 months to July 1, 2022. Second, CMS proposed to delay the April 1, 2022, inclusion date in the amended regulatory definitions of ''States'' and ''United States'', adopted in the interim final rule with comment period entitled ''Medicaid Program; Covered Outpatient Drugs; Further Delay of Inclusion of Territories in Definitions of States and United States'' (84 FR 64783), for 2 years until April 1, 2024, or in the alternative, to a date earlier than April 1, 2024, but not before January 1, 2023 based on public comments.

B. Proposed Delay of Effective Date of Amendatory Instruction 10.a.

The December 31, 2020 final rule advanced CMS' efforts to support state flexibility to enter into innovative value-based purchasing (VBP) arrangements with drug manufacturers for new and innovative, and often costly therapies, such as gene therapies, and codified new approaches required by section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018) and the existing Medicaid DUR program to improve the clinical use of opioids and reduce the potential for abuse in Medicaid patients. In addition, it codified in regulation several changes made in recent legislation and clarified other provisions of regulations relating to the Medicaid Drug Rebate Program (MDRP).

The regulations included in the December 31, 2020 final rule went into effect on March 1, 2021, except for certain amendatory instructions, including instruction 10.a., which is effective on January 1, 2022. In the proposed rule, we proposed to delay the January 1, 2022 effective date for amendatory instruction 10.a. of the December 31, 2020 final rule on manufacturer reporting of multiple best prices connected to a VBP arrangement, to July 1, 2022, and sought public comment on the proposed delay. As discussed in the proposed rule, we believed a delay of 6 months is warranted to assure that stakeholders have the ability to implement the new VBP policy in a manner that assures patient access and quality of care are protected. We sought public comments on this proposed delay in the effective date, including the impact of this delay on affected beneficiaries. The primary reason for the original delay, and the proposed delay, was to provide more time for CMS, states, and manufacturers to make the complex system changes necessary to implement the new best price and VBP program, and assure patient access and quality of care, given the current need to devote resources to the public health emergency (PHE) relating to COVID–19 that has been in effect, and will likely remain in effect at least through 2021. On April 21, 2021, the Secretary of Health and Human Services (the Secretary) renewed the PHE initially declared on January 31,

2020, to continue giving CMS programs (including Medicaid) flexibility to support beneficiaries during the COVID–19 pandemic. This PHE was most recently renewed on October 15, 2021. In response to the PHE, CMS put in place its own pandemic plan (*https://www.cms.gov/files/document/covid-pandemic-plan.pdf*) to address the needs of its stakeholders, as well as the beneficiaries of its various programs including Medicaid. As part of that plan, CMS provided that it may approve waivers, amendments, and flexibilities for U.S. states, including the District of Columbia, and U.S. territories to allow Medicaid and CHIP programs to adapt their operations as necessary to respond to the pandemic. The pandemic plan also provided that it may make adjustments to the agency's value-based payment initiatives to allow health providers, healthcare facilities, Medicare Advantage and Part D plans, and States to focus on providing needed care to beneficiaries. In addition to the flexibilities granted to states under the PHE, the President signed into law on March 11, 2021, the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) to address the health care and economic needs of the country during the pandemic. This law is one of the most significant expansions of Medicaid since enactment of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), and includes several new mandatory benefit requirements on states that will take time to implement.

We acknowledged in the December 31, 2020 final rule that the changes to the reporting of multiple best prices by manufacturers under the MDRP (a VBP policy) adopted under the amendatory instruction 10.a would require additional time to provide operational guidance and complex system changes to implement. Thus, we delayed the effective date of the VBP provision until January 1, 2022. States that opt to participate in VBP models offered by manufacturers under the multiple best price approach must ensure that beneficiaries have appropriate access to care under such arrangements by developing systems and methods to track beneficiaries and their outcomes, retrieving and evaluating the patient-specific outcomes data, and securing the cooperation of providers and beneficiaries to enter into some of the more complex outcome-based arrangements offered by the manufacturers. Thus, there will be requirements on states to develop significant capabilities to build an infrastructure that will be able to implement VBP.

We also noted that we want to be sure that our own technology infrastructure will be ready to receive multiple VBP offers from manufacturers that will report them to CMS, and subsequently report them to states. We developed a new Medicaid Drug Program (MDP) system. This MDP system will replace CMS' current legacy system with certain aspects of the system expected to be transitioned in the summer of 2022. However, because of other events that have transpired since the regulation was published on December 31, 2020, we explained in the proposed rule that we did not believe that certain aspects of the system necessary for states and manufacturers to operationalize the VBP multiple best price program would be transitioned at that time, making a January 1, 2022 effective date infeasible. We also noted that we believed that it is important to have a technically up-to-date system that is ready to support the data requirements necessary for states and manufacturers to operationalize the VBP multiple best price program. When the proposed rule was issued, we were concerned we could have a delay with operationalizing that part of the MDP system, which could mean we would not have the necessary CMS components in place by later this year to implement the program by January 1, 2022, and believed July 1, 2022, to be a more realistic target date. As noted in the proposed rule, the demands on researching, producing, and distributing COVID–19 drug treatments and vaccines have likely diverted some manufacturer financial and human resources from developing and implementing system changes that would be required to enter multiple best price offers in the MDP system.

We also stated that in the proposed rule that we understand that there was interest among patient and consumer groups, states, and manufacturers in the new multiple best price policy, and that we were committed to implementing the VBP multiple best price policy in a manner that assures that Medicaid beneficiaries have access to medications and therapies that are appropriately administered and monitored. However, we remain concerned that there are several challenges the states, providers, and manufacturers are facing during the PHE. These included those resulting from the passage of the ARP, including those relating to implementing expanded eligibility and mandatory benefit requirements under Medicaid (as described below). In summary, states, providers and manufacturers, as well as CMS, will need additional time to operationalize the multiple best prices policy under amendatory instruction 10.a.

Therefore, given the possible delay in the MDP system and the recent developments around the PHE and ARP, we explained in the proposed rule that we believe more time is critical to permit CMS and our partners—states, providers, and manufacturers—to successfully implement the multiple best prices approach so that Medicaid patients benefit from these programs to full extent possible.

Specifically, CMS and all the parties involved with the multiple best prices policies will want to make sure Medicaid patients receive the drug therapies under the VBP approach that are prescribed for them in a timely manner; that the VBP program does not create unnecessary barriers or requirements on the patient to access the drug; that they receive appropriately scheduled doses of a therapy if the patient treatment under the VBP arrangement is based on multiple doses; and that patient outcomes are tracked so that optimal patient care is provided; and, the states can obtain any additional discounts due to them from manufacturers under the VBP arrangement. We also believe it is in the best interest of the Medicaid program and Medicaid beneficiaries, in particular, that states prioritize the Medicaid eligibility and benefit requirements under the ARP (for example, expanded optional Medicaid coverage for postpartum women, expansion of COVID–19 testing and treatment services, and expansion of vaccine administration to limited benefit groups), resulting from enactment of the ARP to address beneficiary needs during the COVID–19 pandemic. Therefore, we proposed a delay to the effective date for amendatory instruction 10.a. (the multiple best price approach) of 6 months (effective July 1, 2022). By allowing more time to address the needs of Medicaid beneficiaries during the PHE, states, CMS, providers, and manufacturers will also have more time to put in place appropriate beneficiary protections as part of the multiple best price approach. Again, by delaying the effective date of the amendment permitting multiple best price reporting for 6 months, the amendatory instruction 10.a would be effective beginning July 1, 2022. In the proposed rule, CMS also stated it expects to issue additional guidance before that time on operational and policy aspects of the new VBP program, including specifications relating to beneficiary protections.

C. Proposed Delay of Inclusion Date of U.S. Territories in Amended Regulatory Definitions of ''States'' and ''United States''

The Covered Outpatient Drug (COD) final rule, published in the February 1, 2016 **Federal Register** (81 FR 5170), amended the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) for the purposes of the MDRP with a delayed effective date of April 1, 2017. We stated in the preamble to the final rule that U.S. territories may use existing waiver authority to elect not to participate in the MDRP consistent with the statutory waiver standards. Specifically, the Northern Mariana Islands and American Samoa may seek to opt out of participation under the broad waiver that has been granted to them in accordance with section 1902(j) of the Social Security Act (the Act). Puerto Rico, the Virgin Islands, and Guam may use waiver authority under section 1115 of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with the applicable requirements of section 1927 of the Act (81 FR 5203 through 5204).

The change to the definition of ''States'' and ''United States'' under the COD final rule to include the territories would also impact the quarterly calculation of average manufacturer price (AMP) and best price by manufacturers. That is, the change requires manufacturers to include prices paid by entities in the U.S. territories in the same manner in which they include prices paid by entities located in one of the 50 states and District of Columbia (81 FR 5224) in AMP and best price. It requires manufacturers to include eligible sales and associated discounts, rebates, and other financial transactions that take place in the U.S. territories in their calculations of AMP and best price once the revised definitions of ''States'' and ''United States'' take effect, regardless of whether the U.S. territories seek to waive participation in the MDRP.

Once the COD final rule became effective, CMS began discussions with the territories regarding their participation in the MDRP. Based on those discussions, it became evident that interested territories would not be ready to participate in the MDRP by April 1, 2017. Stakeholders also reiterated the concerns in the comments to the COD final rule (81 FR 5224) that drug manufacturers will likely need to increase drug prices paid by U.S. territory Medicaid programs once the territories are included in the definitions of ''States'' and ''United States'' to avoid setting a new, lower best price. That is because if prices for drugs in the territories are lower than those in the states, then those prices could become the Medicaid best price for that drug in the entire Medicaid program. The manufacturers may then increase their drug prices in the territories to avoid this outcome, and an increase in drug prices in the territories could result in an increase in territory Medicaid drug spending without the offsetting benefit of receiving Medicaid rebates. Furthermore, the increase in Medicaid drug spending could adversely impact the availability of drugs to patients in the territories because of their Medicaid funding cap.

As a result of these initial and subsequent discussions on preparedness, the potential for increased Medicaid drug prices in certain territories, and later, due to additional impacts of natural disasters in several of the territories, CMS issued two interim final rules with comment period (IFC) to further delay the effective date for including the U.S. territories in the regulatory definitions of ''States'' and ''United States'' for purposes of the MDRP. The first, the ''Medicaid Program; Covered Outpatient Drug; Delay in Change in Definitions of States and United States'' IFC, was issued on November 15, 2016, amending the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories beginning April 1, 2020, rather than to April 1, 2017 (81 FR 80003). The second, the ''Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States'' IFC, was published on November 25, 2019, and further delayed the inclusion date for amending the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories to April 1, 2022, rather than April 1, 2020 (84 FR 64783).

For similar reasons, in addition to ensuring continued beneficiary access and quality of care protections, we proposed to amend 42 CFR 447.502 to delay the April 1, 2022 inclusion date for the amended regulatory definitions of ''States'' and ''United States'' to April 1, 2024, and sought public comment on the proposed delay. In the alternative, we proposed to finalize an earlier inclusion date, but no earlier than January 1, 2023, based on public comments received. We explained in the proposed rule that we believe an additional delay of 2 years may be warranted because it would allow the territories to focus their human and financial resources on ensuring the health and well-being of their beneficiaries during this PHE, rather than having to divert those resources to the development of systems required to participate in the MDRP, which can take several years to implement from start to finish, and sought public comments on the proposal.

As discussed in the proposed rule, we believe that in light of the pandemic and the resource demands stemming from the PHE (including those established under the ARP) on the Medicaid program and its beneficiaries, it is imperative that the territories prioritize the Medicaid eligibility and mandatory benefit requirements brought about by the ARP to address beneficiary needs during the COVID–19. Therefore, we believe that a further delay in the inclusion date of the U.S. territories in the regulatory definitions of ''States'' and ''United States'' is warranted and proposed an inclusion date beginning April 1, 2024. In the alternative, we proposed to finalize an inclusion date that may be earlier than April 1, 2024, but not before January 1, 2023, based on public comments received.

We explained in the proposed rule that by delaying the inclusion date to April 1, 2024, or in the alternative, a date earlier than April 1, 2024, but not before January 1, 2023, we are allowing the territories additional time to develop needed systems and policy changes, to avoid unintended increases in drug costs and access concerns. The needed systems must be capable of collecting, reporting, validating, and tracking drug utilization on an ongoing basis. In addition, they require extensive advance planning and budgeting.

The proposed delay in inclusion date would also benefit those territories that choose not to participate in the MDRP, which would be required to use human and financial resources that are currently focused on responding to the PHE to complete the section 1115 and section 1902(j) waiver applications that are required to waive out of MDRP participation should the current April 1, 2022 date remain in effect.

Moreover, as explained in the proposed rule, should the amended regulatory definitions of ''States'' and ''United States'' go into effect on April 1, 2022, all manufacturers' sales to the territories and prices paid will be included in the AMP and best price calculations at that time, regardless of whether the territory is participating in the MDRP. As discussed in the COD final rule (81 FR 5224), we heard from various stakeholders who stated concerns that drug manufacturers would likely be prompted to increase drug

prices, including prices paid by the U.S. territory Medicaid programs, once the territories are included in the definitions of ''States'' and ''United States.'' This is because, as currently drafted, section 1927 of the Act requires that eligible sales of drugs within the United States be included in the drug manufacturers calculation of AMP and best price. The inclusion of these prices in AMP and best price could result in the territories that receive a waiver realizing an increase in their Medicaid drug costs without the offsetting benefit of receiving Medicaid rebates. Furthermore, the increase in Medicaid costs could adversely affect territories because of their Medicaid funding cap. As noted previously in the proposed rule, that could result in an increase in drug prices in the territories, making drugs less affordable, and making it more difficult for the territories to address their own public health needs during the PHE. We believe this provides further rationale for delaying the effective date of the inclusion of the territories in the regulatory definitions of ''States'' and ''United States.'' It will ensure that during this PHE, which has the potential to extend into 2022, those territories that opt to waive participation from the MDRP will not face the additional financial burdens associated with increased Medicaid drug costs from drug manufacturers increasing drug prices to the territories.

We proposed a new inclusion date of April 1, 2024, for the amended regulatory definitions of ''States'' and ''United States'' to include the U.S. territories for purposes of the MDRP. In the alternative, we proposed to finalize an inclusion date that may be earlier than April 1, 2024, but before January 1, 2023, based on public comments received. We specifically requested comments on whether April 1, 2024, or an earlier inclusion date, but not earlier than January 1, 2023, would be more appropriate for the amended regulatory definitions. More specifically, we requested public comments that will assist us in understanding all relevant concerns related to establishing a new inclusion date, including whether territories are ready to participate in the MDRP, and whether CMS is able to execute appropriate and necessary waivers for territories that do not want to participate. In any case, manufacturers would be required to include their sales to the territories in their AMP and best price calculations based on the inclusion date finalized in a final rule, which we proposed to be April 1, 2024, or possibly earlier, but no earlier than January 1, 2023 based on public comments.

II. Response to Public Comments and Provisions of the Final Rule

In response to the proposed rule, we received 29 public comments.

A. Delay of Effective Date of Amendatory Instruction 10.a. (§ 447.505(a))

The following is a summary of the comments received and our responses on proposed delay of effective date of amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to value based purchasing (VBP) arrangements.

Comment: Several commenters supported the proposal to delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a. of the December 31, 2020 final rule, which addresses the reporting by manufacturers of multiple best prices connected to a VBP arrangement. These commenters supported the proposed delay because of both the time as well as the state and federal resources that have been taken up by the emergence of the pandemic, implementation of Medicaid expansion under the ARP, and the focus on development, production, and distribution of vaccination efforts related to controlling the spread of the COVID–19 virus. Some commenters indicated that they do not believe that states, providers, and CMS have the infrastructure in place at this time to be able to track the necessary data related to health outcomes to properly implement VBP arrangements. They believe that the proposed delay will allow for some of this work (for example, work associated with pandemic efforts and infrastructure work to collect adequate patient data with appropriate privacy protections) to be finished without compromising care for those who need it in the interim. The commenters also noted that the proposed delay will allow CMS, states, and manufacturers time to develop and test the new MDP system, and allow CMS to develop operational guidance to facilitate multiple best price reporting.

Response: We appreciate the support of the proposed delay of the effective date of amendatory instruction 10.a. to July 1, 2022, and continue to believe that the proposed delay is necessary for CMS, manufacturers, states, and providers to engage in the work necessary to facilitate the multiple best price reporting approach. As commenters noted, we are implementing a new MDP system and, as part of that new system, will include the necessary changes to address multiple best price reporting. The additional 6 months will give us time to upgrade our new MDP system to collect multiple best prices, as well as explore and test these changes with the manufacturers and states that have been anxious to commit to the multiple best price approach. We will also use this time to issue operational guidance for states and manufacturers on reporting and accessing the multiple best price information in the MDP system.

For commenters' concerns regarding infrastructure and data collection, while we plan to provide general operational guidance, we do not plan to issue guidance on how to operationalize, evaluate, or monitor *specific* VBP arrangements as each arrangement will have its own set of specific facts and circumstances associated with the arrangement, such as the drug, the anticipated outcomes, and population included in the arrangement. A ''one size fits all'' approach to operationalizing a VBP arrangement is not possible because of the many different arrangements on the marketplace (85 FR 87018).

Comment: A few commenters urged CMS to effectuate the multiple best price reporting option as established in the final rule, but no later than the proposed delay in effective date of July 1, 2022. Several commenters, while agreeing with the proposed delay, continue to believe that the multiple best price reporting flexibility is essential to ensuring that patients benefit from VBP arrangements. One commenter in particular was disappointed that CMS was considering the proposed 6 month delay in effective date, but understood that putting in place the necessary systems and modifications for a seamless adoption of this new program is challenging. This commenter encouraged CMS to work diligently to ensure the proposed effective date of July 1, 2022 was achievable. Another commenter indicated that any further delay in effective date, beyond the 6 months proposed, will result in substantial negative repercussions for patient access to therapies that address significant unmet need, especially for Medicaid beneficiaries, and therefore, should be a one-time delay.

Response: This delay rule allows states additional time to ensure patient access by Medicaid beneficiaries to certain higher cost therapies. We will continue to assess system readiness for states, manufacturers and CMS to ensure the reporting by manufacturers of multiple best prices connected to a VBP arrangement can be effectuated in

the timeframe established in this delay rule, and we may consider further delays in future rulemaking if systems are not ready.

Comment: Several commenters provided input as to how CMS, states, and manufacturers should utilize the time associated with the proposed 6 month delay in effective date. One commenter encouraged CMS to utilize the proposed 6 month delay to issue subregulatory guidance regarding whether an arrangement would qualify as a VBP arrangement if a State Medicaid Agency is not able to access the same type of patient and outcomes data utilized in the commercial contract that resulted in the multiple best price. In other words, the commenter questioned if the state and the manufacturer will be allowed to modify the commercial sector agreement to better fit the Medicaid population, and how manufacturers will report multiple best prices when multiple commercial and/or state agencies enter into similar contracts but have different outcomes, resulting in different rebates and multiple best prices.

Response: We appreciate the commenters' recommendations for how CMS, states, and manufacturers should utilize the time associated with the proposed 6 month delay in effective date; however, these comments and recommendations are outside of the scope of this rulemaking. We note, however, that CMS plans to provide further operational guidance for states and manufacturers in the near future regarding the implementation of the multiple best price reporting.

Comment: A few commenters requested that CMS take this additional time to consult with Medicaid agencies and other stakeholders to ensure the necessary systems and technology needed to facilitate the collection and reporting of patient clinical outcomes are in place. The commenters further commented that CMS should encourage and incentivize consistency (for example, standard data reporting requirements) in these systems across states.

Response: We agree with the commenters, and as noted in the December 31, 2020 final rule, we plan to develop operational guidance regarding the final policy permitting multiple best price reporting. To that end, we have been available to manufacturers, states, and other stakeholders to discuss what is needed in MDP systems to effectuate the reporting of multiple best prices and intend to issue operational guidance associated with the MDP system changes. We expect to also provide states with guidance regarding existing Medicaid access and beneficiary protections when engaging in VBP arrangements.

With respect to the standardization of reporting systems across states, we understand that such systems would benefit states, patients, and manufacturers, as it would facilitate implementation of VBP programs, and avoid duplication of efforts. Since the MDP systems operated by CMS will not be collecting patient-specific or outcomes data associated with VBP arrangements, we will not be encouraging or providing incentives to standardized data collection reporting associated with VBP arrangements as part of the MDP system. However, we expect that states, working with their supplemental rebate contractors or other VBP vendors, as well as manufacturers, will attempt to create standardized reporting templates and formats that may become industry standards over time.

Comment: A few commenters indicated their appreciation of CMS' December 31, 2020 final rule to enhance flexibility in creating VBP arrangements; however, the commenters do not believe a 6 month delay in the effective date allows CMS sufficient time to adequately address the operational complexities and other legal hurdles (giving examples such as the federal Anti-Kickback Statute or Medicare Part B requirements) that impede adoption of VBP arrangements in a timely fashion. Therefore, the commenters stated that to leverage the full benefit of VBP arrangements, additional flexibilities and clarity are needed that cannot be provided via subregulatory guidance and urged CMS to withdraw the December 31, 2020 final rule and issue a revised proposed rule, or reopen the December 31, 2020 final rule for further public comment. A commenter indicated that while they appreciate CMS' interest in and effort to modernize the MDRP to support innovation that advances high value, patient-centered care through VBP arrangements, the final VBP multiple best price policy lacks clarity and does not consider a full range of operational hurdles. The commenter also indicated that the changes to the MDRP alone are not sufficient to reduce current barriers to VBP arrangements in the commercial market, and therefore, CMS must address the Anti-Kickback Statute (AKS), impact to Average Sales Price (ASP), and other government price reporting barriers to realize the full potential of VBP arrangements.

Another commenter expressed concerns regarding how the final rule on VBP arrangements could be gamed by manufacturers. The commenter suggested and encouraged CMS withdraw the December 31, 2020 final regulation, prohibit manufacturers from reporting multiple best prices, limit outcomes-based arrangements under a bundled approach, and clarify requirements regarding stacking discounts. The commenter expressed concern that CMS' VBP regulations, as finalized in the December 31, 2020 final rule, are not related to the Medicaid program and instead are designed to encourage specific types of contracting in the commercial market. This commenter suggested that the VBP regulations change Medicaid program requirements to achieve a goal outside of the Medicaid program and asserted that it is not appropriate to harm the Medicaid program to promote commercial contracting flexibility.

Response: The proposed rule only proposed a delay in effective date related to the VBP multiple best price reporting policy finalized in the December 31, 2020 final rule. The underlying policy itself was not a subject of the proposed rule open to public comment. Thus, comments related to the underlying policy are outside the scope of this rulemaking. At this time, we believe the 6 month delay beyond the initial delay in inclusion date from the COD final rule will be adequate for manufacturers to provide the data necessary to report multiple best prices in MDP system. Any other legal requirements that manufacturers may be subject to, such as the federal anti-kickback statute or Medicare Part B requirements, are outside of the scope of this rulemaking. However, we do intend to issue additional guidance on the interaction between VBP and Medicare Part B ASP calculations.

Comment: Some commenters continue to request additional clarity on whether, and to what extent, new VBP arrangements run afoul of the federal anti-kickback statute. The commenters indicate that CMS should work to remove barriers imposed by AKS that limit or prevent adoption of VBP arrangements.

Response: While we appreciate the comments received, these issues are outside the scope of this rulemaking. As noted above, the underlying policy regarding VBP arrangements was not a subject of the proposed rule open to public comment. Rather, the proposed rule specifically proposed a 6 month delay to the effective date for the policy permitting manufacturers to report multiple best prices related to a VBP arrangement. Questions regarding these

issues should be directed to the Office of the Inspector General (OIG).

Comment: A couple of commenters reiterated their comments provided on the ''Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements'' proposed rule that appeared in the June 19, 2020 **Federal Register** (85 FR 37256), including comments regarding the drug utilization review requirements.

Response: The DUR requirements set forth in the December 31, 2020 final rule were not a subject of this proposed rule and were not impacted by the proposed delay.

After consideration of the comments received regarding the proposed delay to amendatory instruction 10.a. of the December 31, 2020 final rule, we are finalizing the proposed July 1, 2022 effective date.

B. Delay of Inclusion Date of U.S. Territories in Amended Regulatory Definitions of ''States'' and ''United States'' (§ 447.502)

The following is a summary of the comments received and our responses on the proposed delay of the inclusion date for the U.S. territories in the definition of ''States'' and ''United States'' at § 447.502 to April 1, 2024, or, alternatively, a date that is earlier than April 1, 2024, but not before January 1, 2023 based on public comments received.

Comment: Several commenters supported the proposed delay of the April 1, 2022 inclusion date to April 1, 2024, or, alternatively, to a date earlier than April 1, 2024, but not before January 1, 2023 based on public comments. These commenters supported the proposed delay because of the territories' current need to focus on the PHE relating to COVID–19 and the time needed to prepare for the technology infrastructure changes necessary to support participation in the MDRP. The commenters also noted concern that manufacturers may increase their drug prices in the territories as a result of their participation in the MDRP. One commenter specifically noted concern as to whether the territories would be capable of participating in the MDRP prior to April 1, 2024.

Another commenter supported the proposed delay, given the various programs and processes that a state has to put in place to effectively and efficiently participate in the MDRP, such as establishing a drug manufacturer rebate billing mechanism, a state drug utilization reporting mechanism, a process to assure that all drugs of a manufacturer that sign a rebate agreement with the Secretary of HHS are covered, a dispute resolution process, and a Drug Utilization Review (DUR) program.

Another commenter supported a proposed delay of the April 1, 2022 inclusion date and suggested October 1, 2023 as an alternative inclusion date. The commenter stated that an October 1, 2023 inclusion date would provide an additional eighteen months beyond April 1, 2022 before the territories are included in the amended regulatory definitions of ''States'' and ''United States'', and believed that an October 1, 2023 inclusion date is justified because some interested territories have requested more time to prepare for MDRP participation and suggested potential policy changes to address increases in drug prices. In addition, the commenter indicated that the territories and manufacturers will need this additional time because their resources continue to be diverted to the COVID–19 pandemic response.

Another commenter found it difficult to envision territories having the infrastructure or funding in place to fully transition to the MDRP given the PHE. The commenter also noted that even if a territory was prepared to make this transition, the providers, including hospitals and others across the healthcare marketplace that prescribe and provide prescription drugs, would need to update their systems, resulting in significant confusion and patient access barriers. The commenter believed further guidance is necessary to prepare the territories for this transition, as well as the providers of care within those programs. The commenter restated these reasons for prior delays in implementing this requirement as rationale for reversing the 2016 COD final rule including territories in the definition of ''States'' and ''United States.''

Other commenters indicated that they did not support the proposed delay because one territory in particular, Puerto Rico, has made significant efforts to prepare for participation in the program. The commenter indicated that the proposed delay would be financially harmful to that territory because it has already written a request for proposal (RFP) to procure a vendor to manage participation in the MDRP, which has an expected launch date of July 1, 2022, and a delay would result in the need for multiple modifications to the territory's RFP. The commenter also noted that the territory has undertaken a significant amount of budgeting and financial forecasting as part of their efforts, which indicated that there would be a financial loss as a result of unrealized federal rebates for both brand and generic drugs if there is a delay beyond the territory's FY 2023, which runs from July 2022 through June 2023.

Response: In proposing this delay, and in finalizing a new inclusion date of January 1, 2023, we considered all public comments received, the needs of all the stakeholders, including territories and manufacturers, while considering the impact that the delay could have on access to necessary and affordable medications for the citizens of the territories, both those that would and would not participate in MDRP.

To balance the willingness of territories that want to participate, while accommodating the time to prepare waivers for those that do not, we have determined that the January 1, 2023 date, which falls within the scope of the alternative proposal, is appropriate.

Based on the information available to us at this time, we believe that of the five territories, only two will make efforts to participate in MDRP, regardless of the ultimate inclusion date, and the others will require additional time to request the applicable waivers. Of the two territories that we anticipate will make efforts to participate in MDRP, only one (Puerto Rico) has definitively indicated that they are ready and will be able to participate in MDRP as early as July 1, 2022, while the other (U.S. Virgin Islands) has previously expressed interest, but may or may not have decided whether to participate by January 1, 2023.

Those territories that do not participate will need time to prepare to waive out of the program through the appropriate Medicaid waiver mechanism.

To accommodate the resource needs of the territories during the PHE, we believe a January 1, 2023 inclusion date gives Puerto Rico the ability to participate sooner than the April 1, 2024 inclusion date, while giving the other territories a firm deadline to make a final decision to participate or waive out of the program. The timeline also recognizes the work done to date by Puerto Rico to prepare to participate in the program. Therefore, the new inclusion date for U.S. Territories in the amended regulatory definitions of ''States'' and ''United States'' for purpose of the Medicaid Drug Rebate Program will be January 1, 2023, which is the earliest new inclusion date that we could have finalized given our proposals in the proposed regulation.

We note the suggestion for a delayed inclusion date of October 1, 2023 made by one of the commenters in light of the additional time needed and requested by some territories. we believe that further delay beyond January 1, 2023 negatively impacts the progress Puerto Rico has made to prepare to participate in the program (for example, Puerto Rico has already invested significantly in consulting costs and begun the request for proposal process for a system contractor). For example, Puerto Rico has indicated it could be ready to participate in the MDRP as early as July 1, 2022, and therefore, an effective date of October 1, 2023 would push back MDRP participation by over a year from that date for the territory that has the overwhelming majority of drug spending, and which stands to benefit most from participation in MDRP.

As for the commenter's request for additional guidance, the delay can be used to help any territory that plans on participating in the program more time to prepare its beneficiaries, pharmacies, and providers. That is because participation in the MDRP will increase the availability of medications that are available in participating territories, but the territories can also use various utilization management techniques, and providers and patients may need time to be educated on how these programs will work. Moreover, a territory participating in MDRP may need technical help from us on reporting its state drug utilization data, and, for example, assuring that all its physician administered drug claims also include National Drug Code (NDC) numbers. Like our state partners, we are available to guide territories that want to participate in MDRP to assure beneficiary access to drugs, as well as to properly invoice participating manufacturers for federal rebates.

Comment: A few commenters noted their general opposition to the expansion of the MDRP beyond the 50 states and DC to include the territories. One commenter remarked that at most, CMS should limit the expansion to only requiring that rebates be paid by the manufacturers to the territories, but not require manufacturers to include sales to the territories in calculation of their AMP or determination of their Best Price because of the enormous burden and compliance concerns that such an expansion would pose on the manufacturer.

A couple of commenters, while supporting the proposed delay of the participation of the territories in the MDRP to April 1, 2024, were still concerned with the decision to include the territories in the definition of ''States'' and ''United States'' in the first place, and urged CMS to address their prior comments requesting the agency to reverse its decision to add the territories to the Medicaid rebate program.

Response: We note that the definitions of ''States'' and ''United States'' at § 447.502 were amended to include the U.S. territories for purposes of the MDRP in the COD final rule with a delayed inclusion date. We did not propose to change the underlying policy, only to delay the inclusion date. As such, comments requesting that we revisit the underlying policy are outside the scope of this rulemaking.

After consideration of the comments received regarding the proposed delay of inclusion date for the U.S. territories in the definitions of ''States'' and ''United States'' at § 447.502, we are finalizing an inclusion date of January 1, 2023.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2021.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENT FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 2. Amend § 447.502 by revising the definitions of ''States'' and ''United States'' to read as follows:

§ 447.502 Definitions.

* * * * *

States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

United States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

* * * * *

■ 3. Effective July 1, 2022, in paragraph (a), by revising the definition of ''Best price'' to read as follows:

§ 447.505 Determination of best price.

(a) * * *

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement.

* * * * *

Dated: November 4, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–25009 Filed 11–17–21; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 211115–0231]

RIN 0648–BK56

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Biennial Specifications; 2021–2022 and 2022–2023 Specifications for Pacific Mackerel

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

ACTION: Final rule.

SUMMARY: NMFS is implementing allowable catch levels including an overfishing limit, an allowable biological catch, and an annual catch limit for Pacific mackerel in the U.S. exclusive economic zone off the West Coast (California, Oregon and Washington) for the fishing seasons 2021–2022 and 2022–2023. This rule is finalized pursuant to the Coastal Pelagic Species Fishery Management Plan. The

harvest guideline and annual catch target for the 2021–2022 fishing season are 8,323 metric tons (mt) and 7,323 mt, respectively. The harvest guideline and annual catch target for the 2022–2023 fishing season are 5,822 mt and 4,822 mt, respectively. If the fishery attains the annual catch target in either fishing season, the directed fishery will close, reserving the 1,000-mt difference between the harvest guideline and annual catch target as a set-aside for incidental landings and other sources of mortality. This rule is intended to conserve and manage the Pacific mackerel stock off the U.S. West Coast.

DATES: Effective December 20, 2021.

FOR FURTHER INFORMATION CONTACT: Taylor Debevec, West Coast Region, NMFS, (562) 619–2052, *Taylor.Debevec@noaa.gov.*

SUPPLEMENTARY INFORMATION: Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.,* NMFS manages the Pacific mackerel fishery in the U.S. exclusive economic zone (EEZ) off the West Coast in accordance with the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The CPS FMP and its implementing regulations require NMFS to set annual harvest specifications for the Pacific mackerel fishery based on the annual specification framework and control rules in the FMP. The control rules in the CPS FMP include the harvest guideline (HG) control rule, which in conjunction with the overfishing limit (OFL) and acceptable biological catch (ABC) rules, are used to manage harvest levels for Pacific mackerel. According to the FMP, the quota for the principal commercial fishery, the HG, is determined using the FMP-specified HG formula. The HG is based, in large part, on the current estimate of stock biomass. The biomass estimate is an explicit part of the various harvest control rules for Pacific mackerel, and as the estimated biomass decreases or increases from one year to the next, the resulting allowable catch levels similarly trend. More information on the Pacific Fishery Management Council's (Council) process for developing Pacific mackerel harvest specifications and more detail on the HG control rule are provided in the proposed rule for this action (86 FR 48969; September 1, 2021) and are not repeated here.

The purpose of this final rule is to implement these harvest specifications, which include allowable harvest levels (*i.e.,* annual catch target (ACT) and HG), an annual catch limit (ACL), and annual catch reference points (*i.e.,* OFL and ABC). The uncertainty surrounding the current biomass estimates for Pacific mackerel for the 2021–2022 and 2022–2023 fishing seasons was taken into consideration in the development of these harvest specifications. The Pacific mackerel fishing season runs from July 1 to June 30. Any Pacific mackerel harvested between July 1, 2021, and the effective date of the final rule would count toward the 2021–2022 ACT and HG.

The Council has recommended, and NMFS is implementing, Pacific mackerel harvest specifications for both the 2021–2022 and 2022–2023 fishing seasons. For the 2021–2022 Pacific mackerel fishing season these include an OFL of 12,145 mt, an ABC and ACL of 9,446 mt, a HG of 8,323 mt, and an annual ACT of 7,323 mt. For the 2022–2023 Pacific mackerel fishing season these include an OFL of 9,644 mt, and ABC and ACL of 7,501 mt, a HG of 5,822 mt, and an ACT of 4,822 mt. These catch specifications are based on the control rules established in the CPS FMP and biomass estimates of 57,832 mt (2021–2022) and 45,925 mt (2022–2023). The biomass estimates are the result of a catch-only stock assessment the NMFS' Southwest Fisheries Science Center completed in June 2021. The Council's Science and Statistical Committee, and the Council approved this stock assessment and resulting biomass estimates as the best scientific information available for management for these two fishing years at the June 2021 Council meeting.

Under this action, in the unlikely event that catch reaches the ACT in either fishing season, directed fishing would close, reserving the difference between the HG and ACT (1,000 mt) as a set-aside for incidental landings in other fisheries and other sources of mortality.[1] For the remainder of the fishing season, incidental landings in CPS fisheries would be constrained to a 45-percent incidental catch allowance (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel); and in non-CPS fisheries, up to 3 mt of Pacific mackerel may be landed incidentally per fishing trip. The incidental set-aside is intended to allow continued operation of fisheries for other stocks, particularly other CPS stocks that may school with Pacific mackerel.

The NMFS West Coast Regional Administrator will publish a notice in the **Federal Register** announcing the date of any closure of directed fishing (when harvest levels reach or exceed the ACT). Additionally, to ensure the regulated community is informed of any closure, NMFS will also make announcements through other means available, including email to fishermen, processors, and state fishery management agencies.

On September 1, 2021, NMFS published a proposed rule in the **Federal Register** (86 FR 48969) soliciting public comments through October 1, 2021. NMFS received two comments from private citizens, one supporting the proposed rule and the other suggesting lowering the catch limit to account for uncertainty. In response to the comment on uncertainty, NMFS has determined that scientific uncertainty has been adequately incorporated in this action through the stock assessment modeling and resulting biomass estimate, as well as in the catch limit by reducing the OFL to the ABC/ACL, to the HG, and finally the ACT. The incorporation of uncertainty and precautionary reductions in the catch limit are to prevent overfishing of mackerel. Additionally, NMFS notes that the Pacific mackerel fishery has been managed with annual or biennial stock assessments and precautionary catch levels for at least the last 20 years.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act. There are no relevant Federal rules that may duplicate, overlap, or conflict with the final action.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Reporting and recordkeeping requirements.

[1] Directed fishing for live bait and minor directed fishing is allowed to continue during a closure of the directed fishery.

Dated: November 15, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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

PART 660—FISHERIES OFF WEST COAST STATES

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

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

■ 2. In § 660.511, revise paragraphs (i) and (j) to read as follows:

§ 660.511 Catch restrictions.

* * * * *

(i) The following harvest specifications apply for Pacific mackerel:

(1) For the Pacific mackerel fishing season July 1, 2021, through June 30, 2022, the harvest guideline is 8,323 mt and the ACT is 7,323 mt; and

(2) For the Pacific mackerel fishing season July 1, 2022, through June 30, 2023, the harvest guideline is 5,822 mt and the ACT of 4,822 mt.

(j) When an ACT in paragraph (i) of this section has been reached or exceeded, then for the remainder of the Pacific mackerel fishing season, Pacific mackerel may not be targeted and landings of Pacific mackerel may not exceed: 45 percent of landings when Pacific mackerel are landed in CPS fisheries (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel), or up to 3 mt of Pacific mackerel when landed in non-CPS fisheries. The NMFS West Coast Regional Administer shall announce in the **Federal Register** the date that an ACT is reached or exceeded, and the date and time that the restrictions described in this paragraph (j) go into effect.

* * * * *

[FR Doc. 2021–25212 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210217–0022; RTID 0648–XB595]

Fisheries of the Exclusive Economic Zone Off Alaska; Shortraker Rockfish in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of shortraker rockfish in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary because the 2021 shortraker rockfish total allowable catch (TAC) in the BSAI has been reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), November 16, 2021, through 2400 hours, A.l.t., December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228.

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

The 2021 shortraker rockfish TAC in the BSAI is 425 metric tons (mt) as established by the final 2021 and 2022 harvest specifications for groundfish in the BSAI (86 FR 11449, February 25, 2021). In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the 2021 shortraker rockfish TAC in the BSAI has been reached. Therefore, NMFS is requiring that shortraker rockfish in the BSAI be treated in the same manner as a prohibited species, as described under § 679.21(a), for the remainder of the year, except shortraker rockfish in the BSAI caught by catcher vessels using hook-and-line, pot, or jig gear as described in § 679.20(j).

Classification

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

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting retention of shortraker rockfish in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 12, 2021.

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

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

Dated: November 16, 2021.

Ngagne Jafnar Gueye,

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

[FR Doc. 2021–25310 Filed 11–16–21; 4:15 pm]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210217–0022; RTID 0648–XB592]

Fisheries of the Exclusive Economic Zone Off Alaska; Several Groundfish Species in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; apportionment of reserves; request for comments.

SUMMARY: NMFS apportions amounts of the non-specified reserve to the initial total allowable catch (ITAC) of Bering Sea (BS) Pacific ocean perch, BS trawl sablefish, Bering Sea and Aleutian Islands (BSAI) shortraker rockfish, BSAI skates, BSAI sharks, and Central Aleutian Islands and Western Aleutian

Islands (CAI/WAI) blackspotted/rougheye rockfish. This action is necessary to allow the fisheries to continue operating. It is intended to promote the goals and objectives of the fishery management plan for the BSAI management area.

DATES: Effective November 16, 2021, through 2400 hrs, Alaska local time, December 31, 2021. Comments must be received at the following address no later than 4:30 p.m., Alaska local time December 1, 2021.

ADDRESSES: Submit your comments, identified by docket number NOAA–NMFS–2020–0141, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov/docket/NOAA-NMFS-2020-0141* click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the comment period ends. All comments received are a part of the public record and NMFS will post the comments for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender is publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

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

The 2021 ITAC of BS Pacific ocean perch was established as 9,165 metric tons (mt), the 2021 ITAC of BS trawl sablefish was established as 1,443 mt, the 2021 ITAC of BSAI shortraker rockfish was established as 425 mt, the 2021 ITAC of BSAI skates was established as 15,300 mt, the 2021 ITAC of BSAI sharks was established as 170 mt, and the 2021 ITAC of CAI/WAI blackspotted/rougheye rockfish was established as 144 mt by the final 2021 and 2022 harvest specifications for groundfish of the BSAI (86 FR 11449, February 25, 2021). In accordance with § 679.20(a)(3) the Regional Administrator, Alaska Region, NMFS, has reviewed the most current available data and finds that the ITACs for BS Pacific ocean perch, BS trawl sablefish, BSAI shortraker rockfish, BSAI skates, BSAI sharks, and CAI/WAI blackspotted/rougheye rockfish need to be supplemented from the non-specified reserve to promote efficiency in the utilization of fishery resources in the BSAI and allow fishing operations to continue.

Therefore, in accordance with § 679.20(b)(3), NMFS apportions from the non-specified reserve of groundfish to ITACs in the BSAI management area as follows: 1,617 mt to BS Pacific ocean perch, 128 mt to BS trawl sablefish, 116 mt to BSAI shortraker rockfish, 4,700 mt to BSAI skates, 347 mt to BSAI sharks, and 25 mt to CAI/WAI blackspotted/rougheye rockfish. These apportionments are consistent with § 679.20(b)(1)(i) and do not result in overfishing of any target species because the revised ITACs and total allowable catches (TACs) are equal to or less than the specifications of the acceptable biological catch in the final 2021 and 2022 harvest specifications for groundfish in the BSAI (86 FR 11449, February 25, 2021).

The harvest specification for the 2021 ITACs and TACs included in the harvest specifications for groundfish in the BSAI are revised as follows 10,782 mt for BS Pacific ocean perch, 1,571 mt for BS trawl sablefish, 541 mt for BSAI shortraker rockfish, 20,000 mt for BSAI skates, 517 mt for BSAI sharks, and 169 mt for CAI/WAI blackspotted/rougheye rockfish.

Classification

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

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the apportionment of the non-specified reserves of groundfish to the BS Pacific ocean perch, BS trawl sablefish, BSAI shortraker rockfish, BSAI skates, BSAI sharks, and CAI/WAI blackspotted/rougheye rockfish. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 9, 2021.

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

Under § 679.20(b)(3)(iii), interested persons are invited to submit written comments on this action (see **ADDRESSES**) until December 1, 2021.

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

Dated: November 16, 2021.

Ngagne Jafnar Gueye,

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

[FR Doc. 2021–25308 Filed 11–16–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210210–0018]

RTID 0648–XA789

Fisheries of the Exclusive Economic Zone off Alaska; Pacific Cod by Catcher/Processors Using Hook-and-Line Gear in the Central Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher/processors using hook-and-line (HAL) gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the annual allowance of the 2021 total allowable catch (TAC) of Pacific cod by catcher/processors using HAL gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), November 15, 2021, through 1200 hrs, A.l.t., December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Allyson Olds, 907–586–7228.

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

The annual allowance of the 2021 Pacific cod TAC apportioned to catcher/processors using HAL gear in the Central Regulatory Area of the GOA is 518 metric tons (mt) as established by the final 2021 and 2022 harvest specifications for groundfish in the GOA (86 FR 10184, February 19, 2021).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the annual allowance of the 2021 Pacific cod TAC apportioned to catcher/processors using HAL gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 502 mt and is setting aside the remaining 16 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher/processors using HAL gear in the Central Regulatory Area of the GOA.

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

Classification

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

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure for Pacific cod by catcher/processors using HAL gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 12, 2021.

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

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

Dated: November 15, 2021.

Ngagne Jafnar Gueye,

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

[FR Doc. 2021–25217 Filed 11–15–21; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 221
Friday, November 19, 2021

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 927

[Doc. No. AMS–SC–21–0069; SC21–927–1 PR]

Pears Grown in Oregon and Washington; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Fresh Pear Committee (Committee) to increase the assessment rate established for the 2021–22 and subsequent fiscal periods. The proposed assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by December 20, 2021.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; or internet: *https://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *https://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Dale Novotny, Marketing Specialist, or Andrew Hatch, Deputy Director, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 356–8202 or Email: *dalej.novotny@usda.gov* or *Andrew.Hatch@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Order No. 927, as amended (7 CFR part 927), regulating the handling of pears grown in Oregon and Washington. Part 927 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of growers and handlers of pears operating within the production area, and a public member.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866 and 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This proposed rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have tribal implications. AMS has determined this proposed rule is unlikely to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate from $0.463 per 44-pound standard box or equivalent of fresh ''summer/fall'' and ''winter'' pears, the rate that was established for the 2018–19 and subsequent fiscal periods, to $0.468 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears for the 2021–22 and subsequent fiscal periods.

The Order authorizes the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. Members are familiar with the Committee's needs and with costs of goods and services in their local area, and they are in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2018–19 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate of $0.463 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears. That assessment rate continues in effect from fiscal period to fiscal period unless

modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on June 3, 2021, and unanimously recommended 2021–22 fiscal period expenditures of $8,472,263 and an assessment rate of $0.468 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears handled for the 2021–22 and subsequent fiscal periods. In comparison, the previous fiscal period's budgeted expenditures were $8,901,114. The proposed assessment rate of $0.468 is $0.005 higher than the rate currently in effect. Due to a smaller estimated 2021–22 crop, the Committee recommended increasing the assessment rate to provide adequate income that, along with reserve funds and interest income, would cover the Committee's budgeted expenses for the 2021–22 fiscal period.

Expenditures recommended by the Committee for the 2021–22 fiscal period include $391,047 for contracted administration, $159,540 for industry development, $964,476 for production research and market development, $27,200 for miscellaneous expenses, and $6,930,000 for promotion and paid advertising for ''summer/fall'' and ''winter'' varieties of fresh pears. Budgeted expenses for these items for the 2020–21 fiscal period were $388,520, $172,000, $997,394, $28,200, and $7,315,000, respectively.

The Committee derived the recommended assessment rate by considering anticipated expenses, and an estimated 2021 crop of 18,000,000 44-pound standard boxes or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears. Income derived from handler assessments, calculated at $8,424,000 (18,000,000 standard boxes or equivalent multiplied by $0.468 assessment rate), along with reserve funds and interest income ($48,263), should be adequate to cover budgeted expenses of $8,472,263.

The assessment rate proposed in this rule would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. Dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2021–22 fiscal period budget, and those for subsequent fiscal periods, would be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 708 growers of fresh pears in the production area and 27 handlers subject to the regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $1,000,000, and small agricultural service firms have been defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS), the 2020 average grower price received for fresh pears produced in Oregon and Washington was $11.39 per standard 44-pound box or equivalent. Committee data indicates total production was 16,290,225 44-pound standard boxes or equivalent in the 2019–20 fiscal period. The total 2019–20 fiscal period value of assessable fresh ''summer/fall'' and ''winter'' pears grown in Oregon and Washington was $185,545,663 (16,290,225 44-pound standard boxes or equivalent times $11.39 per box equals $185,545,663). Dividing the crop value by the estimated number of growers (708) yields an estimated average receipt per grower of $262,070.

According to USDA Market News data, the reported average terminal price for 2020 Oregon and Washington fresh pears was $34.87 per 44-pound standard box or equivalent (data reported in 4/5 bushel). Multiplying the Committee-reported 2019–20 Oregon and Washington total production of 16,290,225 44-pound standard boxes or equivalent by the estimated average price per box or equivalent of $34.87 equals $568,040,146. Dividing this figure by 27 regulated handlers yields estimated average annual handler receipts of $21,038,524.

Therefore, using the above data, the majority of growers of Oregon and Washington fresh pears may be classified as small entities. Assuming a normal distribution, the majority of handlers of Oregon and Washington fresh pears may also be classified as small entities.

As noted above, the average price received by growers in 2020 was $11.39 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears. Given the Committee-estimated production of 18,000,000 44-pound standard boxes or equivalent of assessable fresh pears for the 2021–22 fiscal period, the total grower revenue is estimated to be $205,020,000. The total assessment revenue is expected to be $8,424,000 (18,000,000 boxes multiplied by $0.468 per box). Thus, the total assessment revenue compared to total grower revenue is 4.1 percent ($8,424,000 divided by $205,020,000).

This proposal would increase the assessment rate collected from handlers for the 2021–22 and subsequent fiscal periods from $0.463 to $0.468 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears. The Committee unanimously recommended 2021–22 fiscal period expenditures of $8,472,263 and an assessment rate of $0.468 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears handled. The proposed assessment rate of $0.468 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears is $0.005 higher than the current rate. The volume of assessable fresh ''summer/fall'' pears and ''winter'' pears in the production area for the 2021–22 fiscal period is estimated to be 18,000,000 44-pound standard boxes or equivalent. Thus, the $0.468 per 44-pound standard box or equivalent of assessable fresh ''summer/fall'' pears and ''winter'' pears should provide $8,424,000 in assessment income (18,000,000 multiplied by $0.468). Income derived from handler assessments, along with reserve funds and interest income, should be adequate to cover budgeted expenses of for the 2021–22 fiscal period.

Major expenditures recommended by the Committee for the 2021–22 fiscal

period include $391,047 for contracted administration, $159,540 for industry development, $964,476 for production research and market development, and $6,930,000 for promotion and paid advertising for ''summer/fall'' and ''winter'' varieties of fresh pears. Budgeted expenses for these items for the 2020–21 fiscal period were $388,520, $172,000, $997,394, and $7,315,000, respectively.

Due to a smaller estimated 2021–22 crop, the Committee recommended increasing the assessment rate to provide adequate income that, along with reserve funds and interest income, would cover the Committee's budgeted expenses for the 2021–22 fiscal period. Prior to arriving at this budget and assessment rate recommendation, the Committee discussed various alternatives, including maintaining the current assessment rate and, alternatively, increasing the assessment rate by a different amount. However, the Committee determined that the recommended assessment rate, along with reserve funds and interest income, should adequately fund budgeted expenses.

This proposed rule would increase the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to growers. However, these costs would be offset by the benefits derived by the operation of the Order.

The Committee's meeting was widely publicized throughout the Oregon and Washington pear industry. All interested persons were invited to attend the meeting and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the June 3, 2021, meeting was a public meeting, and all entities, both large and small, were able to express views on this issue. Interested persons are invited to submit comments on this proposed rule, including regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189, Fruit Crops. No changes in those requirements would be necessary as a result of this proposed rule. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large Oregon and Washington pear handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 927

Marketing agreements, Pears, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, 7 CFR part 927 is proposed to be amended as follows:

PART 927—PEARS GROWN IN OREGON AND WASHINGTON

■ 1. The authority citation for 7 CFR part 927 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 927.236, revise the introductory text and paragraphs (a) and (b) to read as follows:

§ 927.236 Fresh pear assessment rate.

On and after July 1, 2021, the following base rates of assessment for fresh pears are established for the Fresh Pear Committee:

(a) $0.468 per 44-pound net weight standard box or container equivalent for any or all varieties or subvarieties of fresh pears classified as ''summer/fall'';

(b) $0.468 per 44-pound net weight standard box or container equivalent for any or all varieties or subvarieties of fresh pears classified as ''winter''; and

* * * * *

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–25160 Filed 11–18–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1003; Project Identifier AD–2021–01141–R]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Inc. (Type Certificate Previously Held by Bell Helicopter Textron Inc.) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2021–15–51, which applies to Bell Textron Inc. (type certificate previously held by Bell Helicopter Textron Inc.) Model 204B, 205A, 205A–1, 205B, and 212 helicopters. AD 2021–15–51 requires removing certain main rotor hub strap pins (pin) from service and prohibits installing them on any helicopter. Since the FAA issued AD 2021–15–51, it was determined that a defective pin could also be installed on Bell Textron Inc. Model 210 helicopters. This proposed AD would continue to require the actions in AD 2021–15–51 and expand the applicability to add Model 210 helicopters. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 20, 2021.

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

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

p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bell Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; email *productsupport@bellflight.com;* or at *https://www.bellflight.com/support/contact-support.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1003; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: David Wilson, Aerospace Engineer, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5786; email *david.wilson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–1003; Project Identifier AD–2021–01141–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to David Wilson, Aerospace Engineer, DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5786; email *david.wilson@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued Emergency AD 2021–15–51 on July 6, 2021, and it published as a Final rule; request for comments on August 9, 2021 as Amendment 39–21678 (86 FR 43406) (AD 2021–15–51). AD 2021–15–51 applies to Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, and 212 helicopters with a pin part number (P/N) 204–012–104–005 with a serial number (S/N) prefix ''FNFS'' installed. AD 2021–15–51 requires removing from service all P/N 204–012–104–005 pins with an S/N prefix ''FNFS'' before further flight and prohibits installing an affected pin on any helicopter as of the effective date of the AD. AD 2021–15–51 was prompted by a fatal accident of a Model 212 helicopter in which a pin P/N 204–012–104–005 with an S/N prefix ''FNFS'' sheared off during flight, which resulted in the main rotor blade and the main rotor head detaching from the helicopter. The pin had accumulated only 20 total hours time-in-service (TIS). An inspection of a different Model 212 helicopter revealed that another pin installed, and made by the same manufacturer and with the same S/N prefix, was deformed; this pin had accumulated only 29 total hours TIS. Pins of the same P/N can also be installed on Bell Textron Inc., Model 204B, 205A, 205A–1, 205B, and 210 helicopters. Failure of the pin could result in the main rotor blade detaching from the helicopter and subsequent loss of control of the helicopter.

Actions Since AD 2021–15–51 Was Issued

Since the FAA issued AD 2021–15–51, it was determined that pin P/N 204–012–104–005 with S/N prefix ''FNFS'' can also be installed on Model 210 helicopters. Additionally, the FAA discovered that an incorrect U.S. fleet count was provided in the Costs of Compliance section of AD 2021–15–51. This proposed AD corrects that count and adds Model 210 helicopters to that count. Additionally, while AD 2021–15–51 was initially issued as an emergency AD and then published in the **Federal Register** as a Final rule; request for comments, the FAA has determined that an NPRM is appropriate to add the Model 210 helicopter to the applicability. Even though the unsafe condition exists, the four Model 210 helicopters on the U.S. Registry do not currently have an affected pin installed making immediate adoption of an AD to add the Model 210 helicopter to the applicability without providing an opportunity for public comments prior to adoption unnecessary.

Lastly, service information discussed in AD 2021–15–51 has been revised to include updated warranty information and additional accomplishment instructions for disposing of the affected pins, therefore, this proposed AD discusses this revised service information.

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

FAA's Determination

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

Related Service Information

The FAA reviewed the following Bell Alert Service Bulletins (ASBs), each Revision A and dated July 22, 2021:

- ASB 204B–21–74 for Model 204B helicopters, S/Ns 2001 through 2070 and 2196 through 2199;
- ASB 205–21–117 for Model 205A and 205A–1 helicopters, S/Ns 30001 through 30065, 30067 through 30165, 30167 through 30187, 30189 through 30296, and 30298 through 30332;
- ASB 205B–21–71 for Model 205B helicopters, S/Ns 30066, 30166, 30188 and 30297;
- ASB 210–21–14 for all Model 210 helicopters, and

• ASB 212–21–165 for Model 212 helicopters, S/Ns 30501 through 30999, 31101 through 31311, 32101 through 32142, and 35001 through 35103.

The ASBs specify removing all P/N 204–012–104–005 pins with an S/N prefix ''FNFS'' before further flight. The ASBs also specify that, although the investigation is still in progress, removing these pins from service is required. The ASBs state that these pins may not have been manufactured in accordance with the engineering design requirements and may therefore shear as a result of this nonconformance.

Proposed AD Requirements in This NPRM

This proposed AD would retain all of the requirements of AD 2021–15–51. This proposed AD would apply to all helicopters that were affected by AD 2021–15–51 and would add Model 210 helicopters to the applicability.

Interim Action

The FAA considers that this proposed AD would be an interim action. If final action is later identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 155 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Replacing up to four pins would take about 20 work-hours and parts would cost about $1,756 for four pins for an estimated cost of up to $3,456 per helicopter, and up to $535,680 for the U.S. fleet.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive AD 2021–15–51, Amendment 39–21678 (86 FR 43406, August 9, 2021); and

■ b. Adding the following new airworthiness directive:

Bell Textron Inc. (Type Certificate Previously Held By Bell Helicopter Textron Inc.): Docket No. FAA–2021–1003; Project Identifier AD–2021–01141–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) action by December 20, 2021.

(b) Affected ADs

This AD replaces AD 2021–15–51, Amendment 39–21678 (86 FR 43406, August 9, 2021) (AD 2021–15–51).

(c) Applicability

This AD applies to Bell Textron Inc. (type certificate previously held by Bell Helicopter Textron Inc.) Model 204B, 205A, 205A–1, 205B, 210, and 212 helicopters, certificated in any category, with an outboard main rotor hub strap pin (pin) part number 204–012–104–005 with a serial number prefix ''FNFS'' installed.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6200, Main Rotor System.

(e) Unsafe Condition

This AD was prompted by a fatal accident in which a pin sheared off during flight, which resulted in the main rotor blade and the main rotor head detaching from the helicopter. The FAA is issuing this AD to address this unsafe condition and prevent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) For Model 204B, 205A, 205A–1, 205B, and 212 helicopters:

(i) Before further flight from August 24, 2021 (the effective date of AD 2021–15–51), remove from service any pin that is identified in paragraph (c) of this AD.

(ii) After August 24, 2021 (the effective date of AD 2021–15–51), do not install any pin that is identified in paragraph (c) of this AD on any helicopter.

(2) For Model 210 helicopters:

(i) Before further flight after the effective date of this AD, remove from service any pin that is identified in paragraph (c) of this AD.

(ii) As of the effective date of this AD, do not install any pin that is identified in paragraph (c) of this AD on any helicopter.

(h) Special Flight Permits

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, DSCO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the DSCO Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ASW-190-COS@faa.gov.*

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

(j) Related Information

For more information about this AD, contact David Wilson, Aerospace Engineer,

DSCO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5786; email *david.wilson@faa.gov.*

Issued on November 14, 2021.

Ross Landes,

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

[FR Doc. 2021–25205 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0956; Airspace Docket No. 21–ANM–41]

RIN 2120–AA66

Proposed Modification of Class E Airspace; Gold Beach Municipal Airport, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E airspace at Gold Beach Municipal Airport, Gold Beach, OR. This action would ensure the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before January 3, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0956; Airspace Docket No. 21–ANM–41, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

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

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–0956; Airspace Docket No. 21–ANM–41''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by modifying the Class E airspace, extending upward from 700 feet above the surface, at Gold Beach Municipal Airport, OR. This airspace is designed to contain arriving IFR aircraft descending below 1,500 feet above the surface and departing IFR aircraft until reaching 1,200 feet above the surface. To properly contain IFR operations at the airport, the radius of the airspace should be increased from ''6.3 miles'' to ''7.2 miles'' and the extension northwest of the airport should be removed. Additionally, terminal IFR operations east of the airport are not authorized, due to terrain. Because of this limitation, a portion of the Class E airspace east of the airport should be removed.

Class E5 airspace designations are published in paragraphs 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14

CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANM OR E5 Gold Beach, OR

Gold Beach Municipal Airport, OR
(Lat. 42°24′55″ N, long. 124°25′30″ W)

That airspace extending upward from 700 feet above the surface within an area beginning at 7.2 miles on the 010° bearing from the airport, then to a point at 7.2 miles on the 160° bearing from the airport, then within a 7.2-mile radius of the airport clockwise to the point of beginning 7.2 miles north of the airport.

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

B.G. Chew,

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

[FR Doc. 2021–25220 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

14 CFR Part 382

[Docket No. DOT–OST–2019–0180]

Accessible Lavatories on Single-Aisle Aircraft: Part 1; Reopening of Comment Period and Public Meeting

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking; reopening of comment period; public meeting; request for public comments.

SUMMARY: The U.S. Department of Transportation (Department or DOT), jointly with the Architectural Transportation Barriers and Compliance Board (Access Board or Board), is hosting a public meeting, to be held virtually, on a DOT notice of proposed rulemaking (NPRM) issued on January 2, 2020, and on Access Board's proposed advisory guidelines for aircraft onboard wheelchairs issued on August 20, 2019. The NPRM proposed specific measures for improving accessibility of lavatories on single-aisle aircraft for passengers with disabilities. The public meeting will focus on one aspect of this NPRM—improvements to the aircraft's onboard wheelchair (OBW). The meeting will also serve as a means for the Access Board to gather additional information on onboard wheelchair loads and onboard wheelchair casters before finalizing its advisory guidelines for aircraft onboard wheelchairs, which potentially could be a means of complying with OBW performance standards established by the Department. A Notice relating to this joint public meeting and the Access Board's reopening of the comment period for its OBW guidelines is published elsewhere in this issue of the **Federal Register**.

DATES:

Public Comments—The comment period on the proposed rule published at 85 FR 27 (Jan. 2, 2020) is reopened from December 16, 2021 (date of public meeting) to January 17, 2022.

Public Meeting—The virtual public meeting is scheduled for December 16, 2021, from 9:30 a.m. to 11:30 a.m. and from 1 p.m. to 3 p.m., Eastern Time. Requests to attend the meeting must be received by December 9, 2021. Communication access real-time translation and sign language interpretation will be provided, but requests for additional accommodations because of a disability must be received by December 9, 2021. Requests to submit written materials to be reviewed during the meeting must also be received no later than December 9, 2021. If you wish to speak during the meeting, you must submit a request by December 9, 2021. See below, **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**, for the point of contacts for these requests.

ADDRESSES:

Public Meeting—Requests to attend the meeting must be submitted to *https://usdot.zoomgov.com/webinar/register/WN_8PChAZcLQsmDm1xathLEjw.* Requests for additional accommodations because of a disability must be submitted to *OBWpublicmeeting@dot.gov.* Requests to submit written materials to be reviewed during the meeting must be submitted to *OBWpublicmeeting@dot.gov.* If you wish to speak during the meeting, you must submit a request to DOT at *OBWpublicmeeting@dot.gov.* The virtual meeting will be open to the public, subject to any technical and/or capacity limitations, and held via the Zoom Webinar Platform. Virtual attendance information will be provided upon registration. An agenda will be provided to registered participants and placed in the docket in advance of the meeting.

Public Comments—You may file comments identified by docket number DOT–OST–2019–0180 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building

Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Fax:* (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2019–0180 or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comment. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: To register and attend this virtual meeting, please contact the Department at: *https://usdot.zoomgov.com/webinar/register/WN_8PChAZcLQsmDm1xathLEjw.* For further information, contact Robert Gorman, DOT Senior Attorney at *robert.gorman@dot.gov* or 202–366–9342. You may also contact Wendy Marshall of the Access Board by email at *marshall@access-board.gov.*

SUPPLEMENTARY INFORMATION:

Background

In April 2016, the Department established and appointed members to the Advisory Committee on Accessible Air Transportation (ACCESS Advisory Committee or Committee) to negotiate and develop proposed regulations addressing, among other things, accessible lavatories on single-aisle aircraft.[1] During the first meeting, the Department committed to the Committee that if it came to a consensus on the terms of a proposed rule and the Department does not cast a dissenting vote on the consensus product, the Department would exercise good faith efforts to issue a proposed rule reflecting that consensus to the extent possible. The Committee gathered data, conducted meetings and site visits, and engaged in negotiations from May 2016 through November 2016.

On November 22, 2016, the ACCESS Advisory Committee reached consensus on recommendations for new regulatory proposals to improve the accessibility of lavatories on single-aisle aircraft and the Department did not cast a dissenting vote.[2] The accessible lavatory Term Sheet included agreements for both short-term and long-term accessibility improvements. The short-term improvements would be required on new single-aisle aircraft delivered three years after the effective date of the DOT final rule that implements the agreement. The short-term improvements included a proposed requirement that single-aisle aircraft with 125 or more passenger seats would have at least one lavatory with a number of accessibility features, including accessible door locks, flush handles, call buttons, faucets, and assist handles. Single-aisle aircraft with 125 or more passenger seats would also be required to include an OBW that: (1) Permits passage in the aircraft aisle; (2) fits within an available certificated OBW stowage space; and (3) accomplishes its functions without requiring modification to the interior arrangement of the aircraft or the lavatory. The Term Sheet called on the Department to ''consult with advocates, airlines, aircraft manufacturers, manufacturers of OBW, flight attendant association(s) and other stakeholders in developing these standards,'' and to ''include the proposed new standards for an OBW and replacement of OBW on existing aircraft as described above in its notice of proposed rulemaking.'' [3]

The Department determined that the most appropriate method for developing initial OBW design standards was to seek technical assistance from the Access Board.[4] The Access Board is a Federal agency that specializes in producing accessibility guidelines and standards for the built environment, transportation systems, information and communication technology, and medical diagnostic equipment. On August 20, 2019, the Access Board published in the **Federal Register** ''Proposed Advisory Guidelines for Aircraft Onboard Wheelchairs,'' and sought public comment.[5] The Access Board's guidelines provide design criteria for onboard wheelchair seats, back support, armrests, footrests, movement, stowage, stability, loads, caster wheels, assist handles, and torso and leg restraints. These guidelines provided for the OBW to be backed fully into the lavatory and positioned over the closed toilet so that the lavatory door can be completely closed. The guidelines also provided for the OBW to be maneuvered partially into lavatories in a forward direction to allow users the option to make a stand-and-pivot transfer to the toilet.

The Access Board held a public hearing on these advisory guidelines on September 12, 2019. In response to its proposed guidelines, the Access Board received over 40 comments from various interest groups and stakeholders, including people with disabilities, advocacy groups, aircraft manufacturers, trade associations, manufacturers of onboard wheelchairs, researchers, and others.[6]

On January 2, 2020, the Department published a notice of proposed rulemaking (NPRM) titled ''Accessible Lavatories on Single-Aisle Aircraft: Part 1.'' [7] This NPRM included proposals for short-term improvements to lavatory accessibility, including new proposed requirements for OBWs. In developing its own proposed rules for OBWs, the Department started with the Access Board's design-based guidelines and adapted them into more flexible performance standards. The performance standards were designed to allow manufacturers to find efficient and innovative means for meeting performance expectations. At the same time, the proposed rule states that airlines may use the Access Board's advisory guidelines for technical assistance in furnishing an OBW that meets the Department's performance standards.

Under the proposed rule, OBWs meeting the new standards must be installed on new single-aisle aircraft with an FAA-certificated maximum capacity of 125 seats or more that enter service three years after the effective date of a final rule issued by the Department in this proceeding. The proposed rule would require the OBW to be designed in such a manner as to enable the OBW to completely enter the lavatory in a backward orientation. Specifically, the proposed rule would require the OBW to fit over the closed toilet lid in a manner that permits the lavatory door to close completely. It is anticipated that the attendant would push the OBW backward into the lavatory by means of handles on the front of the OBW. After the OBW is situated over the closed toilet lid, the

[1] A full list of ACCESS Advisory Committee members and other information on the Committee may be found at *https://www.transportation.gov/access-advisory-committee;* see also *https://www.regulations.gov/docket?D=DOT-OST-2015-0246* (ACCESS Advisory Committee docket).

[2] *https://www.transportation.gov/office-general-counsel/negotiated-regulations/final-resolution-access-committee.*

[3] *https://www.transportation.gov/sites/dot.gov/files/docs/Annex%20A.Lav_.Agreed%20Text.pdf.*

[4] *https://www.access-board.gov.*

[5] See 84 FR 43100; *https://www.federalregister.gov/documents/2019/08/20/2019-17873/advisory-guidelines-for-aircraft-onboard-wheelchairs.* The Access Board's Docket for OBW standards is found at *https://www.regulations.gov/docket?D=ATBCB-2019-0002.*

[6] See Docket No. ATBCB–2019–0002 at *https://www.regulations.gov/docket/ATBCB-2019-0002.*

[7] See 85 FR 27; *https://www.federalregister.gov/documents/2020/01/02/2019-27631/accessible-lavatories-on-single-aisle-aircraft-part-1.*

door would be closed and the passenger would be able to perform non-toileting lavatory functions in privacy.

The proposed rule would also require that the OBW be designed such that it could, at a minimum, partially enter the lavatory in a forward orientation. The purpose of this provision is to facilitate a stand-and-pivot maneuver from the OBW to the toilet seat, for passengers who are able to do so. With a stand-and-pivot maneuver, the passenger would partially enter the lavatory by means of the OBW, stand up, and pivot 180 degrees to reach the toilet seat.

The proposed OBW rule also contained safety elements. For example, the proposed rule would require that the height of the OBW seat must align with the height of the aircraft seat to the maximum extent practicable, in order to permit a safe transfer between the OBW and the aircraft seat. The proposed rule would require the wheels of the OBW to lock in the direction of travel, in order to avoid contact with aircraft seats and other obstructions as it moves down the aisle. Any other moving parts of the OBW would need to be capable of being secured such that they do not move while the occupied onboard wheelchair is being maneuvered. The wheels would also be required to lock in place so as to provide stability during transfers. The OBW would be required not to tip or fall in any direction under normal operating conditions when occupied for use.

The OBW would also be required to have a padded seat and backrest, in order to preserve skin integrity, and to prevent spasticity and injury.[8] The proposed rule would also require the OBW to be free of sharp or abrasive components. The OBW would also be required to have arm supports that are sufficient to facilitate transfers; arm supports that are repositionable to permit unobstructed transfers between the OBW and the aircraft seat; torso and leg restraints to ensure stability and prevent injury; as well as a unitary foot support that would provide adequate clearance over the lavatory threshold and also allow for an unobstructed transfer between the OBW and the lavatory. Under the proposed rule, restraints would be operable by the passenger in order to permit the passenger the option to adjust the restraints unassisted. Finally, the proposed rule would require the OBW to have instructions prominently displayed for proper use.

In keeping with the ACCESS Advisory Committee's Term Sheet, airlines would not be required to modify aircraft interiors, including lavatories and existing OBW stowage spaces, in order to comply with these OBW provisions. The Department sought comment on all aspects of this critical issue of OBW stowage space. Specifically, the Department sought further data regarding: (1) The folded dimensions of OBWs currently in use on single-aisle aircraft; (2) the locations and dimensions of current OBW stowage spaces; and (3) the feasibility of designing and constructing an OBW that meets the listed performance standards, particularly including the ability to enter the lavatory in a backward orientation, while fitting into the existing OBW stowage space for that aircraft. The Department also sought comment on an alternative proposal: Whether to require OBWs to meet the new performance standards set forth in the NPRM even if stowage space must be expanded to accommodate the OBW. The Department sought comment on the costs of expanding OBW stowage spaces to meet these performance standards.

Again in keeping with the ACCESS Advisory Committee's Term Sheet, the proposed rule provided that an airline would not be responsible for the failure of third parties to furnish an OBW that complies with these proposed standards, so long as the airline notifies and substantiates to the Department the efforts it expended to obtain compliant OBWs. The Department recognized that, at present, no commercially available OBW exists that permits backward passage into an aircraft lavatory, and that while airlines may seek to procure an OBW that meets the Department's performance standards, airlines do not design or produce OBWs themselves.[9]

Finally, the proposed rule provided that if an airline replaces an OBW on an aircraft with an FAA-certificated maximum capacity of 125 seats or more three years after the effective date of the rule, then the replacement OBW must comply with DOT's new OBW standards. The Department sought comment on all aspects of the OBW proposal, including costs, benefits, and feasibility.

The comment period to the NPRM closed on March 2, 2020. The Department received relatively few comments about OBW design, and almost no comments that estimated the costs of developing or manufacturing an OBW that would comply with the standards set forth in the proposed rule. Certain disability advocates argued, among other things, that the Department's OBW standards should have tracked more closely the Access Board's design standards.[10] Representatives of the airline industry contended that the Department failed to take into account considerations such as aviation safety and the impact on flight attendants of unpacking, using, and stowing the OBW while in flight.[11] They also argued that the Department failed to adequately consult with stakeholders before issuing its OBW proposal.[12] The Department received no comments from OBW manufacturers.

Announcement of Public Meeting

Under these circumstances, the Department is of the view that it is appropriate to hold a public hearing to gather additional information on all aspects of OBW design before issuing any final binding regulation on the topic. The Department also finds that the public meeting will be an appropriate vehicle for the Access Board to gather additional information before it finalizes advisory guidelines for OBWs.

Questions Relating to DOT's NPRM Regarding OBW Design

The Department seeks further information on all aspects of its NPRM relating to OBW design, including but not limited to:

- Whether the proposed OBW design elements adequately address accessibility concerns;
- The cost and feasibility of designing, manufacturing, and implementing compliant OBWs;
- The cost of developing and implementing procedures for training

[8] DOT specifically sought comment on whether the proposed rule text adequately conveys the degree of back support and seat support necessary to properly accommodate passengers with disabilities, and if not, whether additional standards should be specified.

[9] The Department sought comment on whether there should be a deadline for an airline to notify the Department that the airline has expended its efforts to obtain compliant OBWs, and if so, how many days after an airline becomes aware of such commercial unavailability (*e.g.,* 30 days) would be appropriate for airlines to notify the Department. The Department also recognized the uncertainties surrounding the issue of whether OBWs meeting the Department's new standards can fit within existing OBW stowage spaces. The intent of the proposal was to encourage innovation in meeting the proposed standards by affirmatively requiring airlines to engage in reasonable efforts to obtain compliant OBWs from third parties. The Department sought comment on whether the ''reasonable efforts'' clause is the most appropriate means of reaching the overarching goal of ensuring that OBWs with the new accessibility features are acquired.

[10] See, *e.g.,* Comment of Paralyzed Veterans of America, *https://www.regulations.gov/comment/DOT-OST-2019-0180-0335,* at 5.

[11] See, *e.g.,* Comment of Airlines for America, *https://www.regulations.gov/comment/DOT-OST-2019-0180-0337,* at 2–3.

[12] Id.

crew in unloading, using, and stowing the OBW;

- The dimensions of current OBW stowage spaces in single-aisle aircraft;
- Whether OBWs that meet the Department's proposed accessibility standards can be stowed in existing stowage spaces; and
- Aviation safety considerations relating to unloading, using, and stowing the OBW while in flight.

We specifically invite disability advocates, airlines, aircraft manufacturers, manufacturers of OBWs, flight attendant associations, and other stakeholders to participate in the public meeting. We also encourage stakeholders and participants to file written materials in the docket when the comment period reopens, which will be from December 16, 2021 (date of public meeting) to January 17, 2022. The Department considers this public meeting, along with its prior actions in this matter, to satisfy the consultation provisions set forth in the ACCESS Advisory Committee's Term Sheet.

Questions Relating to Access Board's Proposed Voluntary Design Standards

As stated earlier, the public meeting will also allow the Access Board to gather additional information regarding its advisory guidelines containing recommended dimensions and other technical specifications for a comfortable and functional aircraft onboard wheelchair. More specifically, the Access Board is seeking additional information regarding onboard wheelchair loads and onboard wheelchair casters.

Onboard Wheelchair Loads

The overall weight capacity or load of current onboard wheelchairs varies greatly and ranges from approximately 200 to 800 pounds. In trying to determine the appropriate load, the Board looked to its *Guidelines for Aircraft Boarding Chairs* (1987), which recommends that seats support at least 723 pounds (weight of a 99th percentile male with a 3.0 safety factor). See *https://www.access-board.gov/research/completed-research/guidelines-for-aircraft-boarding-chairs.* Using updated anthropometrics, the weight of a 99th percentile male with a 3.0 safety factor would be 826 pounds. See Department of Health and Human Service Centers for Disease Control and Prevention's Anthropometric Reference Data for Children and Adults: United States, 2011–2014, Table 6, Line 1 (Aug. 2016). However, the boarding chair (used to transfer a passenger from their personal wheelchair to the airplane seat) is different than the proposed onboard wheelchair, in that a boarding chair does not need to fold for storage on the aircraft or require a cantilever design.

The Board is not aware of existing industry standards for onboard wheelchairs that are designed to allow over-the-toilet positioning. In its proposal, it reserved provisions for loads pending further information as to what loads are appropriate for an onboard wheelchair design that accomplishes the proposed functions.

Comments from the public, including aircraft manufacturers, recommended that the Board's guidelines reference load specifications in standards issued by SAE International, ''Foldable On-Board Wheelchairs for Passengers with Disabilities,'' ARP 4120C (Stabilized 2013).'' The SAE standard specifies loads for onboard wheelchair seats, seat backs, arm and foot supports, wheels, and assist handles. These referenced provisions are publicly available (read-only, not for distribution) until the close of the comment period on January 17, 2022, on SAE International's website at: *https://www.sae.org/binaries/content/assets/cm/content/standards/arp4120c_review.pdf.*

Based on its review of the comments on the proposed guidelines, the Board is considering referencing the SAE International's standard for loads for seats (3.2.9.1), arm supports (3.2.9.3), foot support (3.2.9.4), casters (3.2.9.2), and assist handles of onboard wheelchairs (3.2.9.6). The Board seeks comment on whether the loads specified in the SAE International ARP 4120C Standard are appropriate for an onboard wheelchair design that allows the chair to be positioned over the closed lavatory toilet. Alternatively, what other loads should be specified?

Onboard Wheelchair Casters (Size)

The guidelines require that caster wheels of onboard wheelchairs move independently to facilitate maneuvering within the confined space of aircraft aisles and lavatories. For safety and stability, the guidelines also require each caster to have wheel locks and swivel locks. In its proposal, the Board sought comment on whether the guidelines should specify a minimum size for caster wheels so that they are large enough to readily travers thresholds at lavatory entrances. Most commenters recommended that the guidelines specify a performance requirement instead of a minimum caster size. However, the impact of thresholds may be significant since the front assist handles will be used to back occupied onboard wheelchairs into lavatories and to pull them back out. What is the minimum caster wheel diameter that would ensure stability of the occupied onboard wheelchair and allow the chair to easily traverse the lavatory doorway threshold pushing it in and pulling it out of lavatories using only the front assist handles? The Board also requests information on the standard height of lavatory thresholds on single-aisle aircraft with 125 or more passenger seats.

Viewing Documents

You may view documents mentioned in this notice at *https://www.regulations.gov.* After entering the docket number (DOT–OST–2019–0180), click the tab labeled ''Browse & Comment on Documents,'' and choose the document to review.

Issued in Washington, DC, on or about this 9th day of November, 2021.

John E. Putnam,

Deputy General Counsel, U.S. Department of Transportation.

[FR Doc. 2021–25000 Filed 11–18–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 232, 240, 249, 270, 275, and 279

[Release Nos. 34–93518; IA–5903; IC–34415; File No. S7–15–21]

RIN 3235–AM97

Electronic Submission of Applications for Orders Under the Advisers Act and the Investment Company Act, Confidential Treatment Requests for Filings on Form 13F, and Form ADV–NR; Amendments to Form 13F

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission is proposing amendments to rules to convert the filing of certain applications, confidential treatment requests, and forms from paper to electronic submission. Specifically, we propose to amend our rules to require that the following types of filings be submitted via our Electronic Data Gathering, Analysis, and Retrieval (''EDGAR'') system: Applications for orders under any section of the Investment Advisers Act of 1940 (''Advisers Act'') and confidential treatment requests for filings made under section 13(f) of the Securities Exchange Act of 1934 (''Exchange Act''). We also propose rule amendments to harmonize the requirements for the submission of applications for orders

under the Advisers Act and the Investment Company Act of 1940 (''Investment Company Act''). In addition, we propose to amend other rules and a form to require the electronic submission of Form ADV–NR through the Investment Adviser Registration Depository (''IARD'') system. We also propose to require non-resident general partners and non-resident managing agents to amend their Form ADV–NR within 30 days whenever any information contained in the form becomes inaccurate by filing with the Commission a new Form ADV–NR. Further, we are re-proposing amendments to Form 13F to require managers to provide additional identifying information. Finally, we are re-proposing certain technical amendments to Form 13F, including modernizing the structure of data reporting and amending the instructions on Form 13F for confidential treatment requests in light of a recent decision of the U.S. Supreme Court.

DATES: Comments should be received on or before December 20, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/submitcomments.htm*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number S7–15–21 on the subject line.

Paper Comments

- Send paper comments to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–15–21. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's website (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission's public reference room. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the Commission's website. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Zeena Abdul-Rahman, Senior Counsel, Sara Cortes, Senior Special Counsel, Investment Company Rulemaking Office, at (202) 551–6792; or Alexis Palascak, Senior Counsel, Investment Adviser Regulation Office, at (202) 551–6787 or *IM-Rules@sec.gov,* Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission is proposing amendments to 17 CFR 232.11 (''rule 11''), 17 CFR 232.100 (''rule 100''), 17 CFR 232.101 (''rule 101''), 17 CFR 232.102 (''rule 102''), and 17 CFR 232.201 (''rule 201'') of Regulation S–T relating to electronic filing on the EDGAR system; 17 CFR 275.0–4 (''rule 0–4'') and 17 CFR 275.203–1 (''rule 203–1'') under the Advisers Act; 17 CFR 279.4 (''Form ADV–NR'') and the instructions to 17 CFR 279.1 (''Form ADV'') under the Advisers Act; 17 CFR 270.0–2 (''rule 0–2'') under the Investment Company Act; 17 CFR 240.24b–2 (''rule 24b–2'') under the Exchange Act; and 17 CFR 249.325 (''Form 13F'').

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I. Background

The Commission seeks to promote efficiency, transparency, and operational resiliency by modernizing the manner in which information is submitted to us and, where appropriate, disclosed to the public. Electronic filing improves our ability to achieve these goals. Specifically, electronic filing minimizes the risks of delay in staff receiving the information via paper submissions, and it increases efficiency in the staff review process by reducing staff processing time, increasing quality assurance, and improving the ability to review and analyze information contained in electronic submissions. In addition to increasing staff efficiency of review, publicly filed electronic submissions are more readily available on our website in easily searchable formats, which benefits both investors and the asset management industry.

In addition, electronic filing capabilities have proved to be an effective measure in addressing certain of the logistical and operational issues raised by the spread of coronavirus disease (''COVID–19''). We believe that converting paper submissions to electronic submissions would allow the Commission, and those persons filing the submissions, to more effectively and efficiently navigate any future disruptive events—like COVID–19—that make the paper submission process unnecessarily burdensome, impractical, or unavailable. Further, we believe that the proposed electronic submission process better reflects the current business practices and operations of those persons that file the submissions and, as a result, would likely reduce the burden associated with submitting such filings. These benefits are among the reasons that the Commission has

transitioned filings from paper to electronic format in many contexts.[1]

We are proposing to require electronic filing of applications for orders under any section of the Advisers Act,[2] and of confidential treatment requests for filings made under section 13(f) of the Exchange Act (''13(f) Confidential Treatment Requests''). These filings would be required to be submitted through the EDGAR system.[3] In addition, we are re-proposing certain amendments to Form 13F that we originally proposed in July 2020.[4] The Commission is not re-proposing the amendments to raise the reporting thresholds for Form 13F that were included in the 2020 Form 13F Proposal. As discussed further below, and consistent with the original proposal, we are proposing (i) a requirement for an institutional investment manager[5] (''manager'') that files Form 13F to provide certain identifying information, (ii) certain technical amendments to modernize the information reported on Form 13F, consistent with its existing structured eXtensible Markup Language (''XML'') format, and (iii) a modification to instruction 2.d. of Form 13F's Confidential Treatment Instructions to update that instruction and make it consistent with a recent U.S. Supreme Court decision.[6] We also are proposing other rule amendments to harmonize the requirements for submission of applications for orders under the Advisers Act and the Investment Company Act.

Finally, we are proposing to require the electronic submission of Form ADV–NR by non-resident general partners and non-resident managing agents of investment advisers (domestic or non-resident) registered with the Commission. Form ADV–NR is filed in connection with an adviser's initial Form ADV submission and requires a non-resident general partner or managing agent of an investment adviser to appoint an agent for service of process in the United States.[7] Under the proposed amended rules, filers would be required to submit Form ADV–NR through the IARD system.

II. Discussion

A. Applications

1. Electronic Filing

Section 206A of the Advisers Act gives the Commission the authority to provide exemptions from any provision of the Advisers Act or any rule or regulation thereunder, provided the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Advisers Act.[8] Applicants seeking an exemption must apply to the Commission to obtain an order.[9] The processes for submitting an application are addressed in Advisers Act rule 0–4[10] and Commission Guidelines issued in 1985 (''1985 Release'').[11] Since the 1985 Release, the process for handling exemptive applications in the Division of Investment Management (''Division'') has evolved. While an applicant seeking Investment Company Act relief submits its application electronically to the Commission via EDGAR, an applicant seeking Advisers Act relief submits its application, as well as a proposed notice of application, in paper and in quintuplicate.[12] The paper copies of the applications are delivered to the Commission's mailroom for stamping, logging, and ultimately for routing to the Division staff. Staff then create a notification in the EDGAR system in order to assign an appropriate file number, manually upload the application onto our public website, and process the application for internal tracking. The current manual process for submitting and handling Advisers Act applications creates inefficiencies in a number of ways, including those resulting from the absence in Advisers Act rule 0–4 of a specific addressee at the Commission for applications.[13]

Moreover, in order to achieve an expeditious review of an application, applicants often, to the extent possible, adhere to applicable precedent and address any differences from prior applications.[14] Applicants and staff, accordingly, rely on the ready availability of applications that have been evaluated by the Commission and its staff. Commission staff place the applications (including amendments, notices of applications, and the resulting orders) on the Commission's website in order to improve transparency and to facilitate this reliance. Unlike other filings made in EDGAR, Advisers Act applications are not readily available to the public upon submission; instead they require the staff actions described above to be posted.

Prior to the Commission amending its rules in 2008 to mandate electronic submission of applications for orders under any section of the Investment Company Act,[15] applicants filed their

[1] *See* Updating Edgar Filing Requirements, Securities Act Release No. 11005 (Nov. 4, 2021); *see also* Amendments to the Commission's Rules of Practice, Exchange Act Release No. 90442 (Nov. 17, 2020) [85 FR 86464 (Dec. 30, 2020)]; *Cf.* Electronic Signatures in Regulation S–T Rule 302, Securities Act Release No. 10889 (Nov. 17, 2020) [85 FR 78224] (Dec. 4, 2020).

[2] Applications for registration as an investment adviser under the Advisers Act and applications for withdrawal from registration are filed via IARD. *See* 17 CFR 275.203–1; 17 CFR 275.203–2. We are not proposing to alter these requirements.

[3] The EDGAR Filer Manual, which is promulgated by the Commission, sets out the technical formatting requirements for electronic submissions. *See* 17 CFR 232.301.

[4] *See* Reporting Threshold for Institutional Investment Managers, Exchange Act Release No. 89290 (July 10, 2020) [85 FR 46016 (July 31, 2020)] (''2020 Form 13F Proposal'').

[5] The term ''institutional investment manager'' includes any person, other than a natural person, investing in or buying and selling securities for its own account, and any person exercising investment discretion with respect to the account of any other person. *See* section 13(f)(6)(A) of the Exchange Act [15 U.S.C. 78m(f)(6)]. The term ''person'' includes any natural person, company, government, or political subdivision, agency, or instrumentality of a government. *See* section 3(a)(9) of the Exchange Act [15 U.S.C. 78c(3)(9)].

[6] *Food Marketing Institute* v. *Argus Leader Media,* 139 S.Ct. 2356 (2019) (overturning the longstanding interpretation set forth in *National Parks* v. *Morton,* 498 F.2d 765 (D.C. Cir. 1974) of ''confidential'' for purposes of FOIA exemption 4).

[7] *See* proposed amended rule 203–1(d) [17 CFR 275.203–1(d)]. The proposed amendments would continue to permit a paper filing of Form ADV–NR if a continuing hardship exemption is granted under Advisers Act rule 203–3(b) [17 CFR 275.203–3].

[8] *See* section 206A of the Advisers Act [15 U.S.C. 80b–6a].

[9] Possible applicants include, but are not limited to, registered investment advisers, exempt reporting advisers, and persons not registered with the Commission but who meet the definition of investment adviser under the Advisers Act.

[10] 17 CFR 275.0–4.

[11] Commission Policy and Guidelines for Filing of Applications for Exemption from Some or All of the Provisions of the Investment Company Act of 1940 and the Investment Advisers Act of 1940, Investment Advisers Act Release No. 969 (Apr. 30, 1985) (''1985 Release'').

[12] Pursuant to rule 0–4(b), every application for an order under any provision of the Advisers Act, for which a form with instructions is not specifically prescribed, and every amendment to such application shall (among other requirements) be filed in quintuplicate. 17 CFR 275.0–4(b). Rule 0–4(g) requires that a proposed notice of the proceeding initiated by the filing of the application accompany each application as an exhibit thereto. 17 CFR 275.0–4(g).

[13] Any delay between Commission receipt and receipt by the appropriate staff member means that there is delay in public availability of the application. We propose to designate the Secretary of the Commission as the addressee for paper applications for an order under both the Advisers Act and the Investment Company Act (*e.g.,* applications made in paper pursuant to a hardship exemption under Regulation S–T). *See infra* footnotes 33 and 34 and accompanying text.

[14] *See* 1985 Release, *supra* footnote 11 (discussing that applicants should recognize the differences between their proposal and prior applications requesting similar relief and, to the extent possible, bring their proposal within applicable precedent. Further, applicants should cite and discuss applicable precedent.).

[15] *See generally* Mandatory Electronic Submission of Applications for Orders under the Investment

Continued

applications for Investment Company Act orders in paper using a similar process as those seeking orders under the Advisers Act.[16] In our experience, the transition from paper to electronic filing of Investment Company Act applications has led to more streamlined and timely application processing. Commission staff have immediate access to an Investment Company Act application through EDGAR, eliminating the need for manually processing the application. The ability to review applications in EDGAR immediately creates internal efficiencies by shortening the time to create and maintain records as well. Additionally, the Commission has received applications from parties seeking relief under both the Advisers Act and the Investment Company Act that were unable to file a single application because of the current multiple-system requirements for the differing applications.[17] Our proposal would allow such applications to be filed jointly in a single submission.

The transition to electronic submission in the Investment Company Act context has led to increased transparency for filers seeking similar relief, who can now more easily search for and replicate (as appropriate) similar applications for an exemptive order.[18] Similarly requiring Advisers Act applications to be submitted electronically in EDGAR would benefit investors, applicants, and other interested parties by making information contained in these filings more readily and immediately available and more easily searchable. We also believe that making these filings and applications immediately available in electronic format in the EDGAR database would provide a more complete and more easily reviewable picture for the investing public, to the extent such applications might inform investors' decisions with respect to selection or retention of investment advisers.[19]

a. The EDGAR Filing System

While most electronic filings made with the Commission are filed via the EDGAR system,[20] investment advisers submit certain filings and reports electronically via the IARD system (including registration applications under the Advisers Act).[21] We are proposing, however, to require electronic submission of Advisers Act applications on EDGAR.[22] We do so for a number of reasons. First, the cost to advisers of submitting electronic applications through the EDGAR system would be relatively low.[23] Second, the EDGAR system should require fewer technological changes than IARD in order to accept Advisers Act applications, as it is already designed to accept Investment Company Act applications. Third, EDGAR would allow for applications under both the Investment Company Act and the Advisers Act to be made in a single filing.[24] Fourth, the process for filing applications under the Advisers Act on EDGAR would be consistent with the process for filing applications under the Investment Company Act, which we believe would facilitate internal processing efficiencies by Commission staff. Finally, we believe that having applications under both the Investment Company Act and the Advisers Act in the same system would increase transparency for the public as users would only need to learn how to access one system to locate all relevant applications.

b. Proposed Rule Amendments

We are proposing to amend certain rules of Regulation S–T[25] and Advisers Act rule 0–4 to require electronic filing on EDGAR of applications for an order under any section of the Advisers Act. Proposed amendments to rule 101(a)(1) of Regulation S–T would include within its mandatory electronic submissions any application for an order under any section of the Advisers Act.[26] Regulation S–T includes rules concerning mandatory and permissive electronic EDGAR submissions. It also generally requires the electronic filing of any amendments and related correspondence and supplemental information pertaining to a document that is the subject of mandated EDGAR submission.[27] Additionally, Regulation S–T generally requires exhibits to an electronic filing to be filed in electronic format, absent a hardship exemption.[28] The proposed amendments to these requirements would apply to persons who submit applications under the Advisers Act, as they do to persons who

Company Act and Filings Made Pursuant to Regulation E, Securities Act Release No. 8981 (Oct. 29, 2008) [73 FR 65516 (Nov. 4, 2008)] (''2008 IC Applications Release'').

[16] The amendments mandating electronic submission of Investment Company Act exemptive applications followed a report by the Commission's Office of Inspector General that recommended a transition to electronic submission of Investment Company Act applications. *See* IM Exemptive Application Processing, SEC Office of Inspector General, Audit Report No. 408, Recommendation B (Sept. 29, 2006).

[17] For such applications, the applications under the Investment Company Act were made in HTML on EDGAR, and the Advisers Act applications were submitted in paper.

[18] *See* Amendments to Procedures With Respect to Applications Under the Investment Company Act of 1940, Investment Company Act Release No. 33921 (July 6, 2020) [85 FR 57089 (Sept. 15, 2020)] (''2020 IC Applications Procedures Release'') (adopting amendments to rules under the Investment Company Act to establish an expedited review procedure for applications that are substantially identical to recent precedent as well as a rule to establish an internal timeframe for review of applications outside of such expedited procedure). We are not proposing to extend the rules adopted in the 2020 IC Applications Procedures Release to applications for exemptions from provisions of the Advisers Act.

[19] As noted above, because of the current manual process of categorizing and uploading Advisers Act applications, there can be a delay in making a paper application public. *See supra* at text accompanying footnote 13.

[20] This includes applications for orders under any section of the Investment Company Act as well as Regulation E filings of small business investment companies and business development companies. *See* 2008 IC Applications Release, *supra* footnote 15.

[21] *See e.g.,* 17 CFR 275.203–1 (application for investment adviser registration), 275.203–2 (withdrawal from investment adviser registration), 275.203–3 (hardship exemptions from the requirement to make Advisers Act filings electronically with IARD), and 275.204–4 (reporting by exempt reporting advisers).

[22] Although investment advisers register using the IARD system, some advisers may be familiar with the EDGAR system as a result of other required filings on EDGAR, such as certain filings made pursuant to sections 13 and 16 of the Exchange Act or registration statements filed on behalf of registered investment companies they manage. *See* 17 CFR 240.13f–1, 17 CFR 240.13d–1, 15 U.S.C. 78p(a).

[23] *See infra* at text accompanying footnote 143 and section IV.A (discussing the costs associated with submitting applications electronically).

[24] For applications with multiple co-applicants (*i.e.,* if certain applicants were included for Advisers Act relief and others were included for Investment Company Act relief), the applicants would be able to submit the application with all co-applicants included in one submission. The applicants would choose one applicant to list first as the ''primary'' co-applicant. Then, they would include in the EDGAR submission the information for all other co-applicants.

[25] 17 CFR 232.11, 232.100, 232.101, 232.102 and 232.201.

[26] *See* proposed section (a)(1)(xxiii) of rule 101 of Regulation S–T. As part of such changes, we are proposing to add the term ''Investment Advisers Act'' as a defined term in rule 11 of Regulation S–T, meaning the Investment Advisers Act of 1940. *See* proposed amendments to rule 11 of Regulation S–T; *see also infra* footnote 95 (discussing other proposed non-substantive conforming edits to rule 101 of Reg S–T).

[27] *See* rule 101(a)(1) of Regulation S–T [17 CFR 232.101(a)(1)]. Related correspondence and supplemental information are not automatically disseminated publicly through the EDGAR system but are immediately available to the Commission staff.

[28] *See* rule 102(a) of Regulation S–T [17 CFR 232.102(a)]. Proposed amendments to rule 102(a) of Regulation S–T would provide that previously filed exhibits, whether in paper or electronic format, may be incorporated by reference to the extent permitted by Advisers Act rule 0–6 [17 CFR 275.0–6]. *See* EDGAR Filer Manual, Volume II: ''EDGAR Filing'' (Version 57) (Mar. 2021) (''2021 EDGAR Filer Manual''), at Sections 2.1 (EDGAR Filing Process) and 5.2 (Document Formats).

submit applications under the Investment Company Act.[29]

Rule 0–4 generally prescribes requirements for filings made under the Advisers Act.[30] Proposed amendments to rule 0–4 would require that every application for an order under any provision of the Advisers Act, for which a form with instructions is not specifically prescribed, and every amendment to such application, be filed electronically pursuant to Regulation S–T.[31] Rule 0–4's specifications for the submission of paper applications would continue to apply for any remaining paper applications, such as filings made pursuant to a hardship exemption under Regulation S–T.[32] Although we anticipate paper submissions would be rare, we propose to amend rule 0–4 to require that the Secretary of the Commission be the designated addressee of such paper submissions.[33] We propose an identical clarifying change to designate the Secretary of the Commission as addressee of any remaining paper submissions under the Investment Company Act.[34]

c. Request for Comment

We request comment on our proposal to require that applications for orders under any section of the Advisers Act be submitted electronically via EDGAR.

1. Are there burdens or other issues related to electronic filing, as opposed to paper filing, that the Commission should consider with regard to applications for an order under the Advisers Act? Should we allow (but not require) electronic submission of such applications? Should certain types of Advisers Act applications be excluded from mandatory electronic submission? If so, which types of applications should be excluded?

2. Is the EDGAR system the appropriate system for Advisers Act applications? Should the Commission use, for example, the IARD system, or a secure file transfer system instead? Would requiring Advisers Act applications to be filed on IARD be more beneficial for investors and other market participants? If so, why? Alternatively, is there another method of electronic submission that is preferable? If so, please identify the method you believe we should adopt, why you believe it should be used, and the estimated costs of such system for filers.

3. Similar to many other provisions of Regulation S–T, including the provision for Investment Company Act applications, the proposed rule does not specify a particular filing format though we anticipate the filing format would be HTML or ASCII, like many other EDGAR filings, including Investment Company Act applications. What format or formats should the rule permit for filing of Advisers Act applications? Should the Commission require a single, specified format or permit filers to select a format among two or more possible formats? What time or expense is associated with particular formats? What time or expense would be required of the public to view documents in a particular format? Would a particular format require any filers or users to license commercial software they otherwise would not, and, if so, at what expense?

4. Is there any additional information that commenters can provide with respect to the difficulties and/or considerations unique to the proposed amendments? In the event that commenters believe that any aspect of the proposed amendments would affect the costs of filing or using the information, we ask for specific details, quantitative data, and alternative approaches.

2. Availability of Hardship Exemptions

a. General

Under the proposal, temporary hardship exemptions from electronic filing would not be available for applications for orders under the Advisers Act, but continuing hardship exemptions from electronic filing would be available. Rule 201 of Regulation S–T provides that if an electronic filer experiences unanticipated technical difficulties preventing the timely preparation and submission of an electronic filing, the electronic filer may file in paper format no later than one business day after the date on which the filing was to be made, subject to certain requirements and exclusions (''temporary hardship exemption''). This temporary hardship exemption is available automatically but must be followed by a confirming electronic copy within six business days. Currently, rule 201 does not address applications for orders under the Advisers Act because such applications are filed in paper rather than filed electronically. We are proposing to amend rule 201 so it would exclude applications for orders under the Advisers Act, as it does with applications for orders under the Investment Company Act.[35] As a result, temporary hardship exemptions would not be available for applications for orders under the Advisers Act, as is the case with applications for orders under the Investment Company Act. We believe that submission exigencies or submission deadlines associated with applications for orders under the Advisers Act would be rare.

A filer may apply for a continuing hardship exemption from electronic filing under rule 202 of Regulation S–T if it cannot file all or part of a filing without undue burden or expense.[36] A continuing hardship exemption may be granted for a limited time period or indefinitely. Time-limited continuing hardship exemptions may be conditioned upon filing the document in electronic format by a certain date. Continuing hardship exemptions would be available for applications for orders under the Advisers Act under rule 202, as it is currently written, without any amendments.

b. Request for Comment

We request comment on the availability of hardship exemptions.

5. Like applications for orders under the Investment Company Act, should a temporary hardship exemption not be available for applications for orders under the Advisers Act, as proposed? Why or why not? Could there be any submission exigency or submission deadline associated with applications for orders under the Advisers Act? If so, with what frequency might such exigency occur? Alternatively, should a temporary hardship exemption be available for applications for orders under the Investment Company Act or the Advisers Act? Why or why not?

6. Like applications for orders under the Investment Company Act, should a continuing hardship exemption be available for applications for orders under the Advisers Act, as proposed?

[29] In order to clarify that all applicants for an order under the Advisers Act (and not just registered investment advisers) are subject to Regulation S–T, we also propose to amend rule 100(b) to replace the term ''registrants'' and state that ''[p]ersons or entities'' whose filings are subject to review by the Division shall be subject to the electronic filing requirements of Regulation S–T. *See* proposed amendment to section (b) of rule 100 of Regulation S–T, the wording of which would conform to section (c) of the rule.

[30] *See* 17 CFR 275.0–4.

[31] *See* proposed amendment to Advisers Act rule 0–4(b).

[32] *See id.* Regulation S–T generally requires requests for confidential treatment of an application to be filed in paper, and it provides a process for seeking a continuing hardship exemption. *See* rule 101(c)(1)(i) [17 CFR 232.101(c)(1)(i)] (confidential treatment) and rule 202 [17 CFR 232.202] (continuing hardship exemption) of Regulation S–T.

[33] *See* proposed amendment to Advisers Act rule 0–4(a).

[34] *See* proposed amendment to Investment Company Act rule 0–2(a).

[35] *See* 2008 IC Applications Release, *supra* footnote 15.

[36] 17 CFR 232.202.

Should a continuing hardship exemption not be available for applications for orders under the Investment Company Act? Why or why not?

3. Elimination of Certain Requirements

a. General

We are proposing to amend rule 0–4 governing the form of applications under the Advisers Act to harmonize the requirements with the requirements for applications under the Investment Company Act and further reduce the burden of filing such applications.[37] First, we are proposing to eliminate the requirement to have verifications of applications and statements of facts made in connection with applications notarized.[38] We believe that this requirement is unnecessary in the context of these filings.[39] In the 2008 IC Applications Release, we removed the corresponding requirement for applications for an order under the Investment Company Act,[40] and we have not had significant issues or concerns with the removal of notarizations in that context. Second, we are proposing to eliminate the requirement that applicants include proposed notices as exhibits to applications.[41] This requirement was also removed for applications under the Investment Company Act in the 2008 IC Applications Release.[42] Moreover, the elimination of this requirement for applications submitted under the Investment Company Act has resulted in reduced filing burdens for applicants. Finally, we are removing the reference to microfilming in Advisers Act rule 0–4(b) and Investment Company Act rule 0–2(b), as the Commission no longer microfilms applications for an order under either Act.[43]

b. Request for Comment

We request comment on the proposed amendments to eliminate the notarization and proposed notice requirements for Advisers Act applications, to remove the reference to microfilming in Advisers Act rule 0–4 and Investment Company Act rule 0–2, and to revise the wording in Advisers Act rule 0–4(i) related to duplicate original copies in a paper applications.

7. Should we maintain any of these requirements that we are proposing to either modify or eliminate? Why or why not? Should we instead modify, or otherwise replace, any of these requirements with alternative and/or additional requirements? If so, how should we modify and/or supplement these requirements and/or what alternatives should the rule(s) require? If we make these, or other, modifications to the Advisers Act rules, should we also make the same, or similar, modifications to the analogous rules under the Investment Company Act? If so, please describe what, if any, modifications and/or differences we should include in any amendments made to the Investment Company Act rules.

8. What costs, benefits and/or other effects might be associated with the proposed modifications? Please describe how such costs, benefits or other effects relate to the current requirements of the proposed rule.

4. Form ADV–NR

a. General

Filing Form ADV–NR is mandatory for non-resident general partners and non-resident managing agents of investment advisers and must be filed in connection with an adviser's initial Form ADV submission.[44] The Commission collects this information to ensure that a non-resident general partner or managing agent of an investment adviser appoints an agent for service of process in the United States.[45] Currently, Form ADV–NR must be filed as a paper filing submission.[46] The Commission makes Form ADV–NR publicly available by posting an update to EDGAR indicating that the Commission received a Form ADV–NR filing. Members of the public can view such updates by searching for an adviser, and can use the information in the update to request the Form ADV–NR through a Freedom of Information Act (''FOIA'') request.[47]

We are proposing amendments to Advisers Act rule 203–1 to require investment advisers' non-resident general partners and non-resident managing agents to file Form ADV–NR electronically through IARD, which is the same system advisers use to file Form ADV.[48] We anticipate that IARD would present proposed Form ADV–NR in fillable format. Members of the public would be able to view Forms ADV–NR through the same system they view Forms ADV, which is the Investment Adviser Public Disclosures (IAPD), the public interface of IARD. We believe that requiring electronic submission of Form ADV–NR would enhance our ability to collect and access the information on the form and likely reduce the burden associated with filing and processing such forms. Furthermore, we believe that requiring electronic submission of Form ADV–NR would allow filers to more effectively and efficiently navigate future disruptive events—like COVID–19—when staff and filers are unable to access their physical work facilities to complete, submit and process paper fillings. The proposed amendments would still, however, permit those required to file Form ADV–NR to file the form via paper submission if granted a hardship exemption under rule Advisers Act rule 203–3.[49] The proposed amendments would, like the current rule, require (1) advisers, non-resident general partners and a non-resident managing agents to complete and file Form ADV–NR in connection with the adviser's initial registration with the Commission; and (2) a person who becomes a non-resident general partner or a non-resident managing agent after the date the adviser files its

[37] We also propose to correct a typo in [17 CFR 275.0–4(i)] (Advisers Act rule 0–4(i)) concerning duplicate original copies in paper applications (concerning the singular and plural of ''original'').

[38] *See* rule 0–4(d) [17 CFR 275.0–4(d)]; proposed amendments to Advisers Act rule 0–4(d).

[39] Regulation S–T requires that each signatory to an electronic filing manually sign a signature page or other document authenticating, acknowledging or otherwise adopting his or her signature that appears in typed form in the electronic filing. This document must be executed before or at the time the electronic filing is made, must be retained by the filer for a period of five years, and must be made available to the Commission upon request. *See* rule 302(b) of Regulation S–T [17 CFR 232.302(b)]. Moreover, filers must submit a notarized authentication to the Commission when submitting a Form ID to gain initial access to the EDGAR filing system. We believe that these requirements provide sufficient assurance of the legitimacy of signatures contained in the electronic filings so that notarization of each application and each amended application is unnecessary.

[40] *See* 2008 IC Applications Release, *supra* footnote 15, at text accompanying nn.44 and 45.

[41] *See* rule 0–4(g) [17 CFR 275.0–4(g)]; proposed amendments to Advisers Act rule 0–4(g).

[42] *See* 2008 IC Applications Release, *supra* footnote 15, at text accompanying and following n.46.

[43] *See* proposed amendments to Advisers Act rule 0–4(b) and Investment Company Act rule 0–2(b).

[44] 17 CFR 279.4.

[45] *See* 17 CFR 279.4.

[46] *See* 17 CFR 279.4. *See also* 17 CFR 275.0–4(a).

[47] The Commission's website sets forth instructions on how to make a FOIA request, *available at https://www.sec.gov/page/office-foia-services; see* 5 U.S.C. 552.

[48] There is precedent to requiring persons other than the adviser to file a form through IARD. Independent public accountants must file [17 CFR 279.8] (''Form ADV–E'') through IARD. *See* 17 CFR 275.206(4)–2(a)(4) and 17 CFR 279.8. *See* proposed amendments to Advisers Act rule 203–1. As part of the proposed amendments, the signatures required for Form ADV–NR would also be in electronic, rather than ''wet'', format as currently required. We are also proposing conforming technical amendments to the General Instructions of Form ADV and to Form ADV–NR that describe the electronic filing requirements included in the proposed amended rules. *See* proposed amendments to 17 CFR 279.4; proposed amendments to General Instructions to Form ADV.

[49] *See* Advisers Act rule 203–3. *See also* proposed amended rule 203–1(d)(3).

initial registration with the Commission, to file Form ADV–NR with the Commission within 30 days of becoming a non-resident general partner or a non-resident managing agent.[50]

Additionally, we are proposing to require non-resident general partners and non-resident managing agents to amend their Form ADV–NR within 30 days whenever any information contained in the form becomes inaccurate by filing with the Commission a new Form ADV–NR.[51] The current form does not specify when a new Form ADV–NR must be filed with the Commission when the information on a filed Form ADV–NR becomes inaccurate.[52] We believe allowing non-resident general partners and non-resident managing agents 30 days to file a new form provides sufficient time for the filings to be made—without imposing an undue burden on filers—and would help ensure that the Commission has accurate mailing information with which to contact filers.

Proposed amended rule 203–1 also would state that Form ADV–NR is considered filed with the Commission upon acceptance by the IARD and that no fee shall be assessed for filing Form ADV–NR through IARD.[53] Proposed rule 203–1 would specify that each Form ADV–NR (and any amendment to Form ADV–NR) required to be filed under the rule is a ''report'' within the meaning of section 204 and 207 of the Advisers Act.[54] These amendments are similar to those provided for in Advisers Act rule 203–2 for Form ADV–W and are intended to provide specificity to filers regarding their filing obligations.[55]

b. Request for Comment

We request comment on the proposed amendments to require electronic submission of Form ADV–NR through IARD and the related amendments to proposed rule 203–1.

9. Should we amend rule 203–1, as proposed, to require the electronic submission of Form ADV–NR? Why or why not? Would requiring the electronic submission of Form ADV–NR likely reduce the burden of filing the form for filers?

10. Should we require the investment adviser's non-resident general partner and non-resident managing agent to file Form ADV–NR electronically, as proposed, or should we allow or require advisers to file Form ADV–NR on behalf of their non-resident general partner and non-resident managing agent? Why or why not? If advisers would file Form ADV–NR on behalf of their non-resident general partners and non-resident managing agents, how would the non-resident general partners and non-resident managing agents sign Form ADV–NR?

11. Should rule 203–1 require submission of Form ADV–NR through IARD, or an alternative system, such as EDGAR, a file transfer system, or another system? What factors should we consider when selecting a system for filing ADV–NR?

12. Should rule 203–1 require filers of Form ADV–NR to update the form within 30 days of whenever any information contained in the form becomes inaccurate by filing with the Commission a new Form ADV–NR? Should the rule specify some other amount of time? If so, please state what length of time should be allowed and why you believe that length of time to be appropriate and necessary.

B. Rule 13f–1 and Form 13F

Section 13(f) of the Exchange Act, in pertinent part, requires a manager to file a report with the Commission if the manager exercises investment discretion with respect to accounts holding certain equity securities (''13(f) Securities'') having an aggregate fair market value on the last trading day of any month of any calendar year of at least $100 million.[56] The Commission has rulemaking authority under section 13(f) to determine, among other things, the format and frequency of the reporting requirements and the information to be disclosed in each report.[57]

Section 13(f) was designed to increase the public availability of information regarding the securities holdings of managers, to consolidate the information with the Commission as a central repository of the data, and to facilitate consideration of the influence and impact of managers on the maintenance of fair and orderly securities markets and the public policy implications of that influence and impact.[58] To implement the institutional investment disclosure program mandated by Congress in section 13(f), the Commission adopted rule 13f–1 and related Form 13F under the Exchange Act.[59] Rule 13f–1 requires managers that exercise discretion over accounts holding 13(f) Securities having an aggregate fair market value of at least $100 million on the last trading day of any month of any calendar year to file quarterly reports of 13(f) Securities holdings with the Commission on Form 13F within 45 days after the last day of such calendar year and within 45 days after the last day of each of the first three calendar quarters of the subsequent calendar year.[60] In 1999, the Commission required electronic filing through EDGAR of public Form 13F reports.[61] In 2013, the Commission modernized the filing format of Form 13F by replacing the plain-text ASCII format with a structured XML format and accompanying online form.[62] In 2020, the Commission proposed, but did not adopt, certain amendments to Form 13F that would have increased the reporting threshold of Form 13F, required managers to provide additional identifying information, and made certain technical amendments to Form

[50] *See* proposed amended rule 203–1(d)(1).

[51] *See* proposed amended rule 203–1(d)(2).

[52] *See* Form ADV–NR.

[53] *See* proposed amended rule 203–1(d)(4) and (5).

[54] *See* proposed amended rule 203–1(d)(6). The fee associated with submitting Form ADV through IARD contemplates the cost of filing Form ADV–NR. Advisers Act section 207 provides that it shall be unlawful for any person willfully to make any untrue statement of a material fact in any registration application or report filed with the Commission under section 203 or 204, or willfully to omit to state in any such application or report any material fact which is required to be stated therein.

[55] *See* Advisers Act rule 203–2 [17 CFR 275.203–2]. We are also proposing conforming technical amendments to the General Instructions of Form ADV and Form ADV–NR to reflect the proposed requirement to file the form electronically through IARD.

[56] Section 13(f)(1) of the Exchange Act [15 U.S.C. 78m(f)(1)].

[57] The Commission is required under section 13(f) to adopt rules which would create a reporting and disclosure system to collect specific information concerning certain equity securities held in accounts over which certain managers exercise investment discretion. *See* Section 13(f)(4) of the Exchange Act [15 U.S.C. 78m(f)(4)]; *see also* Filing and Reporting Requirements Relating to Institutional Investment Managers, Exchange Act Release No. 15461 (Jan. 5, 1979), at 1 (''13F Quarterly Reporting Release'').

[58] *See* Filing and Reporting Requirements Relating to Institutional Investment Managers, Exchange Act Release No. 14852 (July 31, 1978) (citing to the Securities Acts Amendments of 1975: Report of the Committee on Banking, Housing and Urban Affairs United States Senate to Accompany S. 249, 94th Cong., 1st Sess. (S. Report No. 94–75) (1975), at 85 (''1975 Amendments Senate Report'')).

[59] *Id.*

[60] *See* section 13(f) of the Exchange Act [15 U.S.C. 78m(f)] and rule 13f–1 thereunder [17 CFR 240.13f–1]; *see also* 13F Quarterly Reporting Release, *supra* footnote 57. The Form 13F reports must be filed within 45 days after the last day of such calendar year and within 45 days after the last day of each of the first three calendar quarters of the subsequent calendar year. If two or more managers exercise investment discretion with respect to the same securities, only one of the managers is required to include information regarding such securities in its reports on Form 13F–HR. The other manager(s) are required to file a Form 13F notice report on Form 13F–NT stating the name of the other manager(s) reporting on their behalf.

[61] *See* Rulemaking for EDGAR System, Exchange Act Release No. 40934 (Jan. 12, 1999).

[62] Adoption of Updated EDGAR Filer Manual, Investment Company Act Release No. 30515 (May 14, 2013) [78 FR 29616 (May 21, 2013)] (''EDGAR Filer Manual Release'').

13F.[63] Finally, in 2020, as part of a series of initiatives designed to modernize the agency's filing requirements, the Commission adopted amendments to Regulation S–T that permit the use of electronic signatures when executing authentication documents in connection with certain documents filed with Commission, including Form 13F filings.[64]

Section 13(f) mandates that the Commission disseminate the information appearing in the quarterly reports to the public.[65] Congress recognized that, in some instances, public disclosure of certain types of information could have harmful market effects.[66] Thus, Section 13(f) of the Exchange Act authorizes the Commission, as it determines to be necessary or appropriate in the public interest or for the protection of investors or to maintain fair and orderly markets, to delay or prevent public disclosure of certain Form 13F information in accordance with the FOIA, which is referred to in this release as ''commercial'' information. Section 13(f) also explicitly prohibits the Commission from disclosing to the public any reported personal information that identifies the securities held by the account of a natural person or an estate or trust, other than a business trust or an investment company, which is referred to in this release as ''personal'' information.[67]

Confidential treatment for personal information, as specified in section 13(f)(4), is required for an indefinite time period if public disclosure would identify the securities held by the account of a natural person, an estate, or a trust (other than a business trust or an investment company).[68] The Commission, however, does have discretion to determine whether to grant confidential treatment requests for commercial information in accordance with section 13(f), rule 24b–2, and the FOIA.[69] The Commission provided delegated authority to the Division of Investment Management to grant, deny, or revoke a grant of confidential treatment for any application for confidential treatment that is filed under Exchange Act section 24(b) and rule 24b–2 thereunder for confidential treatment of information filed pursuant to Exchange Act section 13(f) and rule 13f–1.[70]

Currently, a manager seeking confidential treatment must file multiple lists of securities. First, it must electronically file via EDGAR a public Form 13F that identifies the securities that are required to be publicly disclosed under section 13(f) and rule 13f–1, excluding, if applicable, any security(ies) for which it is requesting confidential treatment. Second, it must file a paper 13(f) Confidential Treatment Request that includes both: (i) A separate, non-public Form 13F for the same calendar quarter that lists any 13(f) Security(ies) for which the manager is requesting confidential treatment; and (ii) a supporting request letter to substantiate the substantive basis for confidential treatment. Third, following the submission of a commercial confidential treatment request, a manager must file an amendment(s) upon the expiration or denial of confidential treatment to disclose publicly any security(ies) for which confidential treatment was requested.[71] Furthermore, the 13(f) Confidential Treatment Requests, which are filed in paper, must be filed in quintuplicate with the Commission's Office of the Secretary.[72]

The Form requires 13(f) Confidential Treatment Requests to include the Form 13F reporting information for which the manager requests confidential treatment, as well as factual support to enable the Commission to make an informed judgment as to the merits of the request.[73] The manager also must submit a public filing of Form 13F that lists the manager's quarter-end holdings, and, when confidential treatment is requested, indicates that the confidential portion of the Form 13F has been omitted and filed separately with the Commission.[74] These types of paper confidential treatment request submissions are subject to a time-consuming, manual receipt and distribution process within the Commission and could lead to undue procedural delay that can increase the time that the information receives *de facto* confidential treatment between the time a 13(f) Confidential Treatment Request is received and when the subject holdings are made public in an amendment to the requestor's public Form 13F report following either (i) a denial of a 13(f) Confidential Treatment Request, or (ii) the expiration of confidential treatment.[75] These challenges were highlighted during the COVID–19 pandemic that resulted in delays in receiving paper filings and, ultimately, in granting or denying 13(f) Confidential Treatment Requests filed with the Commission in paper.[76]

[63] *See* 2020 Form 13F Proposal, *supra* footnote 4.

[64] *See* Electronic Signatures in Regulation S–T rule 302, Exchange Act Release No. 10889 (Nov. 17, 2020) [85 FR 78224 (Dec. 4, 2020)].

[65] *See* Section 13(f)(4) of the Exchange Act [15 U.S.C. 78m(f)(4)]. Reports made on Form 13F are publicly available in XML format.

[66] 1975 Amendments Senate Report, *supra* footnote 57.

[67] *See* Sections 13(f)(4) and (5) of the Exchange Act [15 U.S.C. 78m(f)(4)] [15 U.S.C. 78m(f)(5)]; *see also* rule 24b–2(b)(2) under the Exchange Act [17 CFR 240.24b–2]; *see generally* Freedom of Information Act [5 U.S.C. 552]. The Commission amended the instructions to Form 13F pertaining to confidential treatment requests to state the procedural and substantive criteria that such requests must satisfy before they may be granted. *See* Requests for Confidential Treatment of Information Filed by Institutional Investment Managers, Exchange Act Release No. 15979 (July 6, 1979) (''1979 Confidential Treatment Amendments'').

[68] Section 13(f)(4) of the Exchange Act [15 U.S.C. 78m(f)(4)]; *see also* Requests for Confidential Treatment Filed by Institutional Investment Managers, Exchange Act Release No. 21539 (Dec. 4, 1984).

[69] *See* 1975 Amendments Senate Report, *supra* footnote 57. The Commission used this discretion to simplify the requirements for requesting confidential treatment of open risk arbitrage positions based upon a claim that the information is confidential, commercial, or financial. *See* Requests for Confidential Treatment Filed by Institutional Investment Managers, Exchange Act Release No. 22038 (May 14, 1985) (adopting requirement for good faith representations in Confidential Treatment Instruction 2.f., and limiting the confidential treatment request to a period of one year or less). The Commission also uses this discretion in evaluating confidential treatment requests for commercial information. *See* Form 13F Instructions for Confidential Treatment Requests; Rulemaking for EDGAR System, Investment Company Act Release No. 23640 (Jan. 12, 1999) (''Form 13F Instructions for Confidential Treatment Requests''); *see also* rule 24b–2(b)(2)(ii) under the Exchange Act [17 CFR 240.24b–2]; *see also* 1979 Confidential Treatment Amendments, *supra* footnote 66.

[70] *See* rule 30–5(c–1)(1) and (2) of the Commission's organizational rules [17 CFR 200.30–5].

[71] *See* Form 13F Instructions for Confidential Treatment Requests, *supra* footnote 68, at instruction 2.g. A manager may need to file multiple amendments in connection with a 13(f) Confidential Treatment Request, such as when the expiration or denial of confidential treatment occurs at different quarterly intervals for different holdings. For example, the period of confidential treatment for open risk arbitrage holdings typically varies between three, six, nine, or twelve months, based on different completion or termination dates for a proposed merger or acquisition.

[72] *See* rule 24b–2 under the Exchange Act [17 CFR 240.24b–2]; *see also* Form 13F Instructions for Confidential Treatment Requests, *supra* footnote 68.

[73] *See* Form 13F Instructions for Confidential Treatment Requests *supra* footnote 68; *see also* rule 101(c)(1)(i) of Regulation S–T; *see also* 1979 Confidential Treatment Amendments, *supra* footnote 66 (stating that requests for confidential treatment should not be broad in scope or conclusory in nature and stating that confidential treatment requests can be granted only to managers who make an affirmative showing that they satisfy the standards of section 13(f)(3)).

[74] *See* rule 24b–2(b) under the Exchange Act [17 CFR 240.24b–2].

[75] *See* Office of Inspector General's Review of the SEC's 13(f) Reporting Requirements (Sept. 27, 2010), *available at https://www.sec.gov/about/offices/oig/reports/audits/2010/480.pdf; see also* rule 24b–2(c) under the Exchange Act (providing confidentiality pending a determination about the merits of a 13(f) Confidential Treatment Request), *infra* footnote 82.

[76] Staff sought to mitigate these delays by, among other things, responding to questions regarding the

1. Electronic Filings of 13(f) Confidential Treatment Requests

a. General

As part of our continuing efforts to modernize filings made with the Commission and enhance the efficiency of the Commission's process in reviewing 13(f) Confidential Treatment Requests, we are proposing amendments to Form 13F and related rules under the Exchange Act and Regulation S–T that would require managers to file requests for confidential treatment electronically via EDGAR.[77] Thus, under the proposed amendments, the 13(f) Confidential Treatment Requests that filers currently submit to the Commission in paper, typically through the mail or by express delivery, would be required to be submitted electronically via EDGAR.[78]

The Commission has permitted or required the electronic submission of other confidential treatment requests.[79] In modernizing the manner in which a confidential treatment request may be submitted, the Commission has previously stated that such rules will reduce the burden on filing entities by avoiding the filing of a separate paper submission, and where such a request is made electronically, will expedite Commission review of the requests for confidential treatment.[80] We believe that this proposal would provide significant benefits to managers that request confidential treatment and would both further the goals of section 13(f) (as noted above) and assist the Commission's review of such requests. First, electronic filings would relieve the burdens on managers of sending paper 13(f) Confidential Treatment Requests to the Commission.[81] In addition, filings made through EDGAR are easier for the Commission to receive and maintain in accordance with the Commission's record retention requirements, particularly during disruptive events like COVID–19.[82] Furthermore, the Commission would be able to review all of a manager's holdings more efficiently because 13(f) Confidential Treatment Requests would be viewable on the same system as a manager's public Form 13F filing.

Electronic filing of 13(f) Confidential Treatment Requests also would assist the staff in evaluating such requests by facilitating more prompt delivery of the requests to the reviewing staff. We believe this increased efficiency could reduce the period of *de facto* confidential treatment that accrues pending review [83] and thus ultimately allow for the quicker public dissemination of Form 13F holdings information consistent with the purpose of section 13(f), thereby enhancing the availability of public information about managers' holdings of 13(f) Securities.[84]

We considered whether we should require 13(f) Confidential Treatment Requests to be filed via a secure file transfer system other than EDGAR.[85] However, in light of the fact that all managers are already familiar with the process of making filings on EDGAR, we believe it would be less burdensome for managers to make 13(f) Confidential Treatment Request filings on EDGAR as well. We also believe such an option would be less efficient for the Commission because the non-public holdings data related to the 13(f) Confidential Treatment Request would not be viewable in the same system as the manager's other holdings.

b. Amendments to Form 13F

As discussed above, we are proposing to modify Form 13F to require electronic filing of 13(f) Confidential Treatment Requests.[86] The proposed changes to Form 13F are described in more detail below.[87]

• *Instructions for Confidential Treatment Requests.* We propose to modify the instructions to require that a 13(f) Confidential Treatment Request be filed electronically.[88] Such requests would be made electronically via EDGAR as a separate, non-public filing. Requests also would include a confidential Form 13F report that is limited to the 13(f) Securities holdings for which the manager is requesting confidential treatment. The proposed changes to the Instructions for

electronic submission of such requests through a secure file transfer service. *See* Division of Investment Management Coronavirus (COVID–19) Response FAQs, *available at https://www.sec.gov/investment/covid-19-response-faq* (stating that filers should contact the staff for questions regarding whether 13(f) Confidential Treatment Requests could be submitted electronically). The FAQs represent the views of the staff of the Division of Investment Management. They are not a rule, regulation, or statement of the Commission. The Commission has neither approved nor disapproved their content. The FAQs, like all staff statements, have no legal force or effect: They do not alter or amend applicable law, and they create no new or additional obligations for any person.

[77] *See* proposed amendments to rule 24b–2(i) under the Exchange Act; *see also* proposed amendments to Form 13F Instructions for Confidential Treatment Requests; *see also* proposed rule 101(a)(1)(xxii) and proposed amendments to rule 101(d) of Regulation S–T; *see also infra* footnote 95 and accompanying text.

[78] *Id.; see also supra* footnotes 25–28 and accompanying text (discussing proposed amendments to the electronic filing requirement of rule 101 of Regulation S–T and rule 0–4 under the Advisers Act).

[79] *See* rule 24b–2(g) (Reg. SCI requires certain entities (including clearing agencies and alternative trading systems, among others), known as SCI Entities, to report certain business events (such as systems and compliance disruptions and system intrusions) to the Commission electronically on Form SCI. Filers may file confidential treatment requests electronically for all of the information reported on Form SCI); *see also* rule 24b–2(h); *see also* Security-Based Swap Data Repository Registration, Duties, and Core Principles, Exchange Act Release No. 74246 (Feb. 11, 2015) (requires security-based swap data repositories (''SDRs'') to register and make certain electronic filings with the Commission via EDGAR. The rules require SDRs, when seeking confidential treatment, to do so electronically via EDGAR).

[80] *See* Regulation Systems Compliance and Integrity (''Reg. SCI''), Exchange Act Release No. 73639 (Nov. 19, 2014) [79 CFR 72251 (Dec. 5, 2014)], at 408 (''Reg. SCI Adopting Release'').

[81] We noted similar benefits to permitting electronic submission of confidential treatment requests in other contexts. *See* Reg. SCI Adopting Release, *supra* footnote 79, at 408–409.

[82] The Commission recognizes the importance of sound data security practices and protocols for confidential information filed electronically, including information that may be competitively sensitive. The Commission has substantial experience handling other non-public information in the course of its regular business, such as, for example, with the storage and use of non-public information reported electronically on Form PF, Form N–PORT, and Form N–LIQUID. As with all other confidential information, the staff would carefully evaluate the data security protocols that would apply to applications for confidential treatment. Drawing on its experience, the staff would work to design controls and systems for the use and handling of such applications and associated confidential data in a manner that reflects the sensitivity of the data and is consistent with the maintenance of its confidentiality. *See* Investment Company Reporting Modernization Adopting Release, Securities Act Release No. 10231 (Oct. 16, 2016), at n.470 and accompanying text.

[83] Rule 24b–2(c) under the Exchange Act preserves the confidentiality of Form 13F holdings that are the subject of a confidential treatment request pending a determination on the merits of such request. [17 CFR. 240.24b–2].

[84] *See, e.g.,* 1975 Amendments Senate Report, *supra* footnote 57, at 82 (''Thus, with the dissemination of data about institutional investment managers, an institutional disclosure program should stimulate a higher degree of confidence among all investors in the integrity of our securities markets.'').

[85] Commission staff utilized such systems for a variety of submissions during the events of COVID–19, including 13(f) Confidential Treatment Requests. *See, e.g.,* SEC Coronavirus (COVID–19) Response, Guidance and Targeted Regulatory Assistance and Relief, *available at https://www.sec.gov/sec-coronavirus-covid-19-response.* The Commission received a limited number of 13(f) Confidential Treatment Requests via such systems.

[86] *See infra* section II.B.2 (discussing other proposed amendments to Form 13F).

[87] In addition to the changes described above, Form 13F's Paperwork Reduction Act Information section would also be modified to remove duplicative information on the form relating to the form's burdens and to update certain citations to section 13(f) of the Exchange Act. *See* proposed amendments to Paperwork Reduction Act Information section of Form 13F.

[88] *See supra* footnote 76. The attached request must also include the period of time for which confidential treatment is requested, and a justification of such requested period of confidential treatment, as required by rule 24b–2(b)(2) under the Exchange Act [17 CFR 240.24b–2(b)(2)]. *See* proposed Instruction 2(e) for Confidential Treatment Requests of Form 13F.

Confidential Treatment Requests would also provide updated references to new subparagraph (i) of rule 24b–2.[89] In order to make the instructions more consistent with current rule 24b–2(b)(2), Instruction 2.e. would be amended to require the manager to ''provide justification for'' the period of time for which confidential treatment of the securities holdings is requested. In order to make the instructions more consistent with current rule 24b–2(e), Instruction 4 would be amended to state that a manager must also submit electronically its updated Form 13F at the expiration of the time period for which a manager requested confidential treatment or earlier, *e.g.,* upon the denial of the 13(f) Confidential Treatment Request.[90]

- *Summary Page.* The summary page as proposed to be amended would include all the same information currently required but would add a requirement for a manager seeking confidential treatment to indicate if confidential treatment is being requested for some or all of the manager's holdings for the quarter-end period.[91]
- *Proposed Special Instructions.* Proposed Special Instruction 6(d) would require managers to identify on the Summary Page if confidential treatment is being requested for some or all of the manager's holdings for the quarter-end period. This instruction would assist the Commission and the public in identifying whether a manager has omitted some or all of its holdings.

Proposed changes to current Special Instruction 13 would remove the EDGAR filing type designation, as such information is now found in the Commission's EDGAR Filer Manual.[92] We are also proposing to revise current Special Instruction 13 to state that filers can consult the Commission's EDGAR Filer Manual for filing instructions.[93]

c. Amendments to Rule 24b–2

We are proposing to amend rule 24b–2 to include an additional subparagraph governing the filing of confidential information required by section 13(f) of the Exchange Act.[94] New subparagraph (i) would require that managers request confidential treatment electronically for any material required to be reported on Form 13F and continue to omit the confidential portion from the materials required to be reported.

d. Amendments to Regulation S–T

Regulation S–T would be amended in connection with the mandatory electronic submission of 13(f) Confidential Treatment Requests. Rule 101(a) would be amended to add 13(f) Confidential Treatment Requests to the list of mandated electronic filings.[95] Additionally, 13(f) Confidential Treatment Requests would be added to the list of requests for confidential treatment required to be submitted in electronic format in rule 101(d).[96]

We seek comment on the proposal to require managers to file requests for confidential treatment of information pursuant to section 13(f) of the Exchange Act and rule 13f–1 thereunder electronically via EDGAR.

13. Do commenters agree that requiring electronic filing of 13(f) Confidential Treatment Requests would improve the 13(f) Confidential Treatment Request process by making it more efficient and secure? What would be the burdens, if any, associated with requiring such requests to be filed electronically?

14. Should we allow, but not require, filers to submit 13(f) Confidential Treatment Requests electronically? Why or why not?

15. Similar to many other provisions of Regulation S–T, proposed rule 101(a)(1)(xxii) of Regulation S–T does not specify a particular filing format for 13(f) Confidential Treatment Requests. We anticipate the filing format would be HTML or ASCII, like many other EDGAR filings. What format or formats should we require for filing 13(f) Confidential Treatment Requests? Should the Commission require a single, specified format or permit filers to select a format among two or more possible formats? What time or expense is associated with particular formats? What time or expense would be required of the public to view documents in a particular format? Would a particular format require any filers or users to license commercial software they otherwise would not, and, if so, at what expense?

16. We are proposing to require electronic 13(f) Confidential Treatment Requests be filed on EDGAR. As an alternative, as discussed above, should we require 13(f) Electronic Treatment Requests to be submitted via an electronic file transfer system? Would an electronic file transfer system be a more appropriate vehicle, and why? Are there any particular costs or burdens with filing such requests on EDGAR as opposed to other systems? If so, what are those costs or burdens and what are potential remedies for them?

17. We are proposing to require the entirety of a 13(f) Confidential Treatment Request, both the list of confidential holdings and the justification, to be filed electronically. As an alternative, should we require managers to complete a separate electronic report on Form 13F that would include the manager's confidential holdings in an XML format and attach the justification portion of the 13(f) Confidential Treatment Request to the Form as a separate file? Why or why not? Would filing a separate confidential electronic report on Form 13F present other burdens? Would the benefits of a separate electronic report on Form 13F be justified notwithstanding the risk of confidential information inadvertently being made public?

18. Currently, rule 24b–2(d)(2) requires the Commission to communicate its decision to deny, or revoke a previously granted, 13(f) Confidential Treatment Request to the requesting manager in paper via registered or certified mail. Should we allow the Commission to communicate its decision to deny or revoke 13(f) Confidential Treatment Requests electronically? Why or why not? If so, should such notification be made via EDGAR? Why or why not?

19. Are there any burdens or efficiencies associated with changing the filing format of 13(f) Confidential Treatment Requests from paper to electronic that we have not discussed? If so, what are these burdens or efficiencies?

2. Other Amendments to Form 13F

a. Additional Identifying Information

We are re-proposing amendments to Form 13F that would require filers to provide additional identifying information.[97] These amendments

[89] *See* proposed amendments to Form 13F; *see also infra* section II.B.1.c.

[90] Conforming amendments would be made to Instruction 2.e. to implement the proposed changes to Instruction 4.

[91] *See* proposed Summary Page of Form 13F; *see also* proposed Special Instruction 6(d) of Form 13F (requiring managers to indicate on the Form 13F summary page whether confidential treatment is being sought for some or all of the manager's holdings for the quarter-end period and to file the 13(f) Confidential Treatment Request in a separate submission).

[92] *See* proposed Special Instruction 12 of Form 13F. Under the proposal, current Special Instruction 13 of Form 13F would be renumbered to Special Instruction 12.

[93] *Id.*

[94] *See* proposed rule 24b–2(i) under the Exchange Act.

[95] *See* proposed rule 101(a)(1)(xxii) of Regulation S–T.

[96] *See* proposed amendments to rule 101(d) of Regulation S–T. We would also make non-substantive conforming edits to rules 101(a)(1)(xxi) and conforming edits to rule 101(a)(3) of Regulation S–T.

[97] The amendments related to additional identifying information that we are proposing in this document are the same as those that were

would require each Form 13F filer to provide its CRD number and SEC file number, if any.[98] If a manager is filing a Form 13F notice report on Form 13F–NT, the manager must include the CRD number and SEC file number, if any, of any other manager included in the ''List of Other Managers Reporting for this Manager'' table on the cover page.[99]

A majority of commenters to the 2020 Form 13F Proposal supported requiring this information.[100] These commenters agreed that this information would allow the Commission and other consumers of Form 13F data to identify a Form 13F filer's other regulatory filings and the interrelationships between managers who share investment discretion over 13(f) Securities more easily.[101] One commenter also stated that the requirement to include additional information would not be unduly burdensome for managers.[102] Another commenter, however, opposed this requirement stating that it did not see a need for managers to provide additional identifying information.[103] We are re-proposing these amendments because we continue to believe that it would be useful to the Commission and the public to be able to efficiently identify interrelationships between managers as well as a manager's other regulatory filings. As we stated in the 2020 Form 13F Proposal, we also believe that this information could identify for the public additional sources of market information.[104]

We seek additional comments on the following issues:

20. Should we require managers to provide their CRD number and SEC file number, if any, on Form 13F?

21. Should we require managers to provide the CRD number and SEC file number, if any, of other managers identified in their 13F report?

22. Would this additional identifying information on Form 13F be useful? If so, how? If not, why not?

23. Would disclosing this information be unduly burdensome for 13F filers?

24. Is there any information currently required that is not useful or does not have a beneficial effect for investors, reporting managers, or other users of the data? If so, are there ways we can enhance the reported information? For example, in addition to, or in lieu of, the CUSIP number for each security, should we permit managers to provide other identifiers such as a Financial Instrument Global Identifier (FIGI) for each security?[105] Why or why not? Would permitting voluntary use of an alternate identifier have a beneficial effect for investors, reporting managers, or other users of the data? What would be the costs associated with obtaining CUSIPs for investments? What would be the costs associated with obtaining a FIGI or other identifier for investments? One commenter on the 2020 Form 13F Proposal stated a belief that requiring a security identifier could increase errors in filings.[106] Do commenters agree? If so, are there measures we could take to mitigate such effects?

b. Instructions for Confidential Treatment Requests

We are proposing an amendment to the instructions on Form 13F for 13(f) Confidential Treatment Requests to require managers seeking confidential treatment for information contained in Form 13F to demonstrate that the information is customarily and actually kept private by the manager and that failure to grant the request for confidential treatment would be likely to cause harm to the manager.[107] We are proposing this amendment to conform our instructions to a June 2019 U.S. Supreme Court decision that overturned the standard for determining whether information is ''confidential'' under Exemption 4 of the FOIA on which the current instruction is based.[108]

We proposed a similar amendment in the 2020 Form 13F Proposal.[109] One commenter to the 2020 Form 13F Proposal opposed this amendment, stating its belief that the current standard is appropriate and not inconsistent with the Supreme Court decision.[110] We disagree with the

included in the 2020 Form 13F Proposal. *See* 2020 Form 13F Proposal, *supra* footnote 4.

[98] *See* proposed amendments to proposed Special Instruction 4 of Form 13F. Under the proposal, current Special Instruction 5 would be renumbered to Special Instruction 4 of Form 13F.

[99] *See supra* footnote 59 (noting that a manager can make a Form 13F–NT filing if all the securities for which the manager has investment discretion are reported by another manager). Similarly, if a manager's Form 13F–HR reports the holdings of managers other than the reporting manager, the reporting manager would be required to include the CRD number and SEC file number of those other managers in the ''List of Other Included Managers'' on the cover page. *See* proposed Special Instruction 7 of Form 13F. Under the proposal, current Special Instruction 8 would be renumbered to Special Instruction 7 of Form 13F.

[100] *See* Comment Letter of Bloomberg L.P. on File No. S7–08–20 (Sept. 28, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7843279-223798.pdf* (''Bloomberg 2020 Form 13F Proposal Comment Letter''); Comment Letter of the Alternative Investment Management Association on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860160-223935.pdf* (''AIMA 2020 Form 13F Proposal Comment Letter''); Comment Letter of Dow Inc. on File No. S7–08–20 (Sept. 11, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7760706-223269.pdf;* Comment Letter of BrilLiquid LLC on File No. S7–08–20 (Sept. 25, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7843321-223785.pdf* (''BrilLiquid 2020 Form 13F Proposal Comment Letter''); Comment Letter of Lumen on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860205-223943.pdf;* Comment Letter of Wachtell, Lipton, Rosen & Katz on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860154-223924.pdf* (''Wachtell Lipton 2020 Form 13F Proposal Comment Letter''); Comment Letter of Epsilon Asset Management on File No. S7–08–20 (July 21, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7455216-221027.htm;* Comment Letter of WhaleWisdom on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860238-223968.pdf* (''WhaleWisdom 2020 Form 13F Proposal Comment Letter''). *See also* 2020 Form 13F Proposal, *supra* footnote 4, at text accompanying n.70.

[101] *Id.*

[102] WhaleWisdom 2020 Form 13F Proposal Comment Letter, *supra* footnote 99.

[103] Comment Letter of the Investment Adviser Association on File No. S7–08–20 (Sept. 29, 2020), at n.11, *available at https://www.sec.gov/comments/s7-08-20/s70820-7859973-223872.pdf* (''IAA 2020 Form 13F Proposal Comment Letter'').

[104] *See* section 13(f)(4) of the Exchange Act [15 U.S.C. 78m(f)(4)] (requiring the Commission to tabulate information contained in Form 13F reports in a manner that would ''maximize the usefulness of the information to other Federal and State authorities and the public''). The ability to identify interrelationships among managers easily could also allow third party vendors that compile Form 13F data to provide more complete information. *See* Edward Pekarek, *Hogging the Hedge? ''Bulldog's'' 13F Theory May Not be So Lucky,* 12 FORDHAM J. CORP. & FIN. LAW 1079 (2007), at n.91 (noting that most academic studies rely on 13F filings compiled quarterly by third party vendors).

[105] The 2020 Form 13F Proposal asked if the Commission should consider omitting Form 13F's requirement to provide a CUSIP number for each security and instead adopt other security identifiers such as the FIGI. Commenter responses to these suggested changes were mixed. *See, e.g.* WhaleWisdom 2020 Form 13F Proposal Comment Letter, *supra* footnote 99; Bloomberg 2020 Form 13F Proposal Comment Letter, *supra* footnote 99 (supporting the adoption of the FIGI in lieu of a CUSIP number); *but see* IAA 2020 Form 13F Proposal Comment Letter, *supra* footnote 102, and BrilLiquid 2020 Form 13F Proposal Comment Letter *supra* footnote 99 (opposing the replacement of the CUSIP number with a different identifier).

[106] IAA 2020 Form 13F Proposal Comment Letter, *supra* footnote 102.

[107] *See* proposed amendments to Instruction 2.d for Confidential Treatment Requests of Form 13F. As is currently required under this instruction, the proposed amendments would continue to require managers to show what use competitors could make of the information and how harm to the Manager could ensue.

[108] 5 U.S.C. 552(b)(4). *See Food Marketing Institute* v. *Argus Leader Media,* 139 S.Ct. 2356 (2019) (''*Food Marketing* v. *Argus Leader*'') (stating that ''[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4'').

[109] *See* 2020 Form 13F Proposal, *supra* footnote 4, at nn.81–83 and accompanying text.

[110] Comment Letter of the Managed Funds Association on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860189-223951.pdf* (''MFA 2020 Form

Continued

commenter. While we recognize that the facts of the case in the Supreme Court decision did not involve 13(f) Confidential Treatment Requests, section 13(f) requires the Commission to conduct a FOIA analysis as part of its determination of whether to grant such requests as discussed above.[111] Because FOIA Exemption 4 typically is relied on in connection with a request for confidential treatment of commercial information under section 13(f) and the Supreme Court overturned the standard on which the current instruction is based, we believe it is necessary to ensure that the instructions for 13(f) Confidential Treatment Requests are consistent with the Supreme Court's decision.[112] We seek additional comment on the following issues:

25. Does the amendment appropriately reflect the requirements of the FOIA, including the effect of the U.S. Supreme Court's June 24, 2019, decision in *Food Marketing Institute* v. *Argus Leader Media* on the type of information that is required to substantiate confidential treatment in accordance with Exchange Act sections 13(f)(4) and (5) and rule 24b–2 thereunder?

26. Are the proposed amendments sufficiently clear? If we adopted the amendments, would managers know how to comply with the new standard? Would managers require additional guidance on how to comply with the new standard? If so, what additional guidance should we provide?

c. Technical Amendments to Form 13F

In addition to the amendments discussed above, we are re-proposing certain technical amendments to Form 13F that were included in the 2020 Form 13F Proposal designed to account for the change in the required format of Form 13F submissions from the plain-text ASCII format to the structured XML data format in 2013.[113] For example, we are re-proposing amendments to simplify the rounding conventions of Form 13F by requiring all dollar values listed on Form 13F to be rounded to the nearest dollar, rather than to the nearest one thousand dollars as is currently required.[114] Additionally, we are re-proposing amendments to remove the requirement that filers, when reporting dollar values on Form 13F, omit the ''000.'' [115] As a space saving measure, current Form 13F instructs filers to omit the ''000'' and thus, for example, report a security with a value of $5 million as $5,000. As re-proposed, such a filer would report the security's value as $5,000,000. Since column width is no longer an issue with the structured XML data format, we believe that this change will reduce filer mistakes and data inaccuracies.[116] For similar reasons, we also are re-proposing to remove the 80 character limit imposed on the information filers can include on the cover page and the summary page and the 132 character limit on the information table.[117]

Two commenters on the 2020 Form 13F Proposal supported these amendments, noting that they have identified instances of data errors resulting from incorrect application of the Form 13F's rounding conventions.[118] One commenter opposed these amendments, stating that they are not aware of data inaccuracies resulting from current rounding conventions and that the implementation costs associated with these amendments would outweigh any marginal benefit from these changes.[119] Based on staff experience, we have observed instances of data errors resulting from incorrect rounding that justify the implementation costs of the change.[120] As we stated in the 2020 Form 13F Proposal, we continue to believe that these amendments would enhance the accuracy of the data provided on Form 13F and make it easier to understand and use, both for the Commission and for the public. Additionally we are proposing to remove duplicative definitions and streamline certain sections to simplify Form 13F's instructions.[121]

We request comment on our proposed technical amendments, and the following issues:

27. Should we require filers to round all dollar values listed on Form 13F to the nearest dollar and remove the requirement to omit ''000''? Should we, alternatively, maintain the current rounding conventions? Should we adopt some other rounding conventions? Should we no longer permit rounding?

28. Would our proposed technical amendments increase the accuracy of Form 13F data? Specifically, have users of 13F data encountered issues as a result of the current instructions requiring rounding and omission of the last three digits? Have filers encountered costs as a result of the current requirement?

29. Would these proposed technical amendments impose costs or burdens on filers? Please provide estimates of such costs.

30. Are there any other amendments we should make to streamline Form 13F or clarify its instructions? For example, should we amend the instructions for Form 13F to clarify how the form should be completed if a manager no longer has holdings that must be reported on Form 13F, but is required to continue to file Form 13F for the remaining quarters of a calendar year?

C. Compliance Date

We propose to provide a transition period after the effective date of the amendments to give advisers, applicants, and managers sufficient time to modify their procedures to implement the new rule requirements with regard to submitting applications for exemption under the Advisers Act and for filing Form ADV–NR. The proposed transition period would also give an adequate period of time for managers and other service providers to conduct the requisite operational changes to their systems and to establish internal processes to comply with the new electronic filing requirements of 13F Confidential Treatment Requests and implement the other amendments to Form 13F. We are proposing generally a compliance date of 6 months after the amendments' effective date. Based on our experience, we believe

13F Proposal Comment Letter'') (also stating that, if the Commission were to adopt this amendment, the Commission should provide additional guidance to managers on how they can meet the new standard).

[111] Section 13(f)(4) of the Exchange Act [15 U.S.C. 78m(f)(4)]; *see also supra* at text accompanying footnote 66.

[112] *See Food Marketing* v. *Argus Leader, supra* footnote 107 (stating that ''[n]otably lacking from dictionary definitions, early case law, or any other usual source that might shed light on the statute's ordinary meaning is any mention of the 'substantial competitive harm' requirement'').

[113] *See* 2020 Form 13F Proposal, *supra* footnote 4, at nn.74–80 and accompanying text; *see also* EDGAR Filer Manual Release, *supra* footnote 61.

[114] *See* proposed amendments to proposed Special Instruction 8 of Form 13F. Under the proposal, current Special Instruction 9 would be renumbered to Special Instruction 8.

[115] *Id.*

[116] *See* Anne Anderson & Paul Brockman, *An Examination of 13F Filings,* 41 J. FIN. RES. 295, 312–314 (2018) (the authors analyzed the accuracy of Form 13F data and concluded that mistakes in applying Form 13F's rounding guidelines leads to many discrepancies in the reported values on Form 13F).

[117] These character limits are imposed by 17 CFR 232.305 [rule 305 of Regulation S–T].

[118] *See* WhaleWisdom 2020 Form 13F Proposal Comment Letter, *supra* footnote 99; BrilLiquid 2020 Form 13F Proposal Comment Letter, *supra* footnote 99.

[119] *See* IAA 2020 Form 13F Proposal Comment Letter, *supra* footnote 102. The commenter did not provide an estimate of the implementation costs associated with this proposed change.

[120] *Id.*

[121] *See* proposed amendments to General Instruction 3. We are also proposing to delete Special Instruction 2 and renumber the remainder of the Special Instructions accordingly. Additionally, we are proposing to amend newly renumbered Special Instructions 2, 6, 7, and 10 of Form 13F. Finally, we are proposing to streamline the discussion in the Paperwork Reduction Act Section of Form 13F.

that the proposed compliance date would provide an appropriate amount of time for advisers, applicants, and managers to comply with the proposed amendments.

We seek additional comments on the following issues:

31. Is the proposed compliance date appropriate? If not, why not?

32. Is a longer or shorter period necessary for compliance with the proposed amendments? Is a longer or shorter period necessary for compliance with one or more of the particular amendments? If so, which proposed amendments, and what would be an appropriate compliance date?

33. Should we implement a tiered compliance date for each filing based on the size or other characteristics of the filer or, in the case of 13F filers, the amount of 13(f) Securities over which the filer exercises investment discretion? If so, what types or sizes of filers would need a longer compliance period, and how much more time would they need than other filers to comply?

III. Economic Analysis

A. Introduction and Primary Goals of the Proposed Regulations and Form Amendments

The Commission is sensitive to the potential economic effects of the proposed amendments to the rules and form that include, among other things, making mandatory the electronic submission of applications for orders under the Advisers Act and 13(f) Confidential Treatment Requests, and harmonizing the requirements for electronic submission of applications for orders under the Advisers Act and the Investment Company Act (collectively, the ''proposed amendments''). The economic effects include the potential benefits and costs of the proposed amendments, as well as any effects on efficiency, competition, and capital formation.

The Commission is making the proposed amendments to facilitate the efficient submission of applications for orders under the Advisers Act and requests for confidential treatment; to improve the Commission's ability to track and process such filings; to reduce burdens and inefficiencies associated with paper submissions; to allow for quicker dissemination of information to the public; and to modernize the Commission's records management processes.

With respect to the filing of applications for orders under the Advisers Act, the proposed amendments would:

- Require electronic submission of applications for orders under the Advisers Act;
- Designate EDGAR as the filing system for electronic submission;
- Eliminate the requirement to file proposed notices;
- Eliminate the requirement that applications be notarized and certain other technical requirements;
- Make temporary hardship exemptions unavailable for applications for orders under the Advisers Act;
- Designate the Secretary of the Commission as the addressee of any remaining paper submissions under Investment Company Act rules 0–2 and 0–4.

With respect to filing 13(f) Confidential Treatment Requests and Form 13F, the proposed amendments would:

- Require electronic submission of 13(f) Confidential Treatment Requests listing all 13(f) Securities and managers' objection to public disclosure of certain holdings in accordance with the requirements set forth in rule 24b–2 under the Exchange Act;
- Designate EDGAR as the filing system for electronic submissions of 13(f) Confidential Treatment Requests;
- Require that filers include additional identifying information on their Form 13F filings;
- Require all dollar values listed on Form 13F to be rounded to the nearest dollar, remove the requirement that dollar values list on Form 13F omit the ''000,'' and remove character limits on the cover and summary pages of Form 13F.

In addition, we are proposing to require that Form ADV–NR, which is currently filed in paper, be filed electronically through the IARD system. Some of the amendments we are proposing are technical in nature and we do not expect them to have significant economic effects.[122]

We have sought, where possible, to quantify the economic effects of the proposed amendments. However, the effects of the proposed amendments depend on a number of factors, some of which we cannot quantify, such as the value to different market participants of the uses of information contained in the 13(f) Confidential Treatment Requests. Therefore, some of the discussion below is qualitative in nature.

B. Economic Baseline

The economic baseline, from which we measure the proposed amendments' likely economic effects, reflects current regulatory practice as it pertains to potential applicants for orders under the Advisers Act, filers of Form ADV–NR, managers required to file Form 13F. In this section, we describe each of these baseline components.

The proposed amendments with respect to applications for orders under the Advisers Act would affect applicants seeking such orders, applicants who may seek similar orders in the future, clients of applicants, investors in funds managed by applicants, and the Commission. Applicants can include registered investment advisers, exempt reporting advisers, and persons not registered with the Commission, but who meet the definition of investment adviser under the Advisers Act, among others. As of December 31, 2020, there were approximately 13,827 registered investment advisers and 4,804 exempt reporting advisers.[123] In addition, as of December 31, 2020, there were approximately 16,796 state-registered advisers and an unknown number of foreign private advisers, who, while not registered with the Commission, may seek to file applications for orders under the Advisers Act.[124]

In accordance with Advisers Act rules, applicants seeking an order from the Commission under the Advisers Act must submit their applications, as well as a proposed notice, in paper and in quintuplicate, to the Commission's mailroom for stamping and logging.[125] Applications are ultimately routed to the Division's staff to manually upload into the EDGAR system, assign file numbers, and process for internal tracking purposes. Division staff also place the applications (including amendments, notices of applications, and the resulting orders) on the Commission's website.[126] These applications for orders available online

[122] Specifically, we do not believe that the following changes will have significant economic effects as they are likely to result in minimal costs or benefits with respect to the filing of applications for orders under the Advisers Act: (1) Removal of the reference to microfilming; (2) changing the wording related to duplicate original copies of paper applications.

[123] We calculate these estimates using the last Form ADV filing for each adviser in the 15 months prior to January 1, 2020. This allows us to exclude advisers that are technically still registered with the Commission but have not filed a Form ADV for their most recent fiscal year. We use the same approach in calculating statistics for exempt reporting advisers.

[124] Foreign private advisers do not file Form ADV. Therefore, the Commission does not have information on the number of foreign private advisers.

[125] *See* 1985 Release, *supra* footnote 11 (describing Commission internal process for receiving and reviewing Advisers Act applications).

[126] The speed with which items are posted to the Commission's website depends on the availability of staff resources; *see also supra* section II.A.1.

may inform investors' decisions with respect to the selection or retention of investment advisers as well as investment decisions regarding funds managed by these advisers. In addition, applications for orders available online provide potential precedent to be consulted by future applicants. The table below describes the number of initial applications for orders under the Advisers Act and Investment Company Act by year over the last three calendar years as posted on the Commission website.[127] The table shows that initial applications for orders under the Advisers Act are uncommon relative to applications for orders under the Investment Company Act.

TABLE 1

	2017	2018	2019	Total
Advisers Act Initial Applications	4	3	7	14
Investment Company Act Initial Applications	124	97	70	291

We estimate that, under the baseline, the costs of submitting an application for an order under the Advisers Act range from $14,182 to $221,909.[128]

The proposed amendments would affect non-resident general partners and non-resident managing agents of investment advisers, who are currently required to file Form ADV–NR as a paper filing submission, as well as their investment advisers, who currently sign Form ADV–NR.[129] The Commission received 89 Form ADV–NR filings during calendar year 2018, 53 filings during calendar year 2019, and 5 filings during calendar year 2020. We estimate that it currently costs $69 to file Form ADV–NR.[130] These amendments would also affect the Commission to the extent the amendments alter how the Commission receives and processes Form ADV–NR filings.

The proposed amendments with respect to 13(f) Confidential Treatment Requests and Form 13F would affect managers who file Form 13F, the Commission, and users of Form 13F information, including investors and other market participants. The table below describes the number of Form 13F filings and 13(f) Confidential Treatment Requests by calendar year and shows that, over the three year period from 2017–2019, only 0.92% (567/61,404) of Form 13F filings included confidential treatment requests.

TABLE 2

	2017	2018	2019	Total
Form 13F filings	19,184	20,356	21,864	61,404
13(f) Confidential Treatment Requests	186	191	190	567

[127] In order to avoid double counting, we do not include amended applications in our count of the number of initial applications filed each year.

[128] *See infra* note 1 of Table 3.

[129] *See supra* section II.A.4.a.

[130] *See infra* footnote 170.

[131] *See, e.g.,* Gompers, Paul A., and Andrew Metrick, *Institutional Investors and Equity Prices,* 116 Quarterly Journal of Economics 229 (2001); *and* Shi, Zhen, *The Impact of Portfolio Disclosure on Hedge Fund Performance,* 126 Journal of Financial Economics 36, (2017).

Form 13F has provided researchers with additional means to study the impact of institutional investors on securities markets as well as the general value of portfolio disclosures.[131] Members of the public can easily access Form 13F information in a timely manner via the EDGAR system.

Currently, managers who are not requesting confidential treatment submit a single public Form 13F on EDGAR in a custom XML structured data language created specifically for Form 13F. Managers are required to round all dollar values listed on their Form 13F to the nearest one thousand dollars, to omit the corresponding ''000'' in such dollar values, and to limit the length of the information filers include on the form's cover and summary pages to 80 and 132 characters, respectively.

Managers requesting confidential treatment must submit the following documents:[132]

- A public Form 13F, filed electronically on EDGAR in a custom XML data language, that lists the 13(f) Securities for which the Manager is not seeking confidential treatment;
- A concurrent paper 13(f) Confidential Treatment Request that includes: (1) The non-public Form 13F holdings information for all 13(f) Securities for which the Manager requests confidential treatment, and (2) a written request that addresses the section 13(f) confidential treatment requirements and provides sufficient factual support to enable the Commission to make an informed judgment as to the merits of the request. Some managers submitted confidential treatment requests electronically via a secure file transfer service to mitigate delays in receiving paper filings during the events of COVID–19.[133]

We are not able to estimate precisely the aggregate cost of filing 13F Confidential Treatment Requests for two reasons.[134] First, the costs associated with filing a 13(f) Confidential Treatment Request may vary depending on the type of request, the level of complexity involved in providing an appropriate justification for the request, and the number of holdings subject to the request. Second, the costs may also vary depending on the level of a manager's sophistication and resources. For example, some managers may be able to file 13(f) Confidential Treatment Requests in-house, while others may rely heavily on outside counsel to assist them with their requests.

C. Economic Effects

This section discusses the benefits and costs of the proposed amendments, as well as their potential effects on efficiency, competition, and capital formation. Because some of the proposed amendments are technical in nature, they will not have significant economic effects. In addition, where certain benefits or costs of electronic filing apply to multiple proposed amendments, we discuss those benefits or costs together instead of repeating such discussion for each proposed amendment.

1. Benefits

Applications for orders under the Advisers Act, Form ADV–NR, and 13(f) Confidential Treatment Requests are all currently filed with the Commission as paper filings. The most significant effect of the rule will be to require that these filings instead be submitted electronically. Electronic submission would increase the speed and accuracy with which Commission staff receives and initially processes submissions, potentially improving regulatory oversight.[135] The current process surrounding paper submissions is manual in nature, requiring processing by various staff as a filing is received and subsequently routed to the appropriate staff members within the Commission for review. In addition, electronic filings would minimize the risks of delay in staff receiving the information via paper submissions and increase efficiency in the staff review process by reducing staff processing time, increasing quality assurance. Electronic filings are also easier than paper filings for the Commission to maintain in accordance with the Commission's record retention requirements because they are easier to store, easier to access, easier to search, and easier to track.[136] Finally, electronic filings would allow filers to more effectively and efficiently navigate future disruptive events—like COVID–19—when staff and filers are unable to access their physical work facilities to complete, submit and process paper fillings.

Electronic submissions would directly benefit filers of applications for orders under the Advisers Act, Form ADV–NR, and 13(f) Confidential Treatment Requests by reducing printing and delivery costs. To the extent such savings were passed along to investors, investors could benefit indirectly as well. Overall, we expect that such cost reductions and any resulting savings to investors would be minimal.[137]

With respect to applications for orders under the Advisers Act specifically, because electronic submissions would be more quickly available on the Commission's EDGAR system, the public may be able to find and review a filing more quickly by accessing the EDGAR system through the Commission's website or through third-party websites that link to EDGAR. To the extent that applications for orders

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[132] In the 2020 Form 13F Proposal, a commenter stated that complying with the requirements to file a 13(f) Confidential Treatment Request can be particularly time consuming and costly. *See* Comment Letter of the Private Investor Coalition on File No. S7–08–20 (Sept. 3, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7734926-223067.pdf* (''Private Investor Coalition 2020 Form 13F Proposal Comment Letter'').

[133] *See supra* footnote 75.

[134] In 2019, the Commission received a total of 190 13(f) Confidential Treatment Requests (CTR), of which 132 were submitted based on the ''natural person'' exception in 13(f)(4); 41 were submitted based on risk arbitrage; and 17 were based on acquisition, disposition, or other. One commenter (*see supra* footnote 132) claimed that the annual cost of filing quarterly Forms 13F and 13(f) CTR for a typical single family office ranges from $20,000–$40,000. This estimate includes single family office staff time and resources and outside advisers for the CTR filings. Since family offices do not file holdings, the Commission staff presumes that the entire $20,000–$40,000 to be associated with 13(f) CTR costs. Under the assumption that the commenter's claimed CTR costs for family offices are representative of the cost of filing for all filers, the Commission staff estimates the total cost of filing 13(f) CTRs to be $3.8 million–$7.6 million. For the low end of the range, this is calculated as $3.8 million = (132 + 41 + 17) * $20,000. For the high end of the range, this is calculated as $7.6 million = (132 + 41 + 17) * $40,000. This estimate likely understates the aggregate costs of filing 13(f) CTRs because single family offices typically request confidential treatment based on being ''natural persons'', whereas other filers may need to justify their confidential treatment requests for each holding in a given 13(f) CTR. In addition, *see infra* section IV.D for discussion of estimated burdens associated with Form 13F under the Paperwork Reduction Act, which include the cost of filing 13(f) CTRs. Specifically, Table 5 estimates that, under the baseline, the current initial burden is $13,733,909 ($13,080,138 + $435,940 + $217,831) while it is expected to be $19,816,569 under the proposed amendments, implying estimated costs, for PRA purposes, of $6,082,660 = $19,816,569 − $13,733,909 associated with the proposed amendments to Form 13F.

[135] Under the proposed rule, the format requirement for electronic filings on EDGAR would be dictated by the EDGAR Filer Manual, which allows for HTML or ASCII submissions. *See* 2021 EDGAR Filer Manual, *supra* footnote 28, at Sections 2.1 and 5.2. This flexibility should allow filers to choose the format that best suits their needs and minimizes their costs of complying with the rule. The benefits and costs discussed in this Section IV with respect to electronic filings instead of the current paper submissions are those that we would expect to be realized from HTML or ASCII formatted submissions on EDGAR. Both formats are widely used, and neither requires significant special expertise for their preparation, submission, or ingestion. Furthermore, these benefits and costs substantially arise to the same extent regardless of whether the filer chooses the ASCII or HTML format.

[136] *See supra* footnotes 15 and 16 for a discussion of our experience with similar transitions to electronic filings.

[137] *See infra* footnotes 140, 143, and 144.

inform investors' decisions with respect to the selection or retention of investment advisers, investors may be able to make such decisions more expeditiously. In addition, because applicants for orders under the Advisers Act are expected, to the extent possible, to adhere to applicable precedent, applicants and staff rely on recently evaluated applications.[138] The proposed amendments benefit future applicants and the Commission by making such applications more quickly available.

We expect that the proposed amendments regarding applications for orders under the Advisers Act and the Investment Company Act would have several economic benefits specific to both categories of these amendments. First, designating the Secretary of the Commission as the addressee for applications in paper for an order under either act would minimize the risks of delay in staff receiving the application via paper submissions and increase efficiency in the staff review process by reducing staff processing time. Second, applications under both the Investment Company Act and the Advisers Act would be in the same system, so users would only need to learn how to access one system to obtain relevant information related to an exemptive application.

Additionally, the proposed amendments include certain features designed to permit applicants to streamline the application process. The Commission has periodically received applications from parties seeking relief under both the Advisers Act and the Investment Company Act who were unable to file a single application because of the current multiple-system requirements for the differing applications.[139] Thus, the proposed amendments could result in benefits for applicants who are simultaneously applying for orders under both the Advisers Act and the Investment Company Act by allowing them to use a single electronic format and file jointly in a single submission. We expect such savings to be small because, while we do not have precise data on the number of jointly filed applications, staff experience indicates that they are rare relative to independent or non-joint applications. The proposed amendments also make changes to harmonize requirements for submission of applications for orders under the Advisers Act and Investment Company Act, including the elimination of requirements that applications be notarized and that they include proposed notices as exhibits, which would result in direct cost savings for the applicants. As detailed in Section IV, we estimate that the reduction in cost represents approximately 1% of the cost of preparing an application.[140]

We expect that the proposed amendments to rule 13f–1 and Form 13F would have several economic benefits specific to those amendments. First, to the extent that electronic submission of 13(f) Confidential Treatment Requests speeds up the initial process of getting the request to the appropriate Commission staff members, in those instances where a request for confidential treatment is denied, and assuming that there is no petition for review, the corrected holdings information should be publicly available more quickly than if the 13(f) Confidential Treatment Request had been made in paper. This reduction in the length of the *de facto* confidential treatment period of information on Form 13F could benefit users of Form 13F data and enhance investor decision making to the extent that market observers and participants use such data to inform their activities.

Second, the proposed amendments that require each Form 13F and Form 13F–NT filer to provide additional identifying information would allow the Commission and other consumers of Form 13F data to identify a Form 13F filer's other regulatory filings and the interrelationships between managers who share investment discretion over 13(f) Securities more easily. This could identify additional sources of market information for the public that increase their understanding of markets and enhance their ability to make informed investment decisions.[141]

Finally, the proposed technical amendments to Form 13F that eliminate the requirement that dollar values be rounded to the nearest thousand and that the corresponding ''000'' be omitted and remove the character limits on the cover and summary pages of the Form should benefit the Commission and users of Form 13F data by reducing filer mistakes and data inaccuracies.[142]

2. Costs

Requiring electronic submission of applications for orders under the Advisers Act could result in costs to applicants, including those associated with filing a Form ID for the first time in order to obtain the access codes needed to submit an application on the Commission's EDGAR system. As discussed in Section IV below, we expect these costs to be minimal.[143]

Similarly, non-resident general partners and non-resident managing agents of investment advisers, who currently file Form ADV–NR as a paper filing submission, might incur costs associated with switching to filing this form electronically via the IARD system. However, given that these filers are associated with investment advisers that already file Form-ADV through the IARD system, we expect that these costs would be minimal.[144]

The proposed amendments could result in additional costs associated with filing 13(f) Confidential Treatment Requests electronically. However, unlike the case of applications for orders under the Advisers Act where an applicant may have no prior experience with EDGAR and therefore may bear some initial cost, managers, by virtue of the fact that they are already filing Form 13F, are experienced in using the EDGAR system. The proposed amendments would merely change the manner in which a 13(f) Confidential Treatment Request is submitted, should a filer choose to make such a request. While filers are likely to incur some costs associated with the transition to an electronic process for the submission of 13(f) Confidential Treatment Requests, we believe these costs will be offset by the reduction in printing and delivery costs currently associated with paper submissions.[145]

The proposed amendments to Form 13F would also impose costs on managers because they would have to modify their electronic filing processes to, among other things, round dollar values on Form 13F to the nearest dollar, to discontinue omitting the ''000'' for such values, and to remove the character limits on the cover and summary pages.[146] In addition, managers may incur some costs to provide additional identifying information, though we do not believe these costs will be substantial because managers already have this information available. We do not expect the costs associated with these changes to be significant.[147]

[138] *See* 1985 Release, *supra* footnote 11.

[139] For such applications, the applications under the Investment Company Act were made in HTML on EDGAR, and the Advisers Act applications were submitted in paper.

[140] *See infra* footnote 161.

[141] *See supra* footnote 103.

[142] *See supra* footnote 115.

[143] *See infra* footnote 152.

[144] *See infra* section IV.B.1, noting that we estimate that there would be no change to our current internal burden estimate that Form ADV–NR requires an average of one hour to complete.

[145] *See infra* footnote 187.

[146] *See supra* footnote 119.

[147] *See supra* footnote 134.

3. Efficiency, Competition, and Capital Formation

Generally, because most of the proposed amendments simply streamline filing processes, we do not expect these amendments to have a significant effect on efficiency, competition, or capital formation. Nonetheless, in this section, we discuss the effects of the proposed amendments on efficiency, competition, and capital formation.

As discussed above, the proposed amendments regarding applications for orders under the Advisers Act could increase the speed at which the public has access to these applications. To the extent that applications for orders inform investors' decisions with respect to the selection or retention of investment advisers, more timely access to this information could result in more efficient decisions by investors with respect to how they select their investment advisers.

Similarly, as discussed above, the proposed technical amendments to Form 13F requiring that dollar values be rounded to the nearest dollar, that the ''000'' no longer be omitted, and the removal of character limits should increase the accuracy and utility of the information filed on Form 13F. In addition, the requirement that filers include additional identifying information when filing Form 13F should increase the usefulness of the information filed on Form 13F. To the extent the more accurate and useful data available to the public informs investment decisions, the information efficiency of the market may be enhanced.

D. Reasonable Alternatives

In formulating the proposed amendments, we considered several alternatives to the proposed amendments that retain the central requirement that filings that are currently filed on paper be filed electronically, but they differ with respect to how the filings would be made. This section discusses these alternatives.

1. Alternative Filing System for Advisers Act Orders

The proposed amendments would require investment advisers to file applications for orders under the Advisers Act on the Commission's EDGAR system. Alternatively, the Commission could require investment advisers to file applications through some other system. For example, as noted in section III.A.1.a above, advisers who register with the Commission do so through the IARD system rather than EDGAR. Thus, filing through the IARD system would offer the potential benefit of greater applicant familiarity with the filing system.

While we acknowledge that some applicants may be more familiar with the IARD system than EDGAR, we propose to make mandatory electronic submissions of Advisers Act applications on EDGAR for several reasons. First, we believe the cost to advisers would be relatively low because we are proposing to assess no filing fees associated with these submissions through EDGAR. Many advisers also likely have experience submitting electronic filings via EDGAR because their managers may already be required to submit Form 13F via EDGAR, reducing the costs associated with setting up systems and processes to comply with the amendments. Second, filing in EDGAR would allow for applications under the Investment Company Act and the Advisers Act to be filed jointly, reducing filing cost.

2. Alternative Filing System for 13(f) Confidential Treatment Requests

The proposed amendments would require managers to file 13(f) Confidential Treatment Requests on the Commission's EDGAR system. Alternatively, the Commission could require that confidential treatment requests be submitted electronically via a secure file transfer service. Some managers were able to use such a service to submit their confidential treatment requests to mitigate delays in receiving paper filings during the events of COVID–19.[148]

Requiring submission via a secure file transfer service would have the benefit that some managers may already be familiar with the process of submitting filings using such a system based on their experience over the last year. However, in light of the fact that all managers are already familiar with the process of making filings on EDGAR, we believe it would be less burdensome for managers to make 13(f) Confidential Treatment Request filings on EDGAR as well.[149] Additionally, because 13(f) Confidential Treatment Requests would be viewable on the same system as a manager's public Form 13F filing, the Commission would be able to review all of a manager's holdings efficiently.[150]

3. Single Form 13F Filing With Electronic Attachment

Rather than requiring managers to file 13(f) Confidential Treatment Requests electronically via EDGAR, we considered modifying existing Form 13F in such a way that filers would list all reportable 13(f) Securities on the form but indicate for which securities, if any, they were seeking confidential treatment. Filers would indicate that they were seeking confidential treatment for particular securities by checking a box associated with a security and also indicating the length of time for which they were seeking confidential treatment. Securities for which the filer checked the box would not be visible to public users of the EDGAR system. Filers requesting confidential treatment would still be required to attach a confidential electronic document in which they would indicate the type of confidential request and provide factual support to enable the Commission to make an informed judgment as to the merits of the request.

This alternative of a single Form 13F filing offers the benefit of slightly reducing the burden on the filer from filing multiple lists of securities to filing a single list and potentially decreasing the time between when a 13(f) Confidential Treatment Request is denied or expires and the time when an amended Form 13F is filed publicly. However, we believe that this approach would significantly increase the risk of confidential information inadvertently being made public, including by filers who complete the single form incorrectly.

E. Request for Comment

The Commission requests feedback on any aspect of the above economic analysis, including our description of the current economic baseline, the potential costs and benefits of the proposed amendments, their effect on efficiency, competition, and capital formation, and any reasonable alternatives we should consider. In addition, we request comment on the following aspect of the proposal:

34. Would filers, investors, or other members of the public realize any benefits if we required that applications for orders under the Advisers Act be submitted in a structured data language, such as a custom XML-based data language, rather than in ASCII or HTML? Please explain why or why not. If so, are there certain data fields in particular that would provide such benefits to filers, investors, and other interested parties if submitted in a

[148] *See supra* footnote 132.

[149] *See supra* footnote 84.

[150] *See supra* text following footnote 82.

structured data language? What costs would these parties incur if we required such applications to be submitted using a structured data language?

IV. Paperwork Reduction Act

The proposed rule and form amendments contain ''collections of information'' within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[151] We are submitting the proposed collections of information to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The titles for the collections of information we are proposing to amend are: (i) ''Rule 0–4 under the Investment Advisers Act of 1940, General Requirements of Papers and Applications'' (OMB Control No. 3235–0633); (ii) ''Form 13F, Report of Institutional Investment Managers (pursuant to sec. 13(f) of the Securities Exchange of 1934)'' (OMB Control No. 3235–0006); and, (iii) ''Rule 0–2 and Form ADV–NR under the Investment Advisers Act of 1940'' (OMB Control No. 3235–0240). We are not proposing to amend the collections of information entitled (i) ''Form ID'' (OMB Control No. 3235–0328),[152] or (ii) ''Form ADV'' (OMB Control No. 3235–0049). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

A. Amendments to Rule 0–4

Rule 0–4 under the Advisers Act prescribes general instructions for filing papers and applications under the Advisers Act with the Commission. The proposed amendments to rule 0–4 would require that every application for an order under any provision of the Advisers Act, for which a form with instructions is not specifically prescribed, and every amendment to such application be electronically filed pursuant to Regulation S–T.[153] The proposed amendments to rule 0–4 would eliminate the requirements to have verifications of applications and statements of facts made in connection with applications notarized[154] and would eliminate the requirement that applications include proposed notices as exhibits to applications.[155] In addition, the proposed amendments to rule 0–4 would specify that paper submissions should be addressed to the Secretary of the Commission,[156] remove the reference to microfilming[157] and clarify the wording related to duplicate original copies of paper applications.[158]

Respondents to the collection of information are applying for orders of the Commission exempting them from one or more provisions of the Advisers Act. The requirements of rule 0–4 are designed to provide Commission staff with the necessary information to assess whether granting the orders of exemption is necessary and appropriate, in the public interest and consistent with the protection of investors and the intended purposes of the Act. This collection of information is necessary in order to obtain or retain benefits. Responses will not be kept confidential.

Applicants for orders under the Advisers Act file applications as they deem necessary. Applicants can include registered investment advisers, affiliated persons of registered investment advisers and entities seeking to avoid investment adviser status, among others. The Commission estimates that it receives seven initial applications per year submitted under rule 0–4 of the Advisers Act.[159] Although some applications are submitted on behalf of multiple applicants, these applicants in the vast majority of cases are related entities and are treated as a single respondent for purposes of this analysis.

1. Burden Estimate for Rule 0–4

Most of the work of preparing an application is performed by outside counsel and, therefore, imposes no internal hourly burden on the respondents.[160] We do not believe that our proposed amendments would change the burden on applicants. Likewise, we do not believe that our proposed amendments would change the number of such applications that are filed annually. Therefore, because there will continue to be no internal hourly burden we believe that the current initial and annual hour burdens for such applications remain appropriate.

We are, however, proposing to decrease the external costs associated with the existing collection of information for rule 0–4 to reflect the proposed amendments.[161] The proposed amendments would eliminate the requirement to notarize applications. The notary service is typically provided by a secretary or similar administrative employee of the applicant or the outside counsel preparing the application and represents a negligible hour or cost burden to the applicant, so elimination of the notarization requirement would reduce the cost burden only a small amount. However, we believe that these cost savings would be offset by the costs associated with transitioning to an electronic submission process, such as updating policies and procedures, recordkeeping methods and time spent learning to use the IARD system. The proposed amendments would require that paper submissions under rule 0–4 be addressed to the Secretary of the Commission, remove the reference to microfilming[162] and clarify the wording related to duplicate original copies of paper applications. These amendments decrease the applicant's cost burden. However, we believe that these cost savings would also be offset by the time and costs associated with transitioning to an electronic submission process. The proposed amendments would also eliminate the requirement that applicants include proposed notices as exhibits to applications. A proposed notice is a summary of the statements in the application. Based on staff experience, we believe that preparation of the proposed notice by outside counsel represents approximately 1% of the cost of preparing an application.[163] We estimate that the total reduction in

[151] 44 U.S.C. 3501 through 3521.

[152] The Commission estimates that each year only one applicant for an order under any provision of the Advisers Act would need to file a Form ID with the Commission in order to gain access to EDGAR. Form ID is used to request the assignment of access codes to file on EDGAR. Any applicant that has made at least one filing with the Commission via EDGAR since 2002 has been entered into the EDGAR system by the Commission and would not need to file Form ID in order to file electronically on EDGAR. However, applicants that have never made a filing with the Commission via EDGAR would need to file Form ID. We estimate that only one applicant for an order under any provision of the Advisers Act would need to file a Form ID with the Commission each year in order to gain access to EDGAR. Thus, we believe that the proposed amendments would not impose substantive new burdens on the overall population of respondents or affect the current overall cost estimates for Form ID. Therefore, we believe that the current burden and cost estimates for Form ID remain appropriate. Accordingly, we are not revising the current burden or cost estimates for Form ID.

[153] Proposed rule 0–4(b).

[154] *See* rule 0–4(d) [17 CFR 275.0–4(d)].

[155] *See* rule 0–4(g) [17 CFR 275.0–4(g)].

[156] Proposed rule 0–4(a).

[157] Proposed rule 0–4(b).

[158] Proposed rule 0–4(i).

[159] *See e.g.,* 17 CFR 275.206(4)–5(e) (providing that the Commission may, upon application, exempt an adviser from certain of the rule's restrictions, and providing a non-exclusive list of factors the Commission will consider when evaluating these applications).

[160] Nevertheless, the Commission continues to estimate one burden annual hour for administrative purposes. *See* Supporting Statement for ''Rule 0–4 under the Investment Advisers Act of 1940, General Requirements of Papers and Applications'' (OMB Control No. 3235–0633).

[161] We most recently estimated the annual cost burden to applicants of filing all applications to be $392,500.

[162] Proposed rule 0–4(b).

[163] *See* 2008 IC Applications Release, *supra* footnote 15.

the external costs would be approximately $4,091.[164]

Table 3 below summarizes the proposed cost burden estimates to applicants applying for exemptive relief under proposed rule 0–4.

TABLE 3

	Types of applications	Current external cost burden per filing [1]	Estimated reduction in external cost [2]	Estimated external cost burden per filing		Number of applications [3]	Estimated external cost burden per filing type
Adviser Act Exemptive Applications.	Well Precedented Applications.	[4] $14,182	$(141)	$14,041	x	3	$42,123
	Medium Complexity Applications.	48,282	(483)	47,799		3	143,397
	High Complexity Applications.	221,909	(2,219)	219,690		1	219,690
				Total estimated annual external cost burden for Advisers Act Applications			405,210

Notes:

[1] Based on conversations with applicants and attorneys, the cost for applications ranges from approximately $14,182 for preparing a well-precedented, routine (or otherwise less involved) application, $48,282 for preparing medium complex applications and approximately $221,909 to prepare a complex or novel application.

[2] We estimate that preparation of the proposed notice by outside counsel represents approximately 1% of the cost of preparing an application.

[3] We estimate that the Commission annually receives three of the well-precedented applications, three applications of medium complexity, and one high complexity applications.

[4] The cost outside counsel charges applicants depends on the complexity of the issues covered by the application and the time required. Based on conversations with applicants and attorneys, the cost for applications ranges from approximately $14,182 for preparing a well-precedented, routine (or otherwise less involved) application to approximately $221,909 to prepare a complex or novel application. $48,282 is the median between $14,182 and $221,909. Supporting Statement for ''Rule 0–4 under the Investment Advisers Act of 1940, General Requirements of Papers and Applications'' (OMB Control No. 3235–0633). We have adjusted these numbers to reflect changes in prices from the 2019 estimates based on the U.S. Bureau of Labor Statistic's CPI Inflation calculator. We estimate that the Commission receives one of the most time-consuming applications annually, three applications of medium complexity, and three of the least complex applications subject to rule 0–4. There are no ongoing expenses.

B. Amendment to Form ADV–NR

Rule 0–2 under the Advisers Act establishes procedures by which a person may serve process, pleadings, or other papers on a non-resident investment adviser, or on a non-resident general partner or non-resident managing agent of an investment adviser.[165] Under Rule 0–2, persons who wish to serve the above-referenced parties may do so by furnishing the Commission with one copy of the papers that are to be served along with one copy for each named party.[166] The Secretary will promptly forward a copy to each named party by registered or certified mail. If the Secretary certifies that the rule was followed, the certification constitutes evidence of service of process under Rule 0–2. Form ADV–NR is required to be submitted by an investment adviser's non-resident general partner and non-resident managing agent in connection with the adviser's initial Form ADV submission or within 30 days of becoming a non-resident after the investment adviser submits its initial Form ADV.[167] The proposed amendments would require an investment adviser's non-resident general partners and non-resident managing agents to file Form ADV–NR electronically through IARD.[168] As part of the proposed amendments, the IARD would be modified to permit non-resident general partners and non-resident managing agents to meet this filing requirement electronically without the need for specialized software or hardware. In addition, IARD would not charge a separate fee for filing the Form ADV–NR or accessing the filing system apart from what IARD charges for filing Form ADV.

The respondents to this information collection would be each non-resident general partner or non-resident managing agent of an SEC-registered investment adviser and each non-resident general partner or non-resident managing agent of an exempt reporting adviser. This collection of information is mandatory. Responses are not kept confidential. The collection of information is necessary to provide appropriate consent to permit the Commission and other parties to bring actions against non-resident partners and managing agents for violations of the federal securities laws and to enable the commencement of legal and/or regulatory actions against investment advisers that are doing business in the United States, but are not residents.

1. Burden Estimate for Form ADV–NR

[164] The total external cost reduction of 1% would amount to $4,091 given the estimated distribution of all applications: ($141 × 3) + ($483 × 3) + ($2,219 × 1) = $4,091. *See* Table 3.

[165] 17 CFR 275.0–2.

[166] 17 CFR 275.0–2.

[167] 17 CFR 279.4, 17 CFR 297.1.

[168] *See* proposed Form ADV–NR.

We estimate that proposed changes to the filing of ADV–NR would require an average of one hour to complete, the same as our current internal burden estimate. The currently approved collection of information burden in Form ADV–NR is 53 hours, which is based on our prior estimate of 53 annual responses at 1 hour per response. During 2018 to 2020 period, a total of 147 registered investment advisers and exempt reporting advisers filed reports with the Commission that included a Form ADV–NR, for an average of 49 filed reports per year.[169] Accordingly, we estimate that, based on the change in the estimate of number of filers of Form ADV–NR, the annual aggregate information collection burden for Form ADV–NR will be 49 hours, a decrease of 4 hours under the currently approved burden of 53 hours.

An adviser would likely use a combination of compliance clerks and general clerks to complete Form ADV–NR and file it with the Commission through IARD. The Commission staff estimates the hourly wage for compliance clerks to be $71 per hour, including benefits,[170] and the hourly wage for general clerks to be $63 per hour, including benefits.[171] For each burden hour, compliance clerks would perform an estimated 0.75 hours, and general clerks also would perform an estimated 0.25 hours. The total cost per response therefore would be an estimated $69,[172] for a total burden cost of $3,381.[173]

TABLE 4—SUMMARY OF THE AGGREGATE ANNUAL NUMBER OF INVESTMENT ADVISERS, TIME BURDEN, AND MONETIZED TIME BURDEN

Description	Requested	Previously approved	Change
Number of registered investment advisers and exempt reporting advisers who filed Form ADV–NR	49	53	(4)
Time burden (hours)	49	53	(4)
Monetized Time Burden (Dollars) [1]	$3,381	$3,657	$(276)

Note:
[1] *See supra* footnotes 173–176 and accompanying text.

C. Form ADV and Rule 203–1

Form ADV is the investment adviser registration form and exempt reporting adviser reporting form filed electronically with the Commission pursuant to rules 203–1 (17 CFR 275.203–1), 204–1 (17 CFR 275.204–1) and 204–4 (17 CFR 275.204–4) under the Advisers Act by advisers registered with the Commission or applying for registration with the Commission or by exempt reporting advisers filing reports with the Commission. Rule 203–1 under the Advisers Act requires every person applying for investment adviser registration with the Commission to file Form ADV.[174] The paperwork burdens associated with rules 203–1, 204–1, and 204–4 are included in the approved annual burden associated with Form ADV and thus do not entail separate collections of information. These collections of information are found at 17 CFR 275.203–1, 275.204–1, 275.204–4 and 279.1 (Form ADV itself) and are mandatory. Responses are not kept confidential.

We are proposing to amend the instructions to Form ADV and rule 203–1 to require an investment adviser's non-resident general partner and non-resident managing agents to file Form ADV–NR electronically through IARD. As discussed above, the collection of information is necessary for us to obtain appropriate consent to permit the Commission and other parties to bring actions against non-resident partners and agents for violations of the federal securities laws and to enable the commencement of legal and/or regulatory actions against investment advisers that are doing business in the United States, but are not residents.[175]

We do not believe that the proposed amendments to Form ADV or rule 203–1 would change the burden on investment advisers' application for registration with the Commission. Likewise, we do not believe that our proposed amendments would change the number of such registrations that are filed annually. Therefore, we believe that the current burden and cost estimates for Form ADV remain appropriate. Accordingly, we are not revising the current burden or cost estimates for Form ADV.

[169] The number of Form ADV–NRs filed between 2018 and 2020 were as follows: 2020, 5 filings; 2019, 53 filings; and, 2018, 89 filings. Three year average: (5 + 53 + 89)/3 = 49.

[170] Data from the SIFMA *Office Salaries in the Securities Industry 2013* report, modified by Commission staff to account for a 1,800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead, suggest that the cost for a compliance clerk is approximately $71 per hour.

[171] Data from the SIFMA *Office Salaries in the Securities Industry 2013* report, modified by Commission staff to account for a 1,800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead, suggest that the cost for a general clerk is approximately $63 per hour.

[172] (0.75 hours per compliance clerk × $71) + (0.25 hours per general clerk × $63) = $69.

[173] $69 per adviser × 49 advisers = $3,381.

[174] Rule 204–4 under the Advisers Act requires certain investment advisers exempt from registration with the Commission (''exempt reporting advisers'') to file reports with the Commission by completing a limited number of items on Form ADV. Rule 204–1 under the Advisers Act requires each registered and exempt reporting adviser to file amendments to Form ADV at least annually, and requires advisers to submit electronic filings through IARD.

[175] *See* section IV.B.

D. Amendments to Form 13F

In our most recent PRA submission for Form 13F, we estimated a total hour burden of 472,521.6 hours, with an internal cost burden of $31,186,425.60, and with no annual external cost burden.[176] In the 2020 Form 13F Proposal, the Commission expressed its belief that these estimates do not appropriately reflect the information collection costs associated with Form 13F.[177] The Commission also noted that the current burden estimates assume that the same number of hours and costs are necessary to prepare and file Form 13F–HR and the abbreviated Form 13F–NT filings, even though reports on Form 13F–HR would involve greater burdens.[178] This results in a current overestimation of the costs associated with filing Form 13F–NT. Therefore, the Commission proposed to revise the current PRA burdens associated with filing Form 13F and requested comment on whether the revised estimates accurately reflected the PRA burdens associated with filing Form 13F.[179]

Commenters generally disagreed with our proposed estimates and stated that we over-estimated the costs associated with complying with the Form 13F filing obligations.[180] Commenters stated that the advances in technology have made the process of completing and filing Form 13F highly automated, reducing the time and external costs to managers in complying with this requirement.[181] One commenter disagreed with our assumption that a compliance attorney would need to be involved with the determination of whether a manager meets the filing threshold for Form 13F.[182] However, another commenter stated that complying with the requirements to file a 13(f) Confidential Treatment Request can be particularly time consuming and costly.[183]

We have considered the comments we received on our proposed estimates and are revising the current PRA burdens associated with filing Form 13F to incorporate the feedback we received from commenters.[184] While we continue to believe that professionals beyond a compliance clerk are involved in complying with Form 13F, we agree with commenters that advances in technology over time have significantly decreased the number of hours managers spend to satisfy their compliance obligations. Additionally, we agree with commenters that using a blended rate for all the professionals involved may overestimate the costs of the time spent on complying with Form 13F.[185] After considering the comments, we also believe that the Commission's proposed revisions to the external costs associated with complying with Form 13F as well as the revisions to the PRA burdens associated with Form 13F amendments that were included in the 2020 Form 13F Proposal are appropriate. Therefore, the table below summarizes our adjustments to the current PRA estimates of complying with Form 13F based on commenter feedback as well as the initial and ongoing annual burden estimates associated with amendments to Form 13F related to the requirements for managers to provide additional identifying information and the technical amendments to Form 13F discussed above.[186] We believe that our proposed amendments to the process for filing 13(f) Confidential Treatment Requests would not change the burden of filing Form 13F Reports with the Commission.[187]

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[176] This estimate is based on the last time the rule's information collection was submitted for PRA renewal in 2018.

[177] *See* 2020 Form 13F Proposal, *supra* footnote 4 (explaining that the current burden estimates for Form 13F assume that all of the functions are carried out by a compliance clerk, whereas we understand that additional professionals are typically involved. The current burden estimates also do not include external costs for third-party vendors, which we understand many managers use in connection with their filings on Form 13F, or external legal counsel, who may provide advice in connection with the form's reporting requirements or actual or potential 13F Confidential Treatment Requests).

[178] *See supra* footnote 98 (explaining the difference between Form 13F–HR and Form 13F–NT).

[179] The Commission did not revise the burden hours previously estimated for Form 13F compliance. Rather, the Commission revised the internal time costs associated with complying with Form 13F by assuming that a compliance attorney and senior programmer, in addition to a compliance clerk, would be involved in completing and filing Form 13F and its related amendments and requests for confidential treatment.

[180] *See e.g.,* Comment Letter of Mack-Cali Realty Corporation on File No. S7–08–20 (Nov. 19, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-8032834-225591.pdf;* Comment Letter of Becker/Glynn on File No. S7–08–20 (Aug. 19, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7669323-222569.pdf;* Comment Letter of the CFA Institute on File No. S7–08–20 (Oct. 1, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7864226-224033.pdf;* Comment Letter of ConocoPhillips on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860025-223864.pdf;* Comment Letter of the Consumer Federation of America on File No. S7–08–20 (Sept. 16, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7777971-223451.pdf;* MFA 2020 Form 13F Proposal Comment Letter, *supra* footnote 120; Comment Letter of Sun Communities Inc. on File No. S7–08–20 (Sept. 21, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7797961-223610.pdf;* Comment Letter of MarketCounsel Consulting, LLC on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860014-223889.pdf* (recommending that the Commission review its estimates through engaging with various managers who may have different cost structures); Wachtell Lipton 2020 Form 13F Proposal Comment Letter, *supra* footnote 110; WhaleWisdom 2020 Form 13F Proposal Comment Letter, *supra* footnote 99.

[181] *Id; see also* Comment Letter of The Security Traders Association of New York, Inc. on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7860080-223918.pdf* (also stating that the Commission's estimated hourly costs of filing likely overestimates costs of reporting by using standard and equal estimate of compliance, attorney, and coding time); Comment Letter of ACN Solutions LLC on File No. S7–08–20 (Sept. 10, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7757531-223233.pdf* (''ACN 2020 Form 13F Proposal Comment Letter'') (stating that the Commission's estimates overstate the burdens of Form 13F on firms and estimating that managers incur $500 in external costs annually); Comment Letter of Global Endowment Management, LP on File No. S7–08–20 (Sept. 29, 2020), *available at https://www.sec.gov/comments/s7-08-20/s70820-7859976-223853.pdf* (estimating that the commenter spends 2 hours of internal time and $125 of external service provider expense each quarter); *see also* AIMA 2020 Form 13F Proposal Comment Letter, *supra* footnote 99 (also noting that the Commission did not take into account other external costs of complying with Form 13F, such as the licensing fees charges for the use of CUSIP numbers).

[182] ACN 2020 Form 13F Proposal Comment Letter, *supra* footnote 180.

[183] *See* Private Investor Coalition 2020 Form 13F Proposal Comment Letter, *supra* footnote 132 (stating that, in addition to the costs of the Form 13F, managers entitled to confidential treatment bear the burdens of preparing a 13(f) Confidential Treatment Request, including the associated expenses of engaging an attorney or other service to file a paper copy of the 13(f) Confidential Treatment Request with the Commission each quarter).

[184] We are proposing to revise the current burden estimates for Form 13F–HR and Form 13F–NT.

[185] In particular, while a compliance attorney may be involved in determining whether a manager can, or should, file a 13(f) Confidential Treatment Request for each Form 13F filing, it is unlikely that a compliance attorney will spend the same amount of time as other professionals tasked with making the Form 13F filing itself, such as a senior programmer and compliance clerk.

[186] *See supra* section II.B.2.

[187] We believe that our proposed amendments to the process for filing 13(f) Confidential Treatment Requests would reduce printing and delivery expenses that managers incur to comply with Form 13F. However, we believe that these savings would be offset by the costs associated with transitioning to an electronic submission process for 13(f) Confidential Treatment Requests. Therefore, for PRA purposes, we do not believe that these proposed amendments would change the burdens associated with complying with Form 13F. We likewise do not believe that our proposed amendments would change the number of Form 13F Reports or Form 13(f) Confidential Treatment Requests that are filed annually.

Table 5: Form 13F PRA Estimates

	Initial hours	Annual hours		Wage rate	Internal time cost	External costs[1]
REVISIONS TO CURRENT PRA BURDEN ESTIMATES						
Revised Burdens for 13F-HR Filings						
Current estimated annual burden of Form 13F-HR per filer		80.8 hours	x	$66[2]	$5,332.80	
Revised current annual estimated burden per filer		10 hours[3]	x	$202.50 (blended rate for senior programmer and compliance clerk)[4]	$2,025	$789[6]
		1 hour[3]		$368 (compliance attorney rate)[5]	$368	
Total revised estimates burden per filer		11 hours			$2,393	$789
Number of filers		5,466 filers[7]			5,466 filers	5,466 filers
Revised current annual burden of Form 13F-HR filings		60,126 hours			$13,080,138	$4,312,674
Revised Burdens for 13F-NT Filings						
Current estimated annual burden of Form 13F-NT		80.8 hours				
Revised current annual burden of Form 13F-NT per filer		4 hours	x	$71 (wage rate for compliance clerk)	$284	$300
Number of filers		1,535 filers[8]			1,535 filers	1,535 filers
		6,140 hours			$435,940	$460,500
Revised Burdens for Form 13F Amendment Filings						
Current estimated burden per amendment filing		4 hours		$66.00	$264	
Revised current estimated burden per amendment		3.5 hours[9]	x	$202.50 (blended rate for senior programmer and compliance clerk)	$708.75	$300
		0.5 hour[9]		$368 (compliance attorney rate)	$184	
Total revised estimated burden per amendment		4 hours			$892.75	$300
Number of amendments		244 amendments[10]			244 amendments	244 amendments
Revised current annual estimated burden of all amendments		976 hours			$217,831	$73,200
PROPOSED AMENDMENTS TO FORM 13F[11]						
Estimated Form 13F-HR Burdens						
Proposed Amendments to Form 13F-HR per filer (additional identifying information and technical amendments)	9 hours	3.5 hours[12]	x	$202.50 (blended rate for senior programmer and compliance clerk)[13]	$708.75	$0
	2 hours	0.67 hours[12]	x	$368 (compliance	$246.56	

				attorney rate)[13]		
Total burden of proposed amendments to Form 13F-HR per filer		4.17			$955.31	
New annual estimated Form 13F-HR burden per filer		15.17 hours			$3,348.31	$789
Number of annual filers		x 5,466 filers			× 5,466 filers	×5,466 filers
Total new annual burden		82,919.2 hours			$18,301,862.5	$4,312,674
Estimated Form 13F-NT Burdens						
Proposed Amendments to Form 13F-NT (additional identifying information)	5 hours	2.17 hours[12]	x	$202.50 (blended rate for senior programmer and compliance clerk)[14]	$439.43	$0
	1 hour	0.33 hours[12]		$368 (compliance attorney rate)[14]	$121.44	
Total burden of proposed amendments to Form 13F-NT		2.5 hours			$560.87	
New annual estimated Form 13F-NT burden per filer		6.5 hours			$844.87	$300
Number of annual filers		1,535 filers			1,535 filers	1,535 filers
Total new annual burden		9,977.5 hours			$1,296,875.45	$460,500
TOTAL ESTIMATED FORM 13F BURDEN						
Currently approved burden estimates	472,521.6 hours				$31,186,425.60	$0
Revised current burden estimates	67,242 hours				$13,733,909	$4,846,374
Burden estimates under the proposal	93,872.7 hours				$19,816,569	$4,846,374

Notes:

1. The external costs of complying with Form 13F can vary among filers. Some filers use third-party vendors for a range of services in connection with filing reports on Form 13F, while other filers use vendors for more limited purposes such as providing more user-friendly versions of the list of section 13(f) Securities. For purposes of the PRA, we estimate that each filer will spend an average of $300 on vendor services each year in connection with the filer's four quarterly reports on Form 13F-HR or Form 13F-NT, as applicable, in addition to the estimated vendor costs associated with any amendments. In addition, some filers engage outside legal services in connection with the preparation of requests for confidential treatment or analyses regarding possible requests, or in connection with the form's disclosure requirements. For purposes of the PRA, we estimate that each manager filing reports on Form 13F-HR will incur $489 for one hour of outside legal services each year.
2. $66 was the estimated wage rate for a compliance clerk in 2018.
3. The estimate reduces the total burden hours associated with complying with the reporting requirements of Form 13F-HR from 80.8 to 11 hours. We believe that this reduction adequately reflects the reduction in the time managers spend complying with Form 13F-HR as a result of advances in technology that have occurred since Form 13F was adopted. The revised estimate also assumes that an in-house compliance attorney would spend 1 hour annually on the preparation of the filing, as well as determining whether a 13(f) Confidential Treatment Request should be filed. The remaining 10 hours would be divided equally between a senior programmer and compliance clerk.
4. The $202.50 wage rate reflects current estimates of the blended hourly rate for an in-house senior programmer ($334) and in-house compliance clerk (S71). $202.50 is based on the following calculation: ($334–$71) / 2 = S202.50. The $334 per hour figure for a senior programmer is based on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association's Office Salaries in the Securities Industry 2013 ("SIFMA Report"), modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead. The $71 per hour figure for a compliance clerk is based on salary information from the SIFMA Report, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead.
5. The $368 per hour figure for a compliance attorney is based on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association's Office Salaries in the Securities Industry 2013 ("SIFMA Report"), modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.
6. $789 includes an estimated $300 paid to a third-party vendor in connection with the Form 13F-HR filing as well as an estimated $489 for one hour of outside legal services. We estimate that Form 13F-HR filers will require some level of external legal counsel in connection with these filings.
7. This estimate is based on the number of 13F-HR filers as of December 2019.
8. This estimate is based on the number of Form 13F-NT filers as of December 2019.
9. The revised assumes that an in-house compliance attorney would spend 0.5 hours annually on the preparation of the filing amendment, as well as determining whether a 13(f) Confidential Treatment Request should be filed. The remaining 3.5 hours would be divided equally between a senior programmer and compliance clerk.
10. This estimate is based on the number of Form 13F amendments filed as of December 2019.
11. We do not believe that the proposed amendments to Form 13F would change the PRA burdens associated with filing amendments to Form 13F.
12. Includes initial burden estimates annualized over a three-year period, plus 0.5 hours of ongoing annual burden hours for a senior programmer and compliance clerk. The estimates assume that a compliance attorney would only be involved in the initial implementation of the amendments.
13. These PRA estimates assume that the same types of professionals would be involved in satisfying the proposed amendments that we believe otherwise would be involved in preparing and filing reports on Form 13F-HR.
14. These PRA estimates assume that the same types of professionals would be involved in satisfying the proposed amendments that we believe otherwise would be involved in preparing and filing reports on Form 13F-NT.

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E. Request for Comments

We request comment on whether our estimates for burden hours and external costs as described above are reasonable. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection

of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) determine whether there are ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Persons wishing to submit comments on the collection of information requirements of the proposed amendments should direct them to the OMB Desk Officer for the Securities and Exchange Commission, *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov,* and should send a copy to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090, with reference to File No. S7–15–21. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication of this release; therefore a comment to OMB is best assured of having its full effect if OMB receives it within 30 days after publication of this release. Requests for materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–15–21, and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

V. Regulatory Flexibility Act Certification

Pursuant to Section 605(b) of the Regulatory Flexibility Act [188] (''RFA''), the Commission hereby certifies that the proposed amendments to rules 11, 100, 101, 102, and 201 of Regulation S–T [189] rule 0–4 under the Advisers Act [190] relating to the electronic filing of applications for orders under the Advisers Act and the Investment Company Act; rule 203–1,[191] Form ADV–NR and the instructions to Form ADV under the Advisers Act [192] relating to the electronic filing of Form ADV–NR, would not, if adopted, have a significant economic impact on a substantial number of small entities.[193] The Commission estimates that it will receive initial applications seeking relief from various provisions of the Advisers Act from six applicants per year. The Commission estimates that few, if any, of the six applicants would be small entities for the purposes of the Advisers Act and the RFA.[194] Moreover, as discussed in Sections III and IV above, the proposed amendments would have little, if any, economic impact. Therefore, there would be no significant economic impact on a substantial number of small entities.

Pursuant to Section 605(b) of the RFA,[195] the Commission hereby certifies that the proposed amendments to rule 0–2 under the Investment Company Act [196] would not, if adopted, have a significant economic impact on a substantial number of small entities.[197] As discussed in Sections III and IV above, the proposed amendments would have little, if any, economic impact. Therefore, there would be no significant economic impact on a substantial number of small entities.

Pursuant to Section 605(b) of the RFA,[198] the Commission hereby certifies that the proposed amendments to rule 24b–2 under the Exchange Act, Form 13F and rules 101(a)(1)(xxii) and 101(d) of Regulation S–T relating to the requirement that Managers electronically file requests for 13(f) Confidential Treatment Requests, along with other amendments to Form 13F, would not, if adopted, have a significant economic impact on a substantial number of small entities. The definition of the term ''small entity'' in rule 0–10 under the Exchange Act does not explicitly reference investment advisers or other investment managers. However, rule 0–10 provides that the Commission may ''otherwise define'' small entities for purposes of a particular rulemaking proceeding. For purposes of the proposed amendments relating to managers electronically filing requests for 13(f) Confidential Treatment Requests and the other amendments to Form 13F, the Commission is defining small entity by using the definition of small entity under rule 0–7(a) under the Advisers Act as more appropriate to the functions of managers.[199] The Commission believes that this definition would help ensure that all persons or entities that might be institutional investment managers under section 13(f) of the Exchange Act will be included within a category addressed by the definition. The Commission requests comments on the use of this definition.

Managers are not required to submit reports on Form 13F unless they exercise investment discretion with respect to accounts holding 13(f) Securities having an aggregate fair market value on the last trading day of any month of any calendar year of at least $100 million. Therefore, no small entities for purposes of rule 0–10 under the Exchange Act are affected by the form. Therefore, there would be no significant economic impact on a substantial number of small entities. The Commission requests written comments regarding these certifications. The Commission requests that commenters describe the nature of any impact on small businesses and provide empirical data to support the extent of the impact.

VI. Consideration of the Impact on the Economy

[188] 5 U.S.C. 605(b).

[189] 17 CFR 232.11, 232.100, 232.101, 232.102, and 232.201.

[190] 17 CFR 275.0–4.

[191] 17 CFR 274.203–1.

[192] 17 CFR 279.4; 17 CFR 279.1.

[193] For the purposes of the Advisers Act and the RFA, an investment adviser generally is a small entity if it: (i) Has assets under management having a total value of less than $25 million; (ii) did not have total assets of $5 million or more on the last day of its most recent fiscal year; and (iii) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management of $25 million or more, or any person (other than a natural person) that had $5 million or more on the last day of its most recent fiscal year. 17 CFR 275.0–7(a).

[194] This estimate is based on the fact that none of the 17 initial applications received over the last three calendar years as posted on the Commission website came from small entities.

[195] *See supra* footnote 187.

[196] 17 CFR 270.0–2.

[197] For purposes of the Investment Company Act and the RFA, an investment company is a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year. 17 CFR 270.0–10(a).

[198] *See supra* footnote 187.

[199] *See supra* footnote 192. Therefore, for purposes of this rulemaking and the RFA, a manager is a small entity if it: (i) Has assets under management having a total value of less than $25 million; (ii) did not have total assets of $5 million or more on the last day of its most recent fiscal year; and (iii) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management of $25 million or more, or any person (other than a natural person) that had total assets of $5 million or more on the last day of its most recent fiscal year.

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or ''SBREFA,'' [200] we must advise OMB whether a proposed regulation constitutes a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results in or is likely to result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effects on competition, investment or innovation.

The Commission requests comment on the potential impact of the proposed amendments on the economy on an annual basis. The Commission requests that commenters provide empirical data and other factual support for their views to the extent possible.

VII. Statutory Authority

The Commission is proposing the amended rules and form under the rulemaking authority set forth in sections 3, 12, 13, 14, 15(d), 23(a), and 35A of the Exchange Act [15 U.S.C. 78c, 78l, 78m, 78n, 78o(d), 78w(a), and 78ll]; sections 8, 30, 31, and 38 of the Investment Company Act [15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37]; and sections 203, 204, 206A, 210, and 211 of the Advisers Act [15 U.S.C. 80b–3, 80b–4, 80b–6a, 80b–10, and 80b–11].

List of Subjects

17 CFR Part 232

Reporting and recordkeeping requirements, Securities.

17 CFR Parts 240 and 249

Reporting and recordkeeping requirements, Securities.

17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

17 CFR Part 275

Investment advisers, Reporting and recordkeeping requirements, Securities.

17 CFR Part 279

Investment advisers, Reporting and recordkeeping requirements, Securities.

Text of Proposed Rule and Form Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

[200] Public Law 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C. and as a note to 5 U.S.C. 601).

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for part 232 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 80b–4, 80b–6a, 80b–10, 80b–11, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Amend § 232.11 by adding the definition of ''Investment Advisers Act'' in alphabetical order to read as follows:

§ 232.11 Definitions of terms used in this part.

* * * * *

Investment Advisers Act. The term *Investment Advisers Act* means the Investment Advisers Act of 1940.

* * * * *

§ 232.100 [Amended]

■ 3. Amend § 232.100 paragraph (b) by removing the term ''Registrants'' and adding in its place ''Persons or entities''.

■ 4. Amend § 232.101 by:

■ a. Revising paragraph (a)(1)(iv);

■ b. In paragraph (a)(1)(xxi), removing the period at the end of the paragraph and adding in its place a semicolon;

■ c. Adding paragraphs (a)(1)(xxii) and (xxiii); and

■ d. Revising paragraph (d).

The revisions and additions read as follows:

§ 232.101 Mandated electronic submissions and exceptions.

(a) * * *

(1) * * *

(iv) Documents filed with the Commission pursuant to sections 8, 17, 20, 23(c), 24(b), 24(e), 24(f), and 30 of the Investment Company Act (15 U.S.C. 80a–8, 80a–17, 80a–20, 80a–23(c), 80a–24(b), 80a–24(e), 80a–24(f), and 80a–29) and any application for an order under any section of the Investment Company Act (15 U.S.C. 80a–1 *et seq.*). The filing of an application for an order under any section of the Investment Company Act must be made on EDGAR as required by the EDGAR Filer Manual, as defined in § 232.11 (Rule 11 of Regulation S–T). Notwithstanding § 232.104 (Rule 104 of Regulation S–T), the documents filed or furnished under this paragraph will be considered as officially filed with or furnished to, as applicable, the Commission;

* * * * *

(xxii) Confidential treatment requests filed with the Commission pursuant to section 13(f) of the Exchange Act (15 U.S.C. 78m(f)) and the rules and regulations thereunder, including Form 13F (17 CFR 249.325). The filings must be made on EDGAR in the format required by the EDGAR Filer Manual, as defined in § 232.11 (Rule 11 of Regulation S–T). Notwithstanding § 232.104 (Rule 104 of Regulation S–T), the documents filed or furnished under this paragraph will be considered as officially filed with or furnished to, as applicable, the Commission; and

(xxiii) Any application for an order under any section of the Investment Advisers Act (15 U.S.C. 80b–1 *et seq.*). The filings must be made on EDGAR in the format required by the EDGAR Filer Manual, as defined in § 232.11 (Rule 11 of Regulation S–T). Notwithstanding § 232.104 (Rule 104 of Regulation S–T), the documents filed or furnished under this paragraph will be considered as officially filed with or furnished to, as applicable, the Commission.

* * * * *

(d) All documents, including any information with respect to which confidential treatment is requested, filed pursuant to section 13(n) (15 U.S.C. 78m(n)) and section 13(f) (15 U.S.C. 78m(f)) of the Exchange Act and the rules and regulations thereunder shall be filed in electronic format.

§ 232.102 [Amended]

■ 5. Amend § 232.102 paragraph (a) by adding the phrase '', Rule 0–6 under the Advisers Act (§ 275.0–6 of this chapter)'' after ''Rule 0–4 under the Investment Company Act (§ 270.0–4 of this chapter),''

■ 6. Amend § 232.201 by revising paragraph (a) introductory text to read as follows:

§ 232.201 Temporary hardship exemption.

(a) If an electronic filer experiences unanticipated technical difficulties preventing the timely preparation and submission of an electronic filing, other than a Form 3 (§ 249.103 of this chapter), a Form 4 (§ 249.104 of this chapter), a Form 5 (§ 249.105 of this chapter), a Form ID (§§ 239.63, 249.446, 269.7 and 274.402 of this chapter), a Form TA–1 (§ 249.100 of this chapter), a Form TA–2 (§ 249.102 of this chapter), a Form TA–W (§ 249.101 of this chapter), a Form D (§ 239.500 of this chapter), an application for an order under any section of the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*), an application for an order under any section of the Investment Advisers Act of 1940 (15 U.S.C. 80b–1 *et seq.*), an Interactive Data File (as defined in § 232.11), or an Asset Data File (as defined in § 232.11), the electronic filer may file the subject filing, under cover of Form TH

(§§ 239.65, 249.447, 269.10 and 274.404 of this chapter), in paper format no later than one business day after the date on which the filing was to be made.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 7. The general authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78o, 78o–4, 78o–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 *et seq.* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

■ 8. Amend § 240.24b–2 by:

■ a. Removing the preliminary note in its entirety;

■ b. Adding an introductory paragraph;

■ c. In paragraph (b) removing the phrase ''paragraphs (g) and (h)'' and adding in its place ''paragraphs (g) through (i)''; and

■ d. Adding paragraph (i).

The additions read as follows:

§ 240.24b–2 Nondisclosure of information filed with the Commission and with any exchange.

Except as otherwise provided in this rule, confidential treatment requests shall be submitted in paper format only, whether or not the filer is required to submit a filing in electronic format.

* * * * *

(i) An institutional investment manager shall omit the confidential portion from the material publicly filed in electronic format pursuant to section 13(f) of the Act (15 U.S.C. 78m(f)) and the rules and regulations thereunder. The institutional investment manager shall indicate in the appropriate place in the material publicly filed that the confidential portion has been so omitted and filed separately with the Commission. In lieu of the procedures described in paragraph (b) of this section, an institutional investment manager shall request confidential treatment electronically pursuant to section 13(f) of the Act (15 U.S.C. 78m(f)) and the rules and regulations thereunder.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 9. The general authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* and 18 U.S.C. 1350; Sec. 953(b), Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3), Pub. L. 112–106, 126 Stat. 309 (2012), Sec. 107, Pub. L. 112–106, 126 Stat. 313 (2012), Sec. 72001, Pub. L. 114–94, 129 Stat. 1312 (2015), and secs. 2 and 3 Pub. L. 116–222, 134 Stat. 1063 (2020), unless otherwise noted.

* * * * *

Note: The text of Form 13F does not, and these amendments will not, appear in the Code of Federal Regulations.

■ 10. Revise Form 13F (referenced in § 249.325) to read as follows:

OMB APPROVAL	
OMB Number:	3235-0006
Expires:	February 28, 2022
Estimated average burden hours per response	23.8

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 13F

INFORMATION REQUIRED OF INSTITUTIONAL INVESTMENT MANAGERS PURSUANT TO SECTION 13(f) OF THE SECURITIES EXCHANGE ACT OF 1934 AND RULES THEREUNDER

GENERAL INSTRUCTIONS

1. Rule as to Use of Form 13F. Institutional investment managers ("Managers") must use Form 13F for reports to the Commission required by Section 13(f) of the Securities Exchange Act of 1934 [15 U.S.C. 78m(f)] ("Exchange Act") and rule 13f-1 [17 CFR 240.13f-1] thereunder. Rule 13f-1(a) provides that every Manager which exercises investment discretion with respect to accounts holding Section 13(f) securities, as defined in rule 13f-1(c), having an aggregate fair market value on the last trading day of any month of any calendar year of at least $100,000,000 shall file a report on Form 13F with the Commission within 45 days after the last day of such calendar year and within 45 days after the last day of each of the first three calendar quarters of the subsequent calendar year.

2. Rules to Prevent Duplicative Reporting. If two or more Managers, each of which is required by rule 13f-1 to file a report on Form 13F for the reporting period, exercise investment discretion with respect to the same securities, only one such Manager must include information regarding such securities in its reports on Form 13F.

   A Manager having securities over which it exercises investment discretion that are reported by another Manager (or Managers) must identify the Manager(s) reporting on its behalf in the manner described in Special Instruction 5.

   A Manager reporting holdings subject to shared investment discretion must identify the other Manager(s) with respect to which the filing is made in the manner described in Special Instruction 7.

3. Filing of Form 13F. Rule 13f-1(a)(1) provides that a Manager must file a Form 13F report with the Commission within 45 days after the end of the calendar year and each of the first three calendar quarters of the subsequent calendar year. Form 13F must be filed electronically on the Commission's Electronic Data Gathering, Analysis, and Retrieval ("EDGAR") system, unless a hardship exemption has been granted. As required by Section 13(f)(5) of the Exchange Act, a Manager which is a bank, the deposits of which are insured in accordance

with the Federal Deposit Insurance Act, must file with the appropriate regulatory agency for the bank a copy of every Form 13F report filed with the Commission pursuant to this subsection by or with respect to such bank. Filers can satisfy their obligation to file with other regulatory agencies by sending a copy either electronically (provided the Manager removes or blanks out the confidential access codes) or in paper.

4. Official List of Section 13(f) Securities. The official list of Section 13(f) securities published by the Commission ("13F List") lists the securities the holdings of which a Manager is to report on Form 13F. See rule 13f-1(c) [17 CFR 240.13f-1(c)]. Form 13F filers may rely on the current 13F List in determining whether they need to report any particular securities holding. The current 13F List is available on www.sec.gov/divisions/investment/13flists.htm. The 13F List is updated quarterly.

INSTRUCTIONS FOR CONFIDENTIAL TREATMENT REQUESTS

Pursuant to Section 13(f)(4) of the Exchange Act [15 U.S.C. 78m(f)(4)], the Commission (1) may prevent or delay public disclosure of information reported on this form in accordance with Section 552 of Title 5 of the United States Code, the Freedom of Information Act [5 U.S.C. 552], and (2) shall not disclose information reported on this form identifying securities held by the account of a natural person or an estate or trust (other than a business trust or investment company). A Manager must submit in accordance with the procedures for requesting confidential treatment any portion of a report which contains information identifying securities held by the account of a natural person or an estate or trust (other than a business trust or investment company).

SEC 1685 (1-12)	Persons who respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number

A Manager should make requests for confidential treatment of information reported on this form in accordance with rule 24b-2(i) under the Exchange Act [17 CFR 240.24b-2]. Requests relating to the non-disclosure of information identifying the securities held by the account of a natural person or an estate or trust (other than a business trust or investment company) must so state but need not, include an analysis of any applicable exemptions from disclosure under the Freedom of Information Act [17 CFR 200.80].

Paragraph (i) of rule 24b-2 requires a Manager filing confidential information with the Commission to indicate at the appropriate place in the public filing that the confidential portion has been so omitted and filed separately with the Commission. A Manager must comply with this provision by including on the Summary Page, after the Report Summary and prior to the List of Other Included Managers, a statement that confidential information has been omitted from the public Form 13F report and filed separately with the Commission.

A Manager must file electronically, in accordance with rule 101(d) of Regulation S-T [17 CFR 232.101(d)], all requests for and information subject to the request for confidential treatment filed pursuant to Section 13(f)(4) of the Exchange Act.

A Manager requesting confidential treatment must provide enough factual support for its request to enable the Commission to make an informed judgment as to the merits of the request. The request must address all pertinent factors, including all of the following that are relevant:

1. If confidential treatment is requested as to more than one holding of securities, discuss each holding separately unless the Manager can identify a class or classes of holdings as to which the nature of the factual circumstances and the legal analysis are substantially the same.

2. If a request for confidential treatment is based upon a claim that the subject information is confidential, commercial or financial information, provide the information required by paragraphs 2.a through 2.e of this Instruction except that, if the subject information concerns security holdings that represent open risk arbitrage positions and no previous requests for confidential treatment of those holdings have been made, the Manager need provide only the information required in paragraph 2.f.

   a. Describe the investment strategy being followed with respect to the relevant securities holdings, including the extent of any program of acquisition and disposition (note that the term "investment strategy," as used in this instruction, also includes activities such as block positioning).

   b. Explain why public disclosure of the securities would, in fact, be likely to reveal the investment strategy; consider this matter in light of the specific reporting requirements of Form 13F (*e.g.*, securities holdings are reported only quarterly and may be aggregated in many cases).

   c. Demonstrate that such revelation of an investment strategy would be premature; indicate whether the Manager was engaged in a program of acquisition or disposition of the security both at the end of the quarter and at the time of the filing; and address whether the existence of such a program may otherwise be known to the public.

   d. Demonstrate whether the information is customarily and actually kept private by the Manager and that failure to grant the request for confidential treatment would be likely to cause harm to the Manager; show what use competitors could make of the information and how harm to the Manager could ensue.

   e. State, and provide justification for, the period of time for which confidential treatment of the securities holdings is requested. The time period specified may not exceed one (1) year from the date that the Manager is required to file the Form 13F report with the Commission.

   f. For securities holdings that represent open risk arbitrage positions, the request must include good faith representations that:

      i. the securities holding represents a risk arbitrage position open on the last day of the period for which the Form 13F report is filed; and

      ii. the reporting Manager has a reasonable belief as of the period end that it may not close the entire position on or before the date that the Manager is required to file the Form 13F report with the Commission.

If the Manager makes these representations in writing at the time that the Form 13F is filed, the Commission will automatically accord the subject securities holdings confidential treatment for a period of up to one (1) year from the date that the Manager is required to file the Form 13F report with the Commission.

g. At the expiration of the period for which confidential treatment has been granted pursuant to paragraph 2.e or 2.f of this Instruction ("Expiration Date") and unless a de novo request for confidential treatment of the information that meets the requirements of paragraphs 2.a through 2.e of this Instruction is filed with the Commission at least fourteen (14) days in advance of the Expiration Date, the Manager will make such security holding(s) public as set forth in Confidential Treatment Instruction 4.

3. If the Commission grants a request for confidential treatment, it may delete details which would identify the Manager and use the information in tabulations required by Section 13(f)(4) absent a separate showing that such use of information could be harmful.

4. Unless a hardship exemption is available, the Manager must submit electronically within 6 business days of the expiration of confidential treatment or notification of denial, as applicable, a Form 13F amendment to its previously filed public Form 13F report(s) for the calendar quarter to list and publicly disclose the holding(s) as to which the Commission denied confidential treatment or for which confidential treatment has expired. Such Form 13F amendment must be timely filed: (i) upon the denial by the Commission of a request for confidential treatment; (ii), upon expiration of the time period for which a Manager has requested confidential treatment; or (iii) upon the expiration of the confidential treatment previously granted for a filing. If a Manager files an amendment, the amendment must not be a restatement; the Manager must designate it as an amendment which adds new holdings entries. The Manager must include at the top of the Form 13F Cover Page the following legend to correctly designate the type of filing being made:

THIS FILING LISTS SECURITIES HOLDINGS REPORTED ON THE FORM 13F FILED ON (DATE) PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND FOR WHICH (THAT REQUEST WAS DENIED/CONFIDENTIAL TREATMENT EXPIRED) ON (DATE).

SPECIAL INSTRUCTIONS

1. This form consists of three parts: the Form 13F Cover Page ("Cover Page"), the Form 13F Summary Page ("Summary Page"), and the Form 13F Information Table ("Information Table").

The Cover Page:

2. The period end date used in the report is the last day of the calendar year or quarter, as appropriate, even though that date may not be the same as the date used for valuation in accordance with Special Instruction 8.

3. Amendments to a Form 13F report must either restate the Form 13F report in its entirety or

include only holdings entries that are being reported in addition to those already reported in a current public Form 13F report for the same period. If the Manager is filing the Form 13F report as an amendment, then, the Manager must check the amendment box on the Cover Page; enter the amendment number; and check the appropriate box to indicate whether the amendment (a) is a restatement or (b) adds new holdings entries. Each amendment must include a complete Cover Page and, if applicable, a Summary Page and Information Table. See rule 13f-1(a)(2) [17 CFR 240.13f-1(a)(2)].

4. Present the Cover Page and the Summary Page information in the format and order provided in the form. If the Manager has a number assigned by the Financial Industry Regulatory Authority's Central Registration Depository system or by the Investment Adviser Registration Depository system ("CRD number"), provide the Manager's CRD number. If the Manager has a file number (*e.g.*, 801-, 8-, 866-, 802-) assigned by the Commission ("SEC file number"), provide the Manager's SEC file number. The Cover Page may include information in addition to the required information, so long as the additional information does not, either by its nature, quantity, or manner of presentation, impede the understanding or presentation of the required information. Place all additional information after the signature of the person signing the report (immediately preceding the Report Type section). Do not include any additional information on the Summary Page or in the Information Table.

5. Designate the Report Type for the Form 13F report by checking the appropriate box in the Report Type section of the Cover Page, and include, where applicable, the List of Other Managers Reporting for this Manager (on the Cover Page), the Summary Page and the Information Table, as follows:

   a. If all of the securities with respect to which a Manager has investment discretion are reported by another Manager (or Managers), check the box for Report Type "13F NOTICE," include (on the Cover Page) the List of Other Managers Reporting for this Manager, and omit both the Summary Page and the Information Table.

   b. If all of the securities with respect to which a Manager has investment discretion are reported in this report, check the box for Report Type "13F HOLDINGS REPORT," omit from the Cover Page the List of Other Managers Reporting for this Manager, and include both the Summary Page and the Information Table.

   c. If only part of the securities with respect to which a Manager has investment discretion is reported by another Manager (or Managers), check the box for Report Type "13F COMBINATION REPORT," include (on the Cover Page) the List of Other Managers Reporting for this Manager, and include both the Summary Page and the Information Table.

Summary Page:

6. Include the Report Summary, containing the Number of Other Included Managers, the Information Table Entry Total and the Information Table Value Total.

   a. Enter as the Number of Other Included Managers the total number of other Managers listed in the List of Other Included Managers, not counting the Manager filing this report.

See Special Instruction 7. If none, enter the number zero ("0").

b. Enter as the Information Table Entry Total the total number of line entries providing holdings information included in the Information Table.

c. Enter as the Information Table Value Total the aggregate fair market value of all holdings reported in this report, i.e., the total for Column 4 (Fair Market Value) of all line entries in the Information Table. The Manager must express this total as a rounded figure, corresponding to the individual Column 4 entries in the Information Table. See Special Instruction 8.

d. Check the box on the Summary Page of the public Form 13F report if confidential treatment is being requested for some or all of the Manager's holdings for this quarter-end period.

7. Include the List of Other Included Managers. Use the title, column headings and format provided.

a. If this Form 13F report does not report the holdings of any Manager other than the Manager filing this report, enter the word "NONE" under the title and omit the column headings and list entries.

b. If this Form 13F report reports the holdings of one or more Managers other than the Manager filing this report, enter in the List of Other Included Managers all such Managers together with any CRD Number or SEC file number assigned to each Manager and, if known, the Managers' respective Form 13F file numbers (The Form 13F file numbers are assigned to Managers when they file their first Form 13F). Assign a number to each Manager in the List of Other Included Managers, and present the list in sequential order. The numbers need not be consecutive. The List of Other Managers must include all other Managers identified in Column 7 of the Information Table. Do not include the Manager filing this report.

Information Table:

8. In determining fair market value, use the value at the close of trading on the last trading day of the calendar year or quarter, as appropriate. Enter values rounded to the nearest dollar.

9. A Manager may omit holdings otherwise reportable if the Manager holds, on the period end date, fewer than 10,000 shares (or less than $200,000 principal amount in the case of convertible debt securities) and less than $200,000 aggregate fair market value (and option holdings to purchase only such amounts).

10. A Manager must report holdings of options only if the options themselves are Section 13(f) securities. For purposes of the $100,000,000 reporting threshold, the Manager should consider only the value of such options, not the value of the underlying shares. The Manager must give the entries in Columns 1 through 5 and in Columns 7 and 8 of the Information Table, however, in terms of the securities underlying the options, not the options themselves. The Manager must answer Column 6 in terms of the discretion to exercise the option. The Manager must make a separate segregation in respect of securities underlying options for

entries for each of the columns, coupled with a designation "PUT" or "CALL" following such segregated entries in Column 5, referring to securities subject respectively to put and call options. A Manager is not required to provide an entry in Column 8 for securities subject to reported call options.

11. Furnish the Information Table using the table title, column headings and format provided. Provide column headings once at the beginning of the Information Table; repetition of column headings on subsequent pages is not required. Present the table in accordance with the column instructions provided in Special Instructions 11.b.i through 12.b.viii. Do not include any additional information in the Information Table. Begin the Information Table on a new page; do not include any portion of the Information Table on either the Cover Page or the Summary Page.

    a. When entering information in Columns 4 through 8 of the Information Table, list securities of the same issuer and class with respect to which the Manager exercises sole investment discretion separately from those with respect to which investment discretion is shared. Special Instruction 11.b.vi for Column 6 describes in detail how to report shared investment discretion.

    b. Instructions for each column in the Information Table:

        i. Column 1. Name of Issuer. Enter in Column 1 the name of the issuer for each class of security reported as it appears in the current 13F List published by the Commission in accordance with rule 13f-1(c). Reasonable abbreviations are permitted.

        ii. Column 2. Title of Class. Enter in Column 2 the title of the class of the security reported as it appears in the 13F List. Reasonable abbreviations are permitted.

        iii. Column 3. CUSIP Number. Enter in Column 3 the nine (9) digit CUSIP number of the security.

        iv. Column 4. Market Value. Enter in Column 4 the market value of the holding of the particular class of security as prescribed by Special Instruction 8.

        v. Column 5. Amount and Type of Security. Enter in Column 5 the total number of shares of the class of security or the principal amount of such class. Use the abbreviation "SH" to designate shares and "PRN" to designate principal amount. If the holdings being reported are put or call options, enter the designation "Put" or "Call," as appropriate

        vi. Column 6. Investment Discretion. Segregate the holdings of securities of a class according to the nature of the investment discretion held by the Manager. Designate investment discretion as "sole" (SOLE); "shared-defined" (DEFINED); or "shared-other" (OTHER), as described below:

            (A) Sole. Designate as "sole" securities over which the Manager exercised sole investment discretion. Report "sole" securities on one line. Enter the word "SOLE" in Column 6.

(B) Shared-Defined. If investment discretion is shared with controlling and controlled companies (such as bank holding companies and their subsidiaries); investment advisers and investment companies advised by those advisers; or insurance companies and their separate accounts, then designate investment discretion as "shared-defined" (DEFINED).

For each holding of DEFINED securities, segregate the securities into two categories: those securities over which investment discretion is shared with another Manager or Managers on whose behalf this Form 13F report is being filed, and those securities over which investment discretion is shared with any other person, other than a Manager on whose behalf this Form 13F report is being filed.

Enter each of the two segregations of DEFINED securities holdings on a separate line, and enter the designation "DFND" in Column 6. See Special Instruction vii for Column 7.

(C) Shared-Other. Designate as "shared-other" securities (OTHER) those over which investment discretion is shared in a manner other than that described in Special Instruction (B) above.

For each holding of OTHER securities, segregate the securities into two categories: those securities over which investment discretion is shared with another Manager or Managers on whose behalf this Form 13F report is being filed, and those securities over which investment discretion is shared with any other person, other than a Manager on whose behalf this Form 13F report is being filed.

Enter each segregation of OTHER securities holdings on a separate line, and enter the designation "OTR" in Column 6. See Special Instruction vii for Column 7.

NOTE: A Manager is deemed to share discretion with respect to all accounts over which any person under its control exercises discretion. A Manager of an institutional account, such as a pension fund or investment company, is not deemed to share discretion with the institution unless the institution actually participated in the investment decision-making.

vii. Column 7. Other Managers. Identify each other Manager on whose behalf this Form 13F report is being filed with whom investment discretion is shared as to any reported holding by entering in this column the number assigned to the Manager in the List of Other Included Managers.

Enter this number in Column 7 opposite the segregated entries in Columns 4, 5 and 8 (and the relevant indication of shared discretion set forth in Column 6) as required by the preceding special instruction. Enter no other names or numbers in Column 7.

A Manager must report the conditions of sharing discretion with other Managers

consistently for all holdings reported on a single line.

viii. Column 8. Voting Authority. Enter the number of shares for which the Manager exercises sole, shared, or no voting authority (none) in this column, as appropriate.

The Commission deems a Manager exercising sole voting authority over specified "routine" matters, and no authority to vote in "non-routine" matters, for purposes of this Form 13F report to have no voting authority. "Non-routine" matters include a contested election of directors, a merger, a sale of substantially all the assets, a change in the articles of incorporation affecting the rights of shareholders, and a change in fundamental investment policy; "routine" matters include selection of an accountant, uncontested election of directors, and approval of an annual report.

If voting authority is shared only in a manner similar to a sharing of investment discretion which would call for a response of "shared-defined" (DEFINED) under Column 6, a Manager should report voting authority as sole under subdivision (a) of Column 8, even though the Manager may be deemed to share investment discretion with that person under Special Instruction 11.b.vi.

Filing of Reports

12. Reports must be filed electronically using EDGAR in accordance with Regulation S-T. Consult the EDGAR Filer Manual and Appendices for EDGAR filing instructions.

PAPERWORK REDUCTION ACT INFORMATION

Persons who are to respond to the collection of information contained in this form are not required to respond to the collection of information unless the form displays a currently valid Office of Management and Budget ("OMB") control number.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 13F

FORM 13F COVER PAGE

Report for the Calendar Year or Quarter Ended:

Check here if Amendment ☐ Amendment Number:
This Amendment (Check only one.): ☐ is a restatement.
☐ adds new holdings entries.

Institutional Investment Manager Filing this Report:

Name:
Address:

Form 13F File Number: 28-_____

CRD Number (if applicable):_____
SEC File Number (if applicable):_____

The institutional investment manager filing this report and the person by whom it is signed hereby represent that the person signing the report is authorized to submit it, that all information contained herein is true, correct and complete, and that it is understood that all required items, statements, schedules, lists, and tables, are considered integral parts of this form.

Person Signing this Report on Behalf of Reporting Manager:

Name:
Title:
Phone:

Signature, Place, and Date of Signing:

_____	_____	_____
[Signature]	[City, State]	[Date]

Report Type (Check only one.):

☐ 13F HOLDINGS REPORT. (Check here if all holdings of this reporting manager are reported in this report.)

☐ 13F NOTICE. (Check here if no holdings reported are in this report, and all holdings are reported by other reporting manager(s).)

☐ 13F COMBINATION REPORT. (Check here if a portion of the holdings for this reporting manager are reported in this report and a portion are reported by other reporting manager(s).)

List of Other Managers Reporting for this Manager:
[If there are no entries in this list, omit this section.]

Form 13F File Number	CRD Number (if applicable)	SEC File Number (if applicable)	Name
28-_____	_____	_____	_____

[Repeat as necessary.]

FORM 13F SUMMARY PAGE

Report Summary:

Number of Other Included Managers:

Form 13F Information Table Entry Total:

Form 13F Information Table Value Total:

(round to nearest dollar)

[ ] Confidential Treatment Requested. (Check here if the Manager has omitted from this public Form 13F and filed separately with the U.S. Securities and Exchange Commission any holding(s) for which it is requesting confidential treatment pursuant to section 13(f) of the Exchange Act and rule 24b-2 thereunder)

List of Other Included Managers:

Provide a numbered list of the name(s) and Form 13F file number(s) of all institutional investment managers with respect to which this report is filed, other than the manager filing this report.

[If there are no entries in this list, state "NONE" and omit the column headings and list entries.]

No. Form 13F File Number CRD Number (if applicable) SEC File Number (if applicable) Name

_28-_____ _____ _____ _____

[Repeat as necessary.]

COLUMN 1	COLUMN 2	COLUMN 3	COLUMN 4	COLUMN 5			COLUMN 6	COLUMN 7	COLUMN 8		
NAME OF ISSUER	TITLE OF CLASS	CUSIP	VALUE (to the nearest dollar)	SHRS OR PRN AMT	SH/ PRN	PUT/ CALL	INVESTMENT DISCRETION	OTHER MANAGER	VOTING AUTHORITY		
									SOLE	SHARED	NONE

[Repeat as Necessary]

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 11. The general authority citation for part 270 continues to read as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, 80a–39, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

§ 270.0–2 [Amended]

■ 12. Amend § 270.0–2 by:

■ a. In paragraph (a), adding the phrase "Secretary of the" after "be delivered through the mails or otherwise to the"; and

■ b. In paragraph (b), removing the sentence "The application must be typed, printed, copied or prepared by any process which, in the opinion of the commission, produces copies suitable for microfilming."

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 13. The general authority citation for part 275 continues to read as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

* * * * *

■ 14. Amend § 275.0–4 by:

■ a. In paragraph (a)(1), adding the phrase ''Secretary of the'' after ''be delivered through the mails or otherwise to the'';

■ b. Revising paragraphs (b), (d) and (i); and

■ c. Removing and reserving paragraph (g).

The revisions read as follows:

§ 275.0–4 General requirements of papers and applications.

* * * * *

(b) *Formal specifications respecting applications.* Every application for an order under any provision of the Act, for which a form with instructions is not specifically prescribed, and every amendment to such application, shall be filed electronically pursuant to 17 CFR part 232 (Regulation S–T). Any filings made in paper, including filings made pursuant to a hardship exemption under Regulation S–T, shall be filed in quintuplicate. One copy shall be signed by the applicant, but the other four copies may have facsimile or typed signatures. Such applications shall be on paper no larger than 8½ × 11 inches in size. To the extent that the reduction of larger documents would render them illegible, those documents may be filed on paper larger than 8½ × 11 inches in size. The left margin should be at least 1½ inches wide and, if the application is bound, it should be bound on the left side. All typewritten or printed matter (including deficits in financial statements) should be set forth in black so as to permit photocopying.

* * * * *

(d) *Verification of applications and statements of fact.* Every application for an order under any provision of the Act, for which a form with instructions is not specifically prescribed, and every amendment to such application, and every statement of fact formally filed in support of, or in opposition to, any application or declaration shall be verified by the person executing the same. An instrument executed on behalf of a corporation shall be verified in substantially the following form, but suitable changes may be made in such form for other kinds of companies and for individuals:

The undersigned states that he or she has duly executed the attached ____ dated, ____20____, for and on behalf of ____ (Name of company); that he or she is the ____ (Title of officer) of such company; and that all action by stockholders, directors, and other bodies necessary to authorize the undersigned to execute and file such instrument has been taken. The undersigned further states that he or she is familiar with such instrument, and the contents thereof, and that the facts therein set forth are true to the best of his or her knowledge, information and belief.

(Signature)

* * * * *

(i) The manually signed original (or in the case of duplicate originals, one duplicate original) of all registrations, applications, statements, reports, or other documents filed under the Investment Advisers Act of 1940, as amended, shall be numbered sequentially (in addition to any internal numbering which otherwise may be present) by handwritten, typed, printed, or other legible form of notation from the facing page of the document through the last page of that document and any exhibits or attachments thereto. Further, the total number of pages contained in a numbered original shall be set forth on the first page of the document.

■ 15. Amend § 275.203–1 by adding paragraph (d) to read as follows:

§ 275.203–1 Application for investment adviser registration.

* * * * *

(d) *Form ADV–NR*—(1) *General Requirements.* Each non-resident, as defined in 17 CFR 275.0–2(b)(2) (Rule 0–2(b)(2)), general partner or a non-resident managing agent, as defined in 17 CFR 275.0–2(b)(2) (Rule 0–2(b)(1)), of any investment adviser registered, or applying for registration with, the Commission must submit Form ADV–NR (17 CFR 279.4). Form ADV–NR must be completed in connection with the adviser's initial registration with the Commission. If a person becomes a non-resident general partner or a non-resident managing agent after the date the adviser files its initial registration with the Commission, the person must file Form ADV–NR with the Commission within 30 days of becoming a non-resident general partner or a non-resident managing agent. If a person serves as a general partner or managing agent for multiple advisers, they must submit a separate Form ADV–NR for each adviser.

(2) *When an amendment is required.* Each non-resident general partner or a non-resident managing agent of any investment adviser must amend its Form ADV–NR within 30 days whenever any information contained in the form becomes inaccurate by filing with the Commission a new Form ADV–NR.

(3) *Electronic filing.* Form ADV–NR (and any amendments to Form ADV–NR) must be filed electronically through the Investment Adviser Registration Depository (IARD), unless a hardship exemption under 17 CFR 275.203–3 (Rule 203–3) has been granted.

(4) *When filed.* Each Form ADV–NR is considered filed with the Commission upon acceptance by the IARD.

(5) *Filing fees.* No fee shall be assessed for filing Form ADV–NR through IARD.

(6) *Form ADV–NR is a report.* Each Form ADV–NR (and any amendment to Form ADV–NR) required to be filed under this rule is a ''report'' within the meaning of sections 204 and 207 of the Act.

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

■ 16. The authority citation for part 279 continues to read as follows:

Authority: The Investment Advisers Act of 1940, 15 U.S.C. 80b-1, *et seq.,* Pub. L. 111–203, 124 Stat. 137617.

■ 17. In Form ADV (referenced in § 279.1):

■ a. Amend the instructions to the form by revising the section entitled ''Who is required to file Form ADV–NR?''; and

■ b. Amend the instructions to the form by adding a section entitled ''How is Form ADV–NR filed?''.

The revision and addition read as follows:

Note: The text of Form ADV does not, and this amendment will not, appear in the Code of Federal Regulations.

FORM ADV (Paper Version)

• UNIFORM APPLICATION FOR INVESTMENT ADVISER REGISTRATION AND

• REPORT FORM BY EXEMPT REPORTING ADVISERS

Form ADV: General Instructions

* * * * *

19. Who is required to file Form ADV-NR?

Every *non-resident* general partner and *managing agent* of all SEC-registered advisers and *exempt reporting advisers*, whether or not the adviser is resident in the United States, must file Form ADV-NR in connection with the adviser's initial application or report. A general partner or *managing agent* of an SEC-registered adviser or *exempt reporting adviser* who becomes a *non-resident* after the adviser's initial application or report has been submitted must file Form ADV-NR within 30 days. Absent a temporary hardship, Form ADV-NR must be filed electronically through IARD.

Failure to file Form ADV-NR promptly may delay SEC consideration of your initial application.

20. How is Form ADV-NR filed?

Form ADV-NR is filed electronically with the Investment Adviser Registration Depository (IARD). Information for how to file with IARD is available on the SEC's website at www.sec.gov/iard and on www.iard.com]

■ 18. Revise § 279.4 to read as follows:

§ 279.4 Form ADV–NR, appointment of agent for service of process by non-resident general partner and non-resident managing agent of an investment adviser.

This form shall be filed and amended pursuant to § 275.203–1 of this chapter (Rule 203–1) as an appointment of agent for service of process by non-resident general partners and non-resident managing agents of an investment adviser pursuant to section 203 of the Investment Advisers Act of 1940.

Note: The next of Form ADV–NR does not, and this amendment will not, appear in the Code of Federal Regulations.

■ 19. Form ADV–NR (referenced in § 279.4) is amended by adding the sections entitled ''Instructions to Form ADV–NR'', ''Who is required to file Form ADV–NR?'' and ''How is Form ADV–NR filed?'' to read as follows:

Form ADV-NR (Paper Version)

APPOINTMENT OF AGENT FOR SERVICE OF PROCESS BY NON-RESIDENT GENERAL PARTNER AND NON-RESIDENT MANAGING AGENT OF AN INVESTMENT ADVISER

Instructions to Form ADV-NR

NOTE: Unless the context clearly indicates otherwise, all terms used in the Form have the same meaning as in the Investment Advisers Act of 1940, the General Rules and Regulations of the Commission thereunder (17 Code of Federal Regulations 275), and in the Glossary of Terms to Form ADV.

1. Who is required to file Form ADV-NR?

Every *non-resident* general partner and *managing agent* of all SEC-registered advisers and *exempt reporting advisers*, whether or not the adviser is resident in the United States, must file Form ADV-NR in connection with the adviser's initial application or report. A general partner or *managing agent* of an SEC-registered adviser or *exempt reporting adviser* who becomes a *non-resident* after the adviser's initial application or report has been submitted must file Form ADV-NR within 30 days. Absent a temporary hardship exemption, Form ADV-NR must be filed electronically.

Failure to file Form ADV-NR promptly may delay SEC consideration of your initial application.

2. How is Form ADV-NR filed?

Form ADV-NR is filed electronically with the Investment Adviser Registration Depository (IARD). Information for how to file with IARD is available on the SEC's website at www.sec.gov/iard and on www.iard.com

Form ADV-NR (Paper Version)

APPOINTMENT OF AGENT FOR SERVICE OF PROCESS BY NON-RESIDENT GENERAL PARTNER AND NON-RESIDENT MANAGING AGENT OF AN INVESTMENT ADVISER

You must submit this Form ADV-NR if you are a *non-resident* general partner or a *non-resident managing agent* of any investment adviser (domestic or *non-resident*). Form ADV-NR must be

signed and submitted in connection with the adviser's initial Form ADV submission. If the mailing address you list below changes, you must file an amended Form ADV-NR to provide the current address. If you become a *non-resident* general partner or a *non-resident managing agent* after the date the adviser files its initial Form ADV, you must file Form ADV-NR with the Commission within 30 days of the date that you became a *non-resident* general partner or a *non-resident managing agent*. If you serve as a general partner or *managing agent* for multiple advisers, you must submit a separate Form ADV-NR for each adviser.

1. Appointment of Agent for Service of Process

By signing this Form ADV-NR, you, the undersigned *non-resident* general partner or *non-resident managing agent,* irrevocably appoint each of the Secretary of the SEC, and the Secretary of State, or equivalent officer, of the state in which the adviser referred to in this form maintains its *principal office and place of business*, if applicable, and any other state in which the adviser is applying for registration, amending its registration, or submitting a *notice filing*, as your agents to receive service, and agree that such *persons* may accept service on your behalf, of any notice, subpoena, summons, *order* instituting *proceedings*, demand for arbitration, or other process or papers, and you further agree that such service may be made by registered or certified mail, in any federal or state action, administrative *proceeding* or arbitration brought against you in any place subject to the jurisdiction of the United States, if the action, *proceeding* or arbitration: (a) arises out of any activity in connection with the investment adviser's business that is subject to the jurisdiction of the United States, and (b) is *founded*, directly or indirectly, upon the provisions of: (i) the Securities Act of 1933, the Securities Exchange Act of 1934, the Trust Indenture Act of 1939, the Investment Company Act of 1940, or the Investment Advisers Act of 1940, or any rule or regulation under any of these acts, or (ii) the laws of the state in which the adviser referred to in this Form maintains its *principal office and place of business*, if applicable, or of any state in which the adviser is applying for registration, amending its registration, or submitting a *notice filing*.

2. Appointment and Consent: Effect on Partnerships

If you are organized as a partnership, this irrevocable power of attorney and consent to service of process will continue in effect if any partner withdraws from or is admitted to the partnership, provided that the admission or withdrawal does not create a new partnership. If the partnership dissolves, this irrevocable power of attorney and consent shall be in effect for any action brought against you or any of your former partners.

Signature

I, the undersigned *non-resident* general partner or *non-resident managing agent,* certify, under penalty of perjury under the laws of the United States of America, that the information contained

in this Form ADV-NR is true and correct and that I am signing this Form ADV-NR as a free and voluntary act.

Signature of Partner or Agent:

_____ Date: _____

Printed Name: _____ Title: _____

Mailing Address of Partner or Agent (no P.O. Boxes):

_____

_____

_____

_____

Signature of Investment Adviser:

_____ Date: _____

Printed Name: _____ Title: _____

Adviser SEC File Number: 801-_____ or 802-_____

Adviser *CRD* Number: _____

Adviser Name:

PRIVACY ACT STATEMENT. Section 211(a) of the Advisers Act [15 U.S.C. § 80b-11(a)] authorizes the Commission to collect the information required by Form ADV-NR. The Commission collects this information to ensure that a non-resident general partner or managing agent of an investment adviser appoints an agent for service of process in the United States. Filing Form ADV-NR is mandatory for non-resident general partners and non-resident managing agents of investment advisers. The Commission maintains the information submitted on Form ADV-NR and makes it publicly available. The Commission may return forms that do not include required information. Intentional misstatements or omissions constitute federal criminal violations under 18 U.S.C. § 1001 and 15 U.S.C. § 80b-17. The information contained in Form ADV-NR is part of a system of records subject to the Privacy Act of 1974, as amended. The Commission has published in the Federal Register the Privacy Act System of Records Notice for these records.

SEC'S COLLECTION OF INFORMATION. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. Section 211(a) of the Advisers Act authorizes the Commission to collect the information on this Form from applicants. *See* 15 U.S.C. § 80b-11(a). Filing of this Form is mandatory for non-resident general partners or managing agents of investment advisers. The principal purpose of this collection of information is to ensure that a non-resident general partner or managing agent of an

investment adviser appoints an agent for service of process in the United States. The Commission will maintain files of the information on Form ADV-NR and will make the information publicly available. Any member of the public may direct to the Commission any comments concerning the accuracy of the burden estimate on page one of Form ADV-NR, and any suggestions for reducing this burden. This collection of information has been reviewed by the Office of Management and Budget in accordance with the clearance requirements of 44 U.S.C. § 3507.

By the Commission.

Dated: November 4, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–24522 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–637]

RIN 1117–AB64

Transfer of Electronic Prescriptions for Schedules II–V Controlled Substances Between Pharmacies for Initial Filling

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to amend its regulations to allow the transfer of electronic prescriptions for schedule II–V controlled substances between registered retail pharmacies for initial filling on a one-time basis. This amendment will specify the procedure that must be followed and the information that must be documented when transferring an electronic controlled substance prescription between DEA-registered retail pharmacies.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before January 18, 2022. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before January 18, 2022

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–637'' on all correspondence, including any attachments.

DEA encourages all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment. Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, VA 22152.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB64/Docket No. DEA–637.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by DEA for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Legal Authority

The Controlled Substances Act (CSA or Act) grants the Attorney General the authority to promulgate and enforce any rules, regulations, and procedures that he may deem necessary and appropriate for the efficient executions of his functions under subchapter I (Control and Enforcement) of the CSA.[1] The Attorney General has delegated this authority to the Administrator of the Drug Enforcement Administration (DEA).[2]

[1] 21 U.S.C. 871(b).

[2] 28 CFR 0.100(b).

Purpose of the Proposed Rule

Currently, DEA regulations do not address the transfer of controlled substance prescriptions (paper or electronic) between pharmacies for initial filling.[3] If a paper prescription is presented at a pharmacy that is unable to fill it, the paper prescription could be returned to the patient, and the patient could then take the prescription to another pharmacy. Although the transfer of paper prescriptions between pharmacies for initial dispensing is not addressed in the regulations, these prescriptions are inherently portable due to the format of the prescription itself.

However, electronic prescriptions are generated using an electronic application and are transmitted directly from the practitioner to the pharmacy in the form of an electronic data file. Consequently, if a pharmacy receives an electronic prescription for a controlled substance (EPCS) that it is unable to fill, the pharmacy cannot give the prescription (*i.e.,* electronic data file) to the patient to take to another pharmacy. Further, DEA regulations do not include provisions for a pharmacy to transfer an EPCS to another pharmacy; the regulations also do not describe how a pharmacy should handle an EPCS that it receives but cannot fill. At present, a pharmacy that receives an EPCS that it is unable to fill can only notify the patient that the prescription cannot be filled. In this scenario, the patient could then call the prescribing practitioner to request that a new EPCS be sent to a different pharmacy. DEA realizes that this scenario creates the potential for duplication of prescriptions if the practitioner transmits a new EPCS to a different pharmacy and does not cancel or void the original EPCS that was sent to the first pharmacy. It also recognizes that this scenario creates additional burden for patients, who have to get back in touch with the original prescribing doctor and request a new prescription.

Therefore, DEA is proposing to revise its regulations to state that, upon request, a registered retail pharmacy may transfer an EPCS to another registered retail pharmacy for initial filling. This proposed rule will also specify the procedures that retail pharmacies must follow and the information that must be documented when transferring electronic prescriptions for controlled substances in schedules II–V. DEA believes that allowing the electronic transfer of controlled substance prescriptions will decrease the potential for duplicate prescriptions and thus reduce the opportunity for diversion or misuse.

Background

The CSA and its implementing regulations specify the requirements for issuing and filling prescriptions for controlled substances. DEA regulations permit a pharmacist to dispense a controlled substance in schedule II only pursuant to a written prescription (including an EPCS), except in limited emergency situations, when dispensing pursuant to an oral prescription is permitted.[4] No prescription for a controlled substance in schedule II may be refilled.[5] DEA regulations permit a pharmacist to dispense a controlled substance in schedules III, IV, and V pursuant to a paper prescription, a facsimile of a signed paper prescription, an EPCS, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist.[6] Prescriptions for schedule III and IV substances may not be filled or refilled more than six months after the date of issuance or be refilled more than five times.[7] The CSA does not address the transfer of controlled substance prescriptions between pharmacies for initial filling. DEA regulations address the transfer of controlled substances prescriptions between pharmacies for refills, but not for initial filling.[8] Hence, DEA is proposing to revise its regulations to state that the transfer of EPCS is permissible between registered retail pharmacies for initial filling on a one-time basis.

Why the Proposed Rule Is Necessary

On March 31, 2010, DEA published an interim final rule, *Electronic Prescriptions for Controlled Substances* (EPCS IFR), which provides practitioners with the option of issuing, and pharmacies with the option of receiving, dispensing, and archiving electronic prescriptions for schedule II–V controlled substances.[9] The EPCS IFR provides the regulations governing the electronic creation, signature, transmission, and processing of schedule II–V controlled substance prescriptions. The regulations, codified at 21 CFR parts 1300, 1304, 1306, and 1311, specifically define an electronic prescription as ''a prescription that is generated on an electronic application and transmitted as an electronic data file.'' [10] The regulations also provide the security and recordkeeping requirements imposed on prescription and pharmacy applications that create, process, and archive electronic controlled substance prescriptions.

Although DEA regulations permit the transfer of prescription information between pharmacies for refill dispensing of schedules III–V controlled substance prescriptions on a one-time basis, the regulations do not address the transfer of controlled substance prescriptions (paper or electronic) for initial dispensing.[11] As previously discussed, a patient can choose to take a paper prescription to another pharmacy if the first pharmacy is unable to fill it. However, because patients do not have a physical copy of an electronic prescription, the patient cannot take the prescription to another pharmacy if it cannot be filled by the first pharmacy.

DEA emphasized in the EPCS IFR that the option for EPCS is in addition to, not a replacement of, the requirements and provisions that exist for paper prescriptions for controlled substances.[12] Thus, the same rules and regulations applicable to paper prescriptions, as well as the same permissions, were also intended to apply to electronic prescriptions for controlled substances. Patients prescribed controlled substances electronically should have the same ability as patients issued paper controlled substance prescriptions to choose an alternate pharmacy if the first pharmacy is unable to fill a prescription. As more practitioners begin to issue controlled substance prescriptions electronically, as discussed below, there is an increasing need to address this issue.

[3] In contrast, as discussed below, 21 CFR 1360.25 already addresses the transfer of controlled substance prescriptions between pharmacies for refill purposes.

[4] 21 CFR 1306.11(a) and (d).

[5] 21 U.S.C. 829(a).

[6] 21 CFR 1306.21(a).

[7] 21 CFR 1306.22(a).

[8] 21 CFR 1306.25.

[9] 75 FR 16236 (Mar. 31, 2010). DEA subsequently reopened the comment period in 2020 to solicit public comment on certain issues. 85 FR 22018 (Apr. 21, 2020).

[10] 21 CFR 1300.03.

[11] 21 CFR 1306.25.

[12] 75 FR 16244.

In a recently published request for information, the Centers for Medicare and Medicaid Services (CMS) reported that it has seen a steady increase in the volume of controlled substance prescriptions submitted electronically since the EPCS IFR was published in 2010.[13] Further, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) was signed into law on October 24, 2018.[14] Section 2003 of the SUPPORT Act mandates the electronic prescribing of schedule II–V controlled substances (with some exceptions) covered under Medicare Part D, beginning on or after January 1, 2021.[15] In addition, in its 2019 National Progress Report, Surescripts, a health information network and electronic prescribing intermediary, noted that more than half of all States now require electronic prescribing of opioids, all controlled substances, or all prescriptions.[16] Thus, it is essential that procedures for transferring an EPCS are established as electronic prescribing of controlled substances becomes more prevalent. This rulemaking is being proposed to address this issue.

If finalized, this proposed rule would allow for the transfer of electronic prescriptions for schedules II–V controlled substances between DEA-registered retail pharmacies for initial filling. This proposed rule would also establish the procedures that must be followed and the information that must be documented when transferring an EPCS. For reasons discussed previously, this proposed rule focuses only on electronic prescriptions for controlled substances for initial dispensing and does not propose to amend 21 CFR 1306.25 which permits the transfer of paper, oral, or electronic prescriptions in schedules III, IV, and V for refill dispensing. A cross-reference to § 1306.25 is included in § 1306.08(i) to provide an easy reference to the regulations regarding the transfer of electronic prescriptions for refill purposes. DEA believes this proposed rule, if finalized, will reduce the potential for duplicate prescriptions, as well as the opportunity for diversion.

[13] *Medicare Program: Electronic Prescribing of Controlled Substances; RFI,* 85 FR 47151 (August 4, 2020).

[14] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Public Law 115–271, 132 Stat. 3894 (2018).

[15] SUPPORT Act, sec. 2003(a)(b). This requirement is codified at 21 U.S.C. 1395w–104(e)(7).

[16] Surescripts, National Progress Report 2019 *https://surescripts.com/news-center/national-progress-report-2019/* (Accessed March 31, 2021).

Summary of Proposed Changes

DEA proposes to amend its regulations to allow the transfer of EPCS between registered retail pharmacies for initial filling on a one-time basis only. The proposed amendment would explicitly state that a DEA-registered retail pharmacy may transfer schedules II–V EPCS to another DEA-registered retail pharmacy for initial dispensing. The proposed amendment would stipulate that: The transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form; and the contents of the prescription required by part 1306 must be unaltered during the transmission. This proposed rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

In addition, the proposed amendment would also describe the documentation requirements for pharmacies transferring an EPCS for initial dispensing. Specifically, the pharmacist transferring the EPCS must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also update the prescription record with the following information: The name, address, and DEA registration number of the pharmacy to which the prescription was transferred; the name of the pharmacist receiving the transfer; the name of the transferring pharmacist; and the date of the transfer. Likewise, the pharmacist receiving the transferred EPCS must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. Finally, under the proposed amendment, the electronic records documenting the transfer must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the EPCS and the pharmacy receiving the EPCS. This proposed rule does not change the existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, or the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. DEA has determined that this proposed rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f).

Analysis of Benefits and Costs

DEA is proposing to amend its regulations to allow the transfer of electronic prescriptions for schedule II–V controlled substances between registered retail pharmacies for initial dispensing on a one-time basis only. This amendment will specify the procedure that must be followed and the information that must be documented when transferring an EPCS between registered retail pharmacies. As described below, DEA estimates the annual cost savings of this proposed rule is $22.0 million.

The proposed amendment would stipulate that: The transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form and the required prescription information must be unaltered during the transmission. In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also record the name, address, and DEA registration number of the pharmacy to which the prescription is being electronically transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Likewise, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. Finally, under the proposed amendment, the electronic records documenting the transfer must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the prescription.

As current DEA regulations do not address the transfer of schedule II–V controlled substance prescriptions in

any form (paper or electronic) from one retail pharmacy to another retail pharmacy for initial filling, DEA anticipates the proposed rule will affect the following parties: The first (transferring) pharmacy, patient, prescriber, and second (receiving) pharmacy. To quantify the economic impact of this proposed rule, DEA estimated the average cost and cost savings for each transfer and applied this cost or cost savings to the estimated number of transfers.[17]

Estimated Cost or Cost Savings per Transfer

To estimate the unit cost or cost savings, DEA compared the anticipated activities for each of the affected parties when a pharmacy receives an EPCS it cannot fill under current practices versus the proposed regulations. The anticipated activities for each of the affected parties under current practices are described below. DEA understands there may be many operational variations; however, DEA believes the scenarios described below are good representations for the purposes of estimating costs.

The anticipated activities for each of the affected parties under current practice are described below.

1. The first pharmacy contacts the patient to inform the patient that they are unable to fill the prescription.

2. The first pharmacy notes action taken, as needed.

3. Patient receives call from the first pharmacy that they are unable to fill the prescription.

4. Patient contacts prescriber and requests new prescription.

5. Prescriber's secretary or administrative personnel receives phone call from the patient (likely by an administrative personnel at the prescriber's office).

6. Prescriber cancels the EPCS at the first pharmacy and issues a new EPCS at an alternate (receiving) pharmacy.

7. Receiving pharmacy receives and fills EPCS.

8. Patient receives filled prescription from the alternate pharmacy.

The anticipated activities for each of the affected parties under the proposed regulations and the economic impact are described below.

1. Transferring pharmacy contacts patient to inform that they are unable to fill the prescription. Assume duration of the call to the patient is same under current and proposed scenarios. Therefore, no impact.

2. The patient receives a call from the transferring pharmacy that they are unable to fill the prescription; the patient requests the prescription be transferred to an alternate (receiving) pharmacy. Assume duration of the call from the transferring pharmacy is same under current and proposed scenarios. Therefore, no impact.

3. Transferring pharmacy transfers prescription (including contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer). Transferring will take longer than simply informing the patient that the prescription cannot be filled. Therefore, additional cost to transfer.

4. Patient does not need to contact prescriber to request a new prescription under proposed regulations. Therefore, cost savings from not needing to contact prescriber.

5. Patient receives filled prescription from receiving pharmacy. Assume same burden, no impact.

6. Prescriber does not receive a call from the patient. Therefore, cost savings.

7. Prescriber does not need to issue a new EPCS. Therefore, cost savings.

8. Receiving pharmacy receives transfer and fills transferred EPCS (including being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer). Anticipate additional costs related to being contacted by the transferring pharmacy and exchanging information.

Table 1 summarizes the activity scenarios under current practices and proposed regulations and the anticipated economic impact.

[17] DEA expects minor system and implementation expenses, which consist of modifying software configurations, updating business processes, and minimal personnel training. DEA estimates the cost of these changes is minimal.

Table 1: Persons and Activities, Current vs. Proposed

Persons	Change in Activity		Economic Impact
	Current	Proposed	
First or Transferring Pharmacy	First pharmacy contacts patient to inform that they are unable to fill the prescription. Note action taken (i.e., void, cancel, etc.), as needed.	Transferring pharmacy contacts patient to inform that they are unable to fill the prescription. Transfer prescription. "Transfer" includes: contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer.	Assume duration of call/contact is same ==> no impact Additional cost to transfer vs. noting action taken.
Patient	Receive call from pharmacy that they are unable to fill the prescription. Contact prescriber to request new prescription. Receive filled prescription from second (receiving) pharmacy.	Receive call from pharmacy that they are unable to fill the prescription, request transfer of the prescription to an alternate (receiving) pharmacy. N/A. Receive filled prescription from receiving pharmacy.	Assume duration of call/contact is same ==> no impact. Cost savings from not having to contact prescriber. Assume same burden ==> no impact.
Prescriber	Receive call from patient. (prescriber's secretary) Cancel prescription sent to first pharmacy and issue new prescription at second (receiving) pharmacy.	N/A. N/A.	Cost savings. Cost savings.
Second (Receiving) Pharmacy	Receive prescription and fill.	Receive transfer and fill. "Transfer" includes: being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to receive and record transfer.

Cost or cost savings is based on applying the loaded labor rate for each of the affected persons to the estimated time to conduct the activity. The Bureau of Labor Statistics (BLS) hourly wage data for various occupation codes was used to estimate the labor rates for each of the affected persons. Using the occupation codes 29–1051 Pharmacists, 00–0000 All Occupations, 43–6013 Medical Secretaries and Administrative Assistants, and 29–1215 Family Medicine Physicians as best representations of first (transferring) and second (receiving) pharmacists, patient, prescriber's secretary, and prescriber, respectively, DEA estimates the median hourly wages for the first (transferring) and second (receiving) pharmacy, patient, prescriber's secretary, and prescriber are $61.58, $19.14, $17.59, and $98.84, respectively.[18] Additionally, BLS reports that average benefits for private industry is 30.0 percent of total compensation. The 30.0 percent of total compensation equates to 42.9 percent (30.0 percent/70.0 percent) load on wages and salaries.[19] The load of 42.9 percent is added to each of the hourly rates to estimate the loaded hourly rates. The loaded hourly rates for the first (transferring) and second (receiving) pharmacy, patient, prescriber's secretary, and prescriber are $88.00, $27.35, $25.14, and $141.24, respectively. Table 2 summarizes the calculation for the loaded hourly wages for each of the affected persons.

[18] BLS, May 2019 National Occupational Employment and Wage Estimates United States. *http://www.bls.gov/oes/current/oes_nat.htm.*

[19] BLS, "Employer Costs for Employee Compensation—September 2020" (ECEC).

TABLE 2—LOADED HOURLY WAGES

Affected persons	Occupation code	Occupation code description	Median hourly wage	Loaded hourly median wage
Patient	00–0000	All Occupations	$19.14	$27.35
Pharmacist	29–1051	Pharmacists	61.58	88.00
Medical secretary	43–6013	Medical Secretaries and Administrative Assistants	17.59	25.14
Prescriber	29–1215	Family Medicine Physicians	98.84	141.24

The below sections describe the calculation conducted to quantify the economic impact associated with the changes in activities under the current and proposed scenarios described above.

1. Currently, the first pharmacy contacts the patient to inform the patient that the pharmacy is unable fill the prescription. DEA estimates that it takes three minutes for the first pharmacist to call the patient. From Table 2, the estimated loaded hourly rate of a pharmacist is $88.00. Multiplying the loaded hourly rate of $88.00 by 0.05 (3/60) hours results in a cost of $4.40. Under the proposed rule, the first (transferring) pharmacist would also contact the patient regarding the inability to fill the prescription. DEA estimates that it would also take three minutes for the transferring pharmacist to call the patient under the proposed rule, resulting in the same cost of $4.40. Therefore, there is no economic impact associated with this activity under the proposed rule.

2. Currently, the first pharmacist notes in the electronic prescription record that the prescription was not filled. DEA estimates that it takes one minute for the first pharmacist to make the entry in the electronic prescription record. From Table 2, the estimated loaded hourly rate of a pharmacist is $88.00. Multiplying the loaded hourly rate of $88.00 by 0.0167 (1/60) hours results in a cost of $1.47. Under the proposed rule, the transferring pharmacy may transfer the prescription, upon request from the patient, to the receiving pharmacy. Additionally, the transferring pharmacy must also contact the receiving pharmacy and exchange and document information such as the transferring pharmacy's name, address and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. DEA estimates that it takes three minutes for the transferring pharmacist to transfer the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is $88.00. Multiplying the loaded hourly rate of $88.00 multiplied by 0.05 (3/60) hours results in a cost of $4.40. Therefore, the net cost to the transferring pharmacy under the proposed rule is $2.93 ($4.40 − $1.47) per transfer.

3. Under current practices, the patient first receives a call from the pharmacist who informs them that their prescription cannot be filled. DEA estimates that the call between the pharmacist and the patient lasts three minutes. From Table 2, the estimated loaded hourly rate of a patient is $27.35. Multiplying the loaded hourly rate of $27.35 multiplied by 0.05 (3/60) hours results in a cost of $1.37 to the patient. Under the proposed rule, this activity does not change. With transfers of an EPCS, the pharmacist must still contact the patient. Thus, under the proposed rule, the patient also receives a call from the pharmacist. Estimating three minutes for the call, there is still a cost of $1.37 to the patient. Therefore, there is no economic impact associated with this activity under the proposed rule.

4. Under current practices, the patient must contact the prescriber to request a new prescription. DEA estimates that it takes five minutes for the patient to contact the prescriber. From Table 2, the estimated loaded hourly rate of the patient is $27.35. Multiplying the loaded hourly rate of $27.35 by 0.083 (5/60) hours results in a cost of $2.28. Under the proposed rule, the patient no longer needs to contact the prescriber; the patient requests an electronic transfer of the prescription from the first (transferring) pharmacy to the second (receiving) pharmacy; thus there is zero cost to the patient. Therefore, this activity under the proposed rule results in a cost savings of $2.28 per transfer.

5. Under current practices, DEA assumes that the patient is informed that the first pharmacy is unable to fill the prescription prior to travelling to pick it up; thus, the patient only makes one trip to the second pharmacy where the prescription was transferred. DEA estimates that it takes 20 minutes for the patient to pick up the filled prescription. From Table 2, the estimated loaded hourly rate of a patient is $27.35. Multiplying the loaded hourly rate of $27.35 by 0.33 (20/60) hours results in a cost of $9.12. Under the proposed rule, DEA also assumes that the patient is informed about the pending transfer of the prescription prior to travelling to pick up the prescription, thus the patient only makes one trip. Estimating 20 minutes for the patient to pick up the filled prescription, under the proposed rule, there is still a cost of $9.12 to the patient. Therefore, there is no economic impact associated with this activity under the proposed rule.

6. Under current practices, the patient has to contact the prescriber asking for a new prescription. DEA estimates that it takes five minutes for the prescriber's medical secretary to receive the call from the patient. From Table 2, the estimated loaded hourly rate of a medical secretary is $25.14. Multiplying the loaded hourly rate of $25.14 by 0.083 (5/60) hours results in a cost of $2.10. Under the proposed rule, the patient no longer needs to contact the prescriber; thus, this interaction will not occur. Therefore, this activity under the proposed rule results in a cost savings of $2.10 per transfer.

7. Under current practices, after the medical secretary receives the call from the patient and the information is relayed to the prescriber, the prescriber issues a new prescription. DEA estimates the prescriber takes two minutes to cancel the first prescription and issue a new prescription. From Table 2, the estimated loaded hourly rate of a prescriber is $141.24. Multiplying the loaded hourly rate of $141.24 by 0.03 (2/60) hours results in a cost of $4.71. Under the proposed rule, the prescriber does not need to issue a new prescription. The original prescription is simply transferred to the receiving pharmacy; thus, this activity will not occur. Therefore, this activity under the proposed rule results in a cost savings of $4.71 per transfer.

8. Under current practices, the second (receiving) pharmacy receives and fills the prescription. DEA estimates that it takes 15 minutes for the second (receiving) pharmacy to receive and fill the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is $88.00. Multiplying the loaded hourly rate of $88.00 by 0.25 (15/60) hours results in a cost of $22.00. Under the proposed rule, DEA also estimates the receiving pharmacist still conducts this activity at the same

loaded labor rate and time duration, resulting in a cost of $22.00. However, under the proposed rule, the receiving pharmacist must also receive and record transfer information from the transferring pharmacy. DEA estimates that it takes three minutes for the receiving pharmacy to receive and record transfer information. From Table 2, the estimated loaded hourly rate of a pharmacist is $88.00. Multiplying the loaded hourly rate of $88.00 by 0.05 (3/60) hours results in a cost of $4.40. Therefore, this activity under the proposed rule results in a cost of $4.40 per transfer.

As shown by Table 3, the proposed rule results in a total cost of $8.80 and a total cost savings of $10.56 per transfer. This results in an overall net cost savings of $1.76 per transfer.

Table 3: Cost/Cost Savings Calculation, Current vs. Proposed

	Current		Proposed		
Person/Activity	Estimated time (minutes)	Cost, Current ($)	Estimated time (minutes)	Cost, Proposed ($)	Costs/ (Cost Savings) ($)
Transferring pharmacist					
1. Contact patient	3	4.40	3	4.40	-
2.a. Void/transfer prescription	1	1.47			(1.47)
2.b. Transfer prescription			3	4.40	4.40
Patient					
3. Receive call from pharmacist	3	1.37	3	1.37	-
4. Contact prescriber	5	2.28	-	-	(2.28)
5. Received filled prescription	20	9.12	20	9.12	-
Prescriber					
6. Receive call from patient (secretary)	5	2.10	-	-	(2.10)
7. Issue new prescription (prescriber)	2	4.71	-	-	(4.71)
Receiving pharmacist					
8.a. Receive prescription and fill	15	22.00	15	22.00	-
8.b. Receive and record transfer info			3	4.40	4.40
Total Costs					8.80
Total Cost Savings					(10.56)
Net Cost Savings					(1.76)

Estimated Number of Transfers

As mentioned earlier, in order to calculate the total cost savings, DEA applied the $1.76 net cost savings per transaction, from above, to the estimated number of total transfers. DEA estimated the number of total transfers by estimating the number of EPCS from 2022 to 2026, the analysis period, and applying an estimated percentage of EPCS that will be transferred.[20]

Surescripts' reports, ''2019 National Progress Report'' and ''2020 National Progress Report'' form the basis for estimating the number of EPCS from 2022 to 2026.[21] The reports indicate that the rate of electronic prescribing for non-controlled substances (E–RX) was 76, 83, and 86, and 89 percent in 2017, 2018, 2019, and 2020, respectively.[22] Additionally, the reports indicate that the rate of electronic prescribing for controlled substances (EPCS) is rising rapidly; the rate was 17, 26, 38, and 58 percent in 2017, 2018, 2019, and 2020, respectively.[23] Furthermore, there were 65.0, 96.8, 134.2, and 203.6 million EPCS filled in 2017, 2018, 2019, and 2020 respectively.[24] Dividing the total EPCS by the rate of EPCS, DEA estimates the total controlled substances prescriptions, electronic and non-electronic, were 382.4, 372.3, 353.2, and 351.0 million in 2017, 2018, 2019, and 2020, respectively. Table 4 summarizes the data provided by the report and the

[20] Due to the rapidly evolving industry and regulatory conditions, the analysis period is from 2022 to 2026.

[21] Surescripts, ''2019 National Progress Report'' for 2017 data and ''2020 National Progress Report'' for 2018–2020 data.

[22] Ibid.

[23] Ibid.

[24] Ibid.

estimated total prescriptions for controlled substances for years 2017–2020.

controlled substances for years 2017–2020.

TABLE 4—ESTIMATED TOTAL PRESCRIPTIONS FOR CONTROLLED SUBSTANCES, 2017–2020

	2017	2018	2019	2020
Non-Controlled Substances:				
Rate of E-Rx (%)	76	83	86	89
Controlled Substances:				
Total Rx, E and non-E (millions of Rx)	382.4	372.3	353.2	351.0
Rate of EPCS (%)	17	26	38	58
Total EPCS (millions of Rx)	65.0	96.8	134.2	203.6

As shown in Table 4, the estimated total prescriptions for controlled substances decreased from 382.4 million in 2017 to 351.0 million in 2020. For the purposes of this analysis, DEA estimates the total number of controlled substances prescriptions will stay constant at 351.0 million from 2022 to 2026.

Also from Table 4, the rate of electronic prescribing for non-controlled substances is higher than that of controlled substances. However, DEA estimates the rate of electronic prescribing for controlled substances will match that of non-controlled substances in 2022 due to a recently published CMS rule, which requires electronic prescribing for all controlled substances (with some exceptions) covered under Medicare Part D.[25] The 2020 rate of electronic prescriptions for non-controlled substances was 89 percent. While it is possible that this rate could continue to increase in the future, DEA has no basis to estimate how much higher the rate would go. As the rate of increase has been slowing over the past several years, DEA conservatively estimates that the rate of electronic prescribing for non-controlled substances has peaked at 89 percent and the rate of electronic prescribing for controlled substances will be 89 percent for the analysis period of 2022–2026. Multiplying the estimated total number of controlled substance prescriptions, 351.0 million per year, by the estimated rate of EPCS of 89 percent, the estimated total EPCS is 312.4 million per year for the analysis period 2022–2026.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.[26] Applying the four percent transfer rate to the total EPCS prescriptions, DEA estimates the number of transfers are 12.5 million per year from 2022–2026.

Total Cost Savings

In order to calculate the total cost savings, DEA applied the $1.76 net cost savings per transaction to the estimated 12.5 million transfers, resulting in a total annual net cost savings of $22.0 million over the analysis period, 2022–2026. The net present value (NPV) of the cost savings is $100.8 million at three percent discount rate and 90.2 million at seven percent discount rate. The annualized cost savings from 2022 to 2026 is $22.0 million at three percent and seven percent. Table 5 summarizes the NPV and annualized cost savings calculation.

TABLE 5—NPV AND ANNUALIZED COST SAVINGS

	3 percent	7 percent
NPV of Cost Savings	$100.8	$90.2
Annualized Cost Savings	22.0	22.0

Executive Order 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rule does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this proposed rule on small entities. DEA's evaluation of economic impact by size category indicates that the proposed rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires an agency to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. DEA has analyzed the economic impact of each provision of this proposed rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

DEA is proposing to amend its regulations to allow the electronic transfer of schedule II–V controlled substance prescriptions between registered retail pharmacies for initial filling on a one-time basis only. This amendment will specify the procedure that must be followed and the information that must be documented when electronically transferring an EPCS between pharmacies. The proposed amendment would stipulate that the transfer must be communicated directly between two licensed pharmacists, the prescription must remain in its electronic form, and the required prescription information must be unaltered during the transmission.

[25] 85 FR 84472 (Dec. 28, 2020).

[26] Conference call between CMS and DEA, January 2021. CMS's estimate is a ''high'' estimate and ''4 percent'' is considered the maximum percent of electronic prescriptions that are transfers.

Nothing in this proposed rule alters the existing pharmacy application requirements as specified in 21 CFR 1311.205.

In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to include information noting that the prescription was transferred. The transferring pharmacist must also record the name, address, and DEA registration number of the pharmacy to which the prescription is being transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Likewise, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. Finally, under the proposed amendment, the electronic records documenting the transfer must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the transfer.

DEA anticipates the proposed rule will affect pharmacies, offices of physicians, and hospitals, as the majority of prescribers are employed by offices of physicians or hospitals. Table 6 indicates the sectors, as defined by the North American Industry Classification System (NAICS), affected by the proposed rule. There may be other small entities under Small Business Administration size standards in other NAICS code industries affected by this proposed rule. However, DEA believes the list in Table 6 is a good general representation of affected small entities and their industries as defined by NAICS.

TABLE 6—AFFECTED INDUSTRIAL SECTORS

Business activity	NAICS code	NAICS code description
Pharmacy	446110	Pharmacies and Drug Stores.
Prescriber	621111	Offices of Physicians (except Mental Health Specialists).
	622110	General Medical and Surgical Hospitals.

Although transfers of EPCS may not be common, as much as four percent of prescriptions, DEA estimates, for the purposes of this analysis, such transfers of EPCS are distributed proportionally across all prescribers and pharmacies. Therefore, DEA estimates a substantial number of small entities in the affected industries would be affected by this proposed rule.

In order to determine if the proposed rule will result in a significant impact on small entities, the following steps were taken:

1. Estimate the cost or cost savings per transfer.

2. Estimate the total cost or cost savings of transfers.

3. Allocate the total cost or cost savings across all affected entities in proportion to their revenue to estimate the cost or cost savings per entity.

4. Compare the cost or cost savings to the annual revenue for the smallest of small entities. If the impact is not significant for the smallest of small entities, then the impact is not significant for the larger small entities.

Table 3 summarizes the cost or cost savings on a per-transfer basis. The net cost to the transferring pharmacy is $2.93 (the cost of transferring the prescription, $4.40 (2.b.), minus the cost of updating the prescription record to note that the prescription was not filled, $1.47 (2.a.)). The cost to the receiving pharmacy is $4.40 (8.b.) per transfer, resulting in a combined net cost of $7.33. Each transfer affects two different pharmacies, transferring and receiving pharmacies. However, to be conservative, the estimated cost per transfer to a pharmacy is $7.33 because the transferring and receiving pharmacies may be different establishments of the same parent entity. Also from Table 3, the total cost savings to a prescriber (office of physician or hospital) is $6.81, sum of the cost savings from not receiving a call from the patient $2.10 (6.) and the cost savings from not issuing a new prescription $4.71 (7.).

To calculate the total cost to pharmacies and total cost savings to prescribers, the unit cost and cost savings are multiplied by the estimated total annual transfers. From above, the estimated number of transfers is 12.5 million per year. Multiplying the net cost of $7.33 per transfer for pharmacies by 12.5 million transfers, the estimated total cost of transfers to all pharmacies is $91,625,000 per year. Multiplying the cost saving of $6.81 per transfer for prescribers (office of physician or hospital) by 12.5 million transfers, the estimated total cost saving to all prescribers is $85,125,000 per year.

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) is an annual series that provides national and subnational data on the distribution of economic data by enterprise size and industry. SUSB data includes the number of firms at various size ranges. For the purposes of this analysis, the term ''firm'' as defined in the SUSB is used interchangeably with ''entity'' as defined in the RFA. Based on SUSB data, there are 18,852, 174,901, and 2,904 firms in 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.[27] Furthermore, the total receipts for all firms, including all size ranges, are $236 billion, $402 billion, and $827 billion (rounded) for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.[28] Table 7 summarizes the SUSB data and provides receipt values without rounding.

[27] SUSB, 2012 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size, U.S., 6-digit NAICS, *https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html* (*https://www2.census.gov/programs-surveys/susb/tables/2012/us_6digitnaics_r_2012.xlsx*). (Accessed February 25, 2021.) 2012 data by enterprise receipt size is the latest available.

[28] Ibid.

TABLE 7—NUMBER OF FIRMS AND TOTAL RECEIPTS

NAICS code	NAICS code description	Receipt size ($)	Number of firms	Receipts ($000)
446110	Pharmacies and Drug Stores	All size ranges	18,852	236,277,373
621111	Offices of Physicians (except Mental Health Specialists)	All size ranges	174,901	402,159,295
622110	General Medical and Surgical Hospitals	All size ranges	2,904	826,654,913

SUSB data also includes the number of firms and receipts for various receipt-size ranges. The smallest size range is firms with annual revenue less than $100,000. The average receipt per firm was calculated based on the number of firms and for the receipts for the firms in the size range. For example, in the 446110—Pharmacies and Drug Stores industry sector, there are 751 firms with receipts under $100,000, and their combined receipts is $36,066,000. Dividing $36,066,000 by 751 results in an average receipt of $48,024 per firm. Performing the same calculation for all three industries, the average receipt per firm is $48,024, $50,493, and $272,286 for the smallest size category in 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 8 summarizes the calculation for the average receipt per firm.

TABLE 8—AVERAGE RECEIPT PER FIRM

NAICS code	NAICS code description	Receipt size ($)	Number of firms	Receipts ($000)	Average receipt per firm ($)
446110	Pharmacies and Drug Stores	<100,000	751	36,066	48,024
621111	Offices of Physicians (except Mental Health Specialists)	<100,000	15,275	771,280	50,493
622110	General Medical and Surgical Hospitals	* 100,000–499,999	14	3,812	272,286

* ''Receipts'' not available for the smallest size range of ''< 100,000''; therefore, used next size range of ''100,000–499,000'' for comparison.

To compare the average cost per firm with the average receipt per firm, DEA allocated the cost and cost savings proportionally by revenue, divided by the number of firms to calculate the average cost per firm, and compared the average cost per firm as a percent of receipt per firm. For example, the receipts for the 751 firms with receipts under $100,000 in 446110—Pharmacies and Drug Stores industry sector is $36,066,000. This is 0.015264 percent of total receipt of $236,277,373,000 for all size ranges. Allocating 0.015264 percent of total cost to pharmacies of $91,625,000 to the 751 firms, the average cost per firm is $19.[29] Dividing the average cost per firm of $19 by the average receipt per firm of $48,024, the average cost per firm is 0.03956 percent of average receipt per firm.

This calculation is repeated for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors. However, the economic impact for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors is a cost savings, rather than a cost. Although employment of prescribers are expected to be split between these two industries, to be conservative, the total cost savings (rather than estimating a split between the two industries) is compared to the average receipt per firm. In summary, the average cost or cost savings per firm as percent of receipt is 0.03956 percent, 0.02179 percent, and 0.01028 percent for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 9 summarizes the calculation and results.

TABLE 9—COST OR COST SAVINGS PER FIRM AS PERCENTAGE OF RECEIPTS

NAICS code	NAICS code description	Receipt size ($)	Number of firms	Receipt as percent of total (percent)	Allocated cost to firms in size range ($)	Average cost per firm ($)	Average cost/ cost savings per firm as percent of receipt (percent)
446110	Pharmacies and Drug Stores	<100,000	751	0.015264	13,762	19	0. 03956
621111	Offices of Physicians (except Mental Health Specialists).	<100,000	15,275	0.191785	160,645	11	* (0.02179)
622110	General Medical and Surgical Hospitals.	100,000–499,999	14	0.000461	386	28	* (0.01028)

* Cost savings.

In conclusion, the average cost or cost savings per firm as percent of receipt of 0.03956 percent, 0.02179 percent, and 0.01028 percent are not significant economic impacts. Therefore, DEA concludes this proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

[29] ($91,625,000 × 0.015264 percent)/751 = $19.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this proposed rule would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA), DEA has identified the following collection of information related to this proposed rule.[30] If adopted, this proposed rule would create additional recordkeeping requirements for pharmacies electronically transferring of schedules II–V EPCS for initial dispensing. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

A. Collections of Information Associated With the Proposed Rule

Title: Recordkeeping Requirements for the electronic transfer of electronic prescriptions for schedules II–V controlled substances between pharmacies for initial filling.

OMB Control Number: 1117–NEW.

DEA Form Number: N/A.

DEA is proposing to require pharmacies to create and maintain certain records relating to the transfer of unfilled EPCS between pharmacies for initial filling. The rulemaking proposes to require the transferring pharmacy to note in the electronic prescription record that the prescription was transferred. The transferring pharmacy would also be required to add to the prescription record the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, as well as the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the proposed rule would require the pharmacy receiving the transfer to record the name, address, and DEA registration number of the transferring pharmacy, the name of the transferring pharmacist, the name of the pharmacist receiving the transfer, and the date of the transfer. In addition, the proposed rule would require the records to be maintained by both pharmacies for at least two years from the date of the transfer. DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 70,567.
- *Frequency of response:* 354.273244 (calculated average).
- *Number of responses:* 25,000,000.
- *Burden per response:* 0.05 hour.
- *Total annual hour burden:* 1,250,000.

The activities described in this information collection are usual and ordinary business activities and no additional cost is anticipated.

B. Request for Comments Regarding the Proposed Collections of Information

- Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Under the PRA, the DEA is required to provide a notice regarding the proposed collections of information in the **Federal Register** with the notice of proposed rulemaking and solicit public comment. Pursuant to section 3506(c)(2) of the PRA, the DEA solicits comment on the following issues: The need for the information collection and its usefulness in carrying out the proper functions of DEA.
- The accuracy of DEA's estimate of the burden the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117–AB64/Docket No. DEA–637. All comments must be submitted to OMB on or before January 18, 2022. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR part 1306 as follows:

PART 1306—PRESCRIPTIONS

■ 1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 823, 829, 829(a), 831, 871(b), unless otherwise noted.

■ 2. Amend § 1306.08 by adding paragraphs (e) through (i) to read as follows:

§ 1306.08 Electronic prescriptions.

* * * * *

(e) The transfer for initial dispensing of an electronic prescription for a controlled substance in schedule II–V is permissible between retail pharmacies on a one-time basis only.

(f) The transfer of an electronic prescription for a controlled substance in schedule II–V between retail pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one retail pharmacy to another retail pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (*e.g.,* facsimile) for transmission.

(2) The contents of the prescription required by part 1306 of this chapter must not be altered during transfer between retail pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) The transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist must add the following to the electronic prescription record:

(i) Information that the prescription has been transferred.

(ii) The name, address, and DEA registration number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(iii) The date of the transfer and the name of the pharmacist transferring the prescription information.

(5) The receiving pharmacist must do the following:

(i) Add the word ''transfer'' to the electronic prescription record at the receiving pharmacy.

(ii) Annotate the prescription record with the name, address, and DEA registration number of the pharmacy from which the prescription was transferred and the name of the pharmacist who transferred the prescription.

(iii) Record the date of the transfer and the name of the pharmacist receiving the prescription information.

(g) The transfer of an electronic prescription for a controlled substance in schedule II–V for the purpose of initial dispensing is permissible only if

[30] 44 U.S.C. 3501 *et seq.*

allowable under existing State or other applicable law.

(h) The electronic records documenting the transfer of the electronic prescription must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the electronic prescription.

(i) A pharmacy may transfer electronic prescription information for a controlled substance in schedule III, IV, and V to another pharmacy for the purpose of refill dispensing pursuant to § 1306.25.

Anne Milgram,

Administrator.

[FR Doc. 2021–24981 Filed 11–18–21; 8:45 am]

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Notices

Federal Register
Vol. 86, No. 221
Friday, November 19, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

[Docket No. ATBCB–2019–0002]

Advisory Guidelines for Aircraft Onboard Wheelchairs; Reopening of Comment Period; Notice of Public Meeting

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Reopening of comment period; notice of meeting.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board or Board), jointly with the U.S. Department of Transportation (DOT), is hosting a virtual public meeting to obtain further information on the Access Board's proposed advisory guidelines for aircraft onboard wheelchairs (OBW) issued on August 20, 2019, and the portion of DOT's notice of proposed rulemaking (NPRM) issued on January 2, 2020 that relates to OBW performance standards. DOT's January 2, 2020 NPRM proposed OBW performance standards as one of various measures for improving accessibility of lavatories on single-aisle aircraft for passengers with disabilities. The Board's draft advisory guidelines provided technical specifications for an OBW that would serve as one means of complying with DOT's proposed performance standards for OBW. This public meeting will serve as a forum for the Access Board and DOT to jointly gather additional information on their respective proposed OBW advisory guidelines and proposed OBW performance standards. A proposed rule from DOT relating to this public meeting and reopening of the comment period on its NPRM containing OBW performance standards is published elsewhere in this issue of the **Federal Register**.

DATES:

Public Comments: The comment period on the Board's draft advisory guidelines on OBW published at 84 FR 43100 (Aug. 20, 2019) is reopened for supplemental comments from December 16, 2021 (*i.e.,* date of public meeting) to January 17, 2022.

Public meeting: December 16, 2021, 9:30 a.m. to 11:30 a.m. and 1 p.m. to 3 p.m., Eastern Time.

Public attendance and testimony: Requests to attend the meeting must be received by December 9, 2021. Communication access real-time translation and sign language interpretation will be provided, but requests for additional accommodations because of a disability must be received by December 9, 2021. If you wish to present oral testimony during the meeting, you must submit a request by December 9, 2021. Requests to submit written materials to be reviewed during the meeting must be received no later than December 9, 2021.

ADDRESSES:

Public Meeting: Requests to attend the meeting must be submitted to *https://usdot.zoomgov.com/webinar/register/WN_8PChAZcLQsmDm1xathLEjw.* Requests for additional accommodations because of a disability must be submitted to *OBWpublicmeeting@dot.gov.* Requests to submit written materials to be reviewed during the meeting must be submitted to *OBWpublicmeeting@dot.gov.* If you wish to speak during the meeting, you must submit a request to DOT at *OBWpublicmeeting@dot.gov.* The virtual meeting will be open to the public, subject to any technical and/or capacity limitations, and held via the Zoom Webinar Platform. Virtual attendance information will be provided upon registration. An agenda will be provided to registered participants and placed in the docket in advance of the meeting.

Public Comments: You may submit comments, identified by docket number (ATBCB–2019–0002), by any of the following methods:

- *Federal rulemaking Portal: https://www.regulations.gov/.* Follow the instructions for submitting comments.
- *Email: docket@access-board.gov.* Include docket number ATBCB–2019–0002 in the subject line of the message.
- *Mail:* Office of Technical and Information Services, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004–1111.

Instructions: All submissions must include the docket number (ATBCB–2019–0002) for this regulatory action. All comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov/document/ATBCB-2019-0002-0001.*

FOR FURTHER INFORMATION CONTACT: To register and attend this virtual meeting, please contact DOT at: *https://usdot.zoomgov.com/webinar/register/WN_8PChAZcLQsmDm1xathLEjw.* For further information, contact Wendy Marshall of the Access Board by email at *marshall@access-board.gov* or by phone at 202–272–0043. You may also contact Robert Gorman, DOT Senior Attorney, by email at *robert.gorman@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

In April 2016, DOT established and appointed members to the Advisory Committee on Accessible Air Transportation (ACCESS Advisory Committee or Committee) to negotiate and develop proposed regulations addressing, among other things, accessible lavatories on single-aisle aircraft.[1] During the first meeting, DOT committed to the Committee that if it came to a consensus on the terms of a proposed rule and the Department does not cast a dissenting vote on the consensus product, DOT would exercise good faith efforts to issue a proposed rule reflecting that consensus to the extent possible. The Committee gathered data, conducted meetings and site visits, and engaged in negotiations from May 2016 through November 2016.

On November 22, 2016, the ACCESS Advisory Committee reached consensus on recommendations for new regulatory proposals to improve the accessibility of lavatories on single-aisle aircraft and the Department does not cast a dissenting

[1] A full list of ACCESS Advisory Committee members and other information on the Committee may be found at *https://www.transportation.gov/access-advisory-committee* ; see also *https://www.regulations.gov/docket?D=DOT-OST-2015-0246* (ACCESS Advisory Committee docket).

vote.[2] The accessible lavatory Term Sheet included agreements for both short-term and long-term accessibility improvements. The short-term improvements would be required on new single-aisle aircraft delivered three years after the effective date of the DOT final rule that implements the agreement. The short-term improvements included a proposed requirement that single-aisle aircraft with 125 or more passenger seats would have at least one lavatory with a number of accessibility features, including accessible door locks, flush handles, call buttons, faucets, and assist handles. Single-aisle aircraft with 125 or more passenger seats would also be required to include an OBW that: (1) Permits passage in the aircraft aisle; (2) fits within an available certificated OBW stowage space; and (3) accomplishes its functions without requiring modification to the interior arrangement of the aircraft or the lavatory. The Term Sheet called on the DOT to ''consult with advocates, airlines, aircraft manufacturers, manufacturers of OBW, flight attendant association(s) and other stakeholders in developing these standards,'' and to ''include the proposed new standards for an OBW and replacement of OBW on existing aircraft as described above in its notice of proposed rulemaking.'' [3]

DOT determined that the most appropriate method for developing initial OBW design standards was to seek technical assistance from the Access Board, the federal agency that specializes in producing accessible design specifications for the built environment, transportation systems, information and communication technology, and medical diagnostic equipment.[4] See 29 U.S.C. 792. In response to DOT's request, on August 20, 2019, the Access Board published in the **Federal Register** ''Proposed Advisory Guidelines for Aircraft Onboard Wheelchairs,'' and sought public comment.[5] The Access Board's guidelines provide design criteria for onboard wheelchair seats, back support, armrests, footrests, movement, stowage, stability, loads, caster wheels, assist handles, and torso and leg restraints. These guidelines provided for the OBW to be backed fully into the lavatory and positioned over the closed toilet so that the lavatory door can be completely closed. The guidelines also provided for the OBW to be maneuvered partially into lavatories in a forward direction to allow users the option to make a stand-and-pivot transfer to the toilet.

The Access Board held a public hearing on these advisory guidelines on September 12, 2019. In response to its proposed guidelines, the Access Board received over 40 comments from various interest groups and stakeholders, including people with disabilities, advocacy groups, aircraft manufacturers, trade associations, manufacturers of onboard wheelchairs, researchers, and others.[6]

On January 2, 2020, DOT published a notice of proposed rulemaking (NPRM) titled ''Accessible Lavatories on Single-Aisle Aircraft: Part 1.'' [7] This NPRM included proposals for short-term improvements to lavatory accessibility, including new proposed requirements for OBWs. In developing its own proposed rules for OBWs, DOT started with the Access Board's design-based guidelines and adapted them into more flexible performance standards. The performance standards were designed to allow manufacturers to find efficient and innovative means for meeting performance expectations. At the same time, the proposed rule states that airlines may use the Access Board's advisory guidelines for technical assistance in furnishing an OBW that meets the DOT's performance standards.

Under the proposed rule, OBWs meeting the new standards must be installed on new single-aisle aircraft with an FAA-certificated maximum capacity of 125 seats or more that enter service three years after the effective date of a final rule issued by DOT in this proceeding. The proposed rule would require the OBW to be designed in such a manner as to enable the OBW to completely enter the lavatory in a backward orientation. Specifically, the rule would require the OBW to fit over the closed toilet lid in a manner that permits the lavatory door to close completely. It is anticipated that the attendant would push the OBW backward into the lavatory by means of handles on the front of the OBW. After the OBW is situated over the closed toilet lid, the door would be closed and the passenger would be able to perform non-toileting lavatory functions in privacy.

The proposed rule would also require that the OBW be designed such that it could, at a minimum, partially enter the lavatory in a forward orientation. The purpose of this provision is to facilitate a stand-and-pivot maneuver from the OBW to the toilet seat, for passengers who are able to do so. With a stand-and-pivot maneuver, the passenger would partially enter the lavatory by means of the OBW, stand up, and pivot 180 degrees to reach the toilet seat.

The proposed OBW rule also contained safety elements. For example, the rule would require that the height of the OBW seat must align with the height of the aircraft seat to the maximum extent practicable, in order to permit a safe transfer between the OBW and the aircraft seat. The rule would require the wheels of the OBW to lock in the direction of travel, in order to avoid contact with aircraft seats and other obstructions as it moves down the aisle. Any other moving parts of the OBW would need to be capable of being secured such that they do not move while the occupied onboard wheelchair is being maneuvered. The wheels would also be required to lock in place so as to provide stability during transfers. The OBW would be required not to tip or fall in any direction under normal operating conditions when occupied for use.

The OBW would also be required to have a padded seat and backrest, in order to preserve skin integrity, and to prevent spasticity and injury.[8] The rule would also require the OBW to be free of sharp or abrasive components. The OBW would also be required to have arm supports that are sufficient to facilitate transfers; arm supports that are repositionable to permit unobstructed transfers between the OBW and the aircraft seat; torso and leg restraints to ensure stability and prevent injury; as well as a unitary foot support that would provide adequate clearance over the lavatory threshold and also allow for an unobstructed transfer between the OBW and the lavatory. Under the proposed rule, restraints would be operable by the passenger in order to permit the passenger the option to adjust the restraints unassisted. Finally, the rule would require the OBW to have instructions prominently displayed for proper use.

In keeping with the ACCESS Advisory Committee's Term Sheet, airlines would

[2] *https://www.transportation.gov/office-general-counsel/negotiated-regulations/final-resolution-access-committee.*

[3] *https://www.transportation.gov/sites/dot.gov/files/docs/Annex%20A.Lav_.Agreed%20Text.pdf.*

[4] *https://www.access-board.gov.*

[5] See 84 FR 43100; *https://www.federalregister.gov/documents/2019/08/20/2019-17873/advisory-guidelines-for-aircraft-onboard-wheelchairs.* The Access Board's Docket for OBW standards is found at *https://www.regulations.gov/docket?D=ATBCB-2019-0002.*

[6] See Docket No. ATBCB–2019–0002 at *https://www.regulations.gov/docket/ATBCB-2019-0002.*

[7] See 85 FR 27; *https://www.federalregister.gov/documents/2020/01/02/2019-27631/accessible-lavatories-on-single-aisle-aircraft-part-1.*

[8] DOT specifically sought comment on whether the proposed rule text adequately conveys the degree of back support and seat support necessary to properly accommodate passengers with disabilities, and if not, whether additional standards should be specified.

not be required to modify aircraft interiors, including lavatories and existing OBW stowage spaces, in order to comply with these OBW provisions. DOT sought comment on all aspects of this critical issue of OBW stowage space. Specifically, DOT sought further data regarding: (1) The folded dimensions of OBWs currently in use on single-aisle aircraft; (2) the locations and dimensions of current OBW stowage spaces; and (3) the feasibility of designing and constructing an OBW that meets the listed performance standards, particularly including the ability to enter the lavatory in a backward orientation, while fitting into the existing OBW stowage space for that aircraft. DOT also sought comment on an alternative proposal: Whether to require OBWs to meet the new performance standards set forth in the NPRM even if stowage space must be expanded to accommodate the OBW. DOT sought comment on the costs of expanding OBW stowage spaces to meet these performance standards.

Again, in keeping with the ACCESS Advisory Committee's Term Sheet, the proposed rule provided that an airline would not be responsible for the failure of third parties to furnish an OBW that complies with these proposed standards, so long as the airline notifies and substantiates to DOT the efforts it expended to obtain compliant OBWs. DOT recognized that, at present, no commercially available OBW exists that permits backward passage into an aircraft lavatory, and that while airlines may seek to procure an OBW that meets DOT's performance standards, airlines do not design or produce OBWs themselves.[9]

Finally, the proposed rule provided that if an airline replaces an OBW on an aircraft with an FAA-certificated maximum capacity of 125 seats or more three years after the effective date of the rule, then the replacement OBW must comply with DOT's new OBW standards. DOT sought comment on all aspects of the OBW proposal, including costs, benefits, and feasibility.

The comment period to the NPRM closed on March 2, 2020. DOT received relatively few comments about OBW design, and almost no comments that estimated the costs of developing or manufacturing an OBW that would comply with the standards set forth in the proposed rule. Certain disability advocates argued, among other things, that DOT's OBW standards should have tracked more closely the Access Board's design standards.[10] Representatives of the airline industry contended that DOT failed to take into account considerations such as aviation safety and the impact on flight attendants of unpacking, using, and stowing the OBW while in flight.[11] They also argued that DOT failed to adequately consult with stakeholders before issuing its OBW proposal.[12] DOT received no comments from OBW manufacturers.

Announcement of Public Meeting

Under these circumstances, the Access Board and DOT are jointly of the view that it is appropriate to hold a public hearing to gather additional information on the OBW design from disability advocates, airlines, aircraft manufacturers, manufacturers of OBWs, flight attendant associations, and other stakeholders. Specifically, the Access Board seeks information on OBW loads and caster wheel size that will help it finalize its advisory guidelines for OBWs. DOT seeks comment on all aspects of OBW design before issuing any final binding regulation on the topic.

Questions Relating to Access Board's Proposed Voluntary Design Standards

The Access Board is seeking additional information regarding OBW loads and OBW casters.

Onboard Wheelchair Loads

The overall weight capacity or load of current OBW varies greatly and ranges from approximately 200 to 800 pounds. In trying to determine the appropriate load, the Access Board looked to its *Guidelines for Aircraft Boarding Chairs* (1987), which recommend that seats support at least 723 pounds (weight of a 99th percentile male with a 3.0 safety factor). See *https://www.access-board.gov/research/completed-research/guidelines-for-aircraft-boarding-chairs.* Using updated anthropometrics, the weight of a 99th percentile male with a 3.0 safety factor would be 826 pounds. See Department of Health and Human Service Centers for Disease Control and Prevention's Anthropometric Reference Data for Children and Adults: United States, 2011–2014, Table 6, Line 1 (Aug. 2016). However, the boarding chair (used to transfer passengers from their personal wheelchairs to the airplane seat) differs from the proposed OBW in that a boarding chair does not need to fold for storage on the aircraft or fit over the seat of a toilet in a cantilever design.

The Board is not aware of existing industry standards for OBW that are designed to allow over-the-toilet positioning. In its proposed advisory guidelines, the Board reserved provisions for loads pending further information as to what loads are appropriate for an OBW design that accomplishes the proposed functions.

The Board received comments from the public, including aircraft manufacturers, recommending that the Board's guidelines reference load specifications in SAE International's standard entitled, ''Foldable On-Board Wheelchairs for Passengers with Disabilities,'' ARP 4120C (Stabilized 2013).'' The SAE standard specifies loads for onboard wheelchair seats, seat backs, arm and foot supports, wheels, and assist handles.

Based on its review of the comments on the proposed guidelines, the Board is considering referencing the SAE International's standard for loads for seats (3.2.9.1), arm supports (3.2.9.3), foot support (3.2.9.4), casters (3.2.9.2), and assist handles of onboard wheelchairs (3.2.9.6). The Board seeks comment on whether the loads specified in the SAE International ARP 4120C Standard are appropriate for an onboard wheelchair design that allows the chair to be positioned over the closed lavatory toilet. SAE International has made these referenced provisions publicly available without cost (read-only, not for distribution) until the close of the comment period on January 17, 2022, at: *https://www.sae.org/binaries/content/assets/cm/content/standards/arp4120c_review.pdf.*

In addition to comments on loads stated in the above-referenced SAE International standard, the Access Board seeks information on alternative appropriate standards for OBW loads.

Onboard Wheelchair Casters (Size)

The draft advisory guidelines require that caster wheels of onboard wheelchairs move independently to facilitate maneuvering within the confined space of aircraft aisles and

[9] DOT sought comment on whether there should be a deadline for an airline to notify DOT that the airline has expended its efforts to obtain compliant OBWs, and if so, how many days after an airline becomes aware of such commercial unavailability (*e.g.,* 30 days) would be appropriate for airlines to notify DOT. DOT also recognized the uncertainties surrounding the issue of whether OBWs meeting DOT's new standards can fit within existing OBW stowage spaces. The intent of the proposal was to encourage innovation in meeting the proposed standards by affirmatively requiring airlines to engage in reasonable efforts to obtain compliant OBWs from third parties. DOT sought comment on whether the ''reasonable efforts'' clause is the most appropriate means of reaching the overarching goal of ensuring that OBWs with the new accessibility features are acquired.

[10] See, *e.g.,* Comment of Paralyzed Veterans of America, *https://www.regulations.gov/comment/DOT-OST-2019-0180-0335,* at 5.

[11] See, *e.g.,* Comment of Airlines for America, *https://www.regulations.gov/comment/DOT-OST-2019-0180-0337,* at 2–3.

[12] Id.

lavatories. For safety and stability, the guidelines also require each caster to have wheel locks and swivel locks. In its proposal, the Board sought comment on whether the guidelines should specify a minimum size for caster wheels so that they are large enough to readily traverse thresholds at lavatory entrances. Commenters recommended that the guidelines specify a performance requirement instead of a minimum caster size. However, the threshold at the lavatory entrance may significantly impact an assistant's ability to back the occupied OBW into the lavatory using the front assist handles and to pull it back out.

The Access Board requests information on the minimum caster wheel diameter that would ensure stability of the occupied OBW and allow the chair to easily traverse the lavatory doorway threshold when propelled using solely the front assist handles. The Board also requests information on the standard height of lavatory thresholds on single-aisle aircraft with 125 or more passenger seats.

Questions Relating to DOT's NPRM Regarding OBW Design

In a notice published elsewhere in this issue of the **Federal Register**, DOT seeks further information on all aspects of its NPRM relating to OBW design, including but not limited to:

- Whether the proposed OBW design elements adequately address accessibility concerns;
- The cost and feasibility of designing, manufacturing, and implementing compliant OBWs;
- The cost of developing and implementing procedures for training crew in unloading, using, and stowing the OBW;
- The dimensions of current OBW stowage spaces in single-aisle aircraft;
- Whether OBWs that meet DOT's proposed accessibility standards can be stowed in existing stowage spaces; and
- Aviation safety considerations relating to unloading, using, and stowing the OBW while in flight.

Invitation for the Submission of Additional Written Comments

The Access Board encourages stakeholders, including disability advocates, airlines, aircraft manufacturers, manufacturers of OBWs, flight attendant associations, public meeting participants, and others to submit written comments to the regulatory docket on its proposed OBW advisory guidelines, oral testimony or written materials discussed at the public hearing, or related matters, during the supplemental period for comment from December 16, 2021 to January 17, 2022.

Gretchen Jacobs,

General Counsel.

[FR Doc. 2021–24980 Filed 11–18–21; 8:45 am]

BILLING CODE 8150–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Maryland Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of planning meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Maryland Advisory Committee to the Commission will convene by WebEx virtual platform and conference call on Tuesday, December 7, 2021, at 12:00 p.m. to continue its work on water accessibility and affordability in Maryland, including speakers on the topic.

DATES: Tuesday, December 7, 2021; 12:00 p.m. (ET).

PUBLIC WEBEX CONFERENCE LINK (video and audio): *https://bit.ly/3ATFxTt.*

IF PHONE ONLY: 1–800–360–9505; Access code: 199 818 3090#.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez at *ero@usccr.gov* or by phone at 202–381–8915.

SUPPLEMENTARY INFORMATION: The meeting is available to the public through the web link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with conference details found through registering at the web link above. To request additional accommodations, please email *bdelaviez@usccr.gov* at least 10 days prior to the meeting.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be emailed to Barbara Delaviez at *ero@usccr.gov.* Persons who desire additional information may contact Barbara Delaviez at 202–539–8246.

Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number or email address.

Agenda

December 7, 2021 (Tuesday); 12:00 p.m. (ET)

- Rollcall
- Planning and Presentations on Water Affordability/Accessibility
- Open Comment
- Adjournment

Dated: November 15, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–25230 Filed 11–18–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; 2020 Post-Census Group Quarters Review

AGENCY: Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on a proposed new information collection, the 2020 Post-Census Group Quarters Review, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 18, 2022.

ADDRESSES: Interested persons are invited to submit written comments by email to *DCMD.PCGQR@census.gov.* Please reference 2020 Post-Census

Group Quarters Review in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2021–0025 to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Sonia Collazo, Supervisory Statistician, 301–763–3350, and *sonia.g.collazo@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The 2020 Post-Census Group Quarters Review (2020 PCGQR) provides a mechanism for tribal, state, and local governmental units in the United States and Puerto Rico, or their designated representatives, to submit a request that the Census Bureau review their population counts for group quarter facilities by block to correct error(s) affecting the inclusion of group quarters and their population from the 2020 Census.

The Census Bureau has a comprehensive program to improve the quality of the population counts. For example, the Census Bureau provides an opportunity for tribal, federal, state, and local governments to review and improve the address lists and maps used to conduct the 2020 Census through the Local Update of Census Addresses program. In 2020, the Census Bureau used administrative records to classify some addresses as occupied, vacant, or nonresidential for enumeration. The Census Bureau also conducts the Population Estimates Program to calculate population change since the most recent decennial census and produce a time series of estimates of population, demographic components of change, and housing units. Beginning in January 2022, the Census Bureau will begin accepting and processing challenges submitted by eligible tribal, state, and local government officials through the Count Question Resolution (CQR) Program. The purpose of CQR is to provide a mechanism for governmental units to request a review of their official Census results and to help ensure that housing and population counts are correctly allocated to census tabulation blocks in the 50 states, District of Columbia and Puerto Rico. CQR provides corrected counts for housing units and population counts existing as of April 1 of the decennial year when the decennial census record shows that a housing unit or its associated population was identified during the enumeration, but erroneously excluded from or included in the census count due to a processing error. As part of the preparation for the 2020 CQR program, the Census Bureau published a **Federal Register** Notice on August 4, 2020 (85 FR 47162). The Census Bureau received several comments urging the Census Bureau to expand the CQR program in 2020 to accept and process submissions of population counts for group quarters facilities that the eligible governmental unit believed was not collected by the Census Bureau in the 2020 decennial census enumeration. Because the CQR program cannot be an extension of the decennial enumeration, the Census Bureau was unable to make changes to CQR consistent with these comments. However, the Census Bureau considered these comments in conjunction with its comprehensive program to improve the quality of the group quarters and associated population counts and the use of administrative records to support Census Bureau programs under Title 13, United States Code. The Census Bureau will conduct a 2020 PCGQR to collect information in support of its ongoing programs, such as the Population Estimates program and the American Community Survey program. The Census Bureau will issue certified population correction counts, as determined by Census Bureau research. The Census Bureau will incorporate all 2020 PCGQR revisions into the intercensal population estimates and American Community Survey estimates starting in 2022 and will post the results on the Census Bureau 2020 PCGQR website.

II. Method of Collection

The Census Bureau will accept 2020 PCGQR cases submitted by tribal, state, and local governmental units from Spring 2022 through Summer 2023. Governmental units wanting to submit a case will be provided an Excel spreadsheet template that will be submitted through the Census Bureau's Secure Web Incoming Module (SWIM). The Census Bureau will only accept cases that initiate from the highest elected or appointed official of tribal, state, and local governmental units, or their designated representative. Regardless of who makes the case submission, the Census Bureau must receive notification from the highest elected or appointed official of the governmental unit that indicates they want the Census Bureau to review their population counts for group quarter facilities data through the 2020 PCGQR process. This level of notification assures the Census Bureau that the highest level of leadership is informed and in agreement with filing a case on behalf of the governmental unit. The notification must accompany the supporting documentation submitted with the case.

While the 2020 PCGQR is not an extension of the CQR or the decennial census program, the Census Bureau will conduct 2020 PCGQR case research by examining the census records for the 2020 tabulation block(s) identified in a 2020 PCGQR case using the Master Address File. All boundaries in the published 2020 Census results are current as of January 1, 2020, and all group quarters and population counts are current as of April 1, 2020; therefore, any changes to counts that occurred past those dates are out of scope. These standards will ensure that the information submitted as part of a 2020 PCGQR case is consistent with existing Census Bureau records, which will allow the Census Bureau to use the submitted records in other Census Bureau programs, such as the Population Estimates Program and American Community Survey. No new decennial information products will be created by the 2020 PCGQR. The Census Bureau will not revise any 2020 Census information products, such as the population counts delivered to the President for apportionment or the 2020 Census Public Law 94–171 Redistricting Data Files and Geographic Products. Federal law requires decennial census data collection to end; therefore, the Census Bureau cannot continue collecting information for the decennial census through a 2020 PCGQR.

When a submission is received, the Census Bureau will conduct research and assess the records contained in that submission for quality. Once the Census Bureau completes this research and assessment, the Census Bureau will respond to the governmental unit in writing with an official determination letter. This determination letter will state how the case was resolved and information on the resolution, such as, if the Census Bureau will or will not

accept the records. If the Census Bureau's research and assessment determines that a submission identifies existing group quarters and its associated population counts, then the Census Bureau will accept the records and update populations counts for the governmental unit for use in Census Bureau programs, as appropriate. The Census Bureau will issue certified population count corrections, which governmental units can use for any purpose requiring their official Census counts. The Census Bureau will incorporate all 2020 PCGQR revisions into the intercensal population estimates and American Community Survey estimates starting in 2022 and will post the new counts on our website. The Census Bureau will attempt to respond to each inquiry within 90 days of receipt and complete all case research and resolution by no later than September 30, 2023.

III. Data

OMB Control Number: 0607–XXXX.

Form Number(s): None.

Type of Review: Regular submission, New Information Collection.

Affected Public: Tribal, State or Local governmental units in the United States and Puerto Rico.

Estimated Number of Respondents: 1,500.

Estimated Time per Response: 5.2 hours.

Estimated Total Annual Burden Hours: 7,800.

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 6.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–25283 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–75–2021]

Foreign-Trade Zone (FTZ) 41—Milwaukee, Wisconsin Notification of Proposed Production Activity GXO Logistics (Thermal Transfer Printers, Data Transmission Devices and Accessories Kitting) Kenosha, Wisconsin

GXO Logistics submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Kenosha, Wisconsin under FTZ 41. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on November 8, 2021.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status components and specific finished products described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished products include: Thermal transfer printers; thermal transfer printer parts and components including kits and bundles; mobile computers, tablets, and handheld devices; mobile computer input/output units—barcode/image readers; vehicle mounted computers; optical readers or barcode scanners or imagers; inventory data transmission devices with phone capability (wireless wide area network); inventory data transmission devices (wireless local area network); cradle chargers with ethernet; cradle chargers and cradle chargers (standard); radio frequency identification (RFID) tag reader module, signal transmission—antennae or beacons; RFID antennae; RFID tags/labels; intelligent cabinet for data transmission devices; location system WhereTag tags; location system receivers; location system beacons; location system hubs; aftermarket kit (AMK) replacement plastic labels for printers; AMK replacement paper labels for printers; AMK replacement cutter and peeler components for printers; AMK repair/replacement components for printers; pick to order kits (PTO) paper labels; PTO power supplies/chargers; PTO repair and replacement parts for enterprise virtual machine (EVM) data transmission products; and, PTO repair and replacement parts for EVM mobile handheld devices (duty rate ranges from duty-free to 5.8%).

The proposed foreign-status components include: Printhead cleaning pens; plastic labels; paper labels; plastic screen protectors and name plates; plastic o-rings and sponge pads and spacers for vibration control; instruction sheets; instruction booklets, manuals, guides; steel screws; helical spring lock washers; steel washers (not spring or lock); wire helical springs; thermal transfer printer printed circuit board assemblies; thermal transfer printer housing parts including capacitors, inductors, resistors, electrical connectors, diodes and transistors; inductor/electromagnetic interference (EMI) ferrite chip beads; mobile computer input output unit components—keyboards and keypads; mobile computer input unit—barcode scanners; barcode scanners, scan engines and imagers; parts/components and accessories of mobile computers and handheld devices—printed circuit board assemblies, housing back, front and ends; clutch for printers; gears and transmission shafts for printers; coaxial cables; cables with fitted with connectors for telecommunications; power cables and extension cords fitted with connectors; data cable fitted with connectors; RFID tags/labels; integrated circuits, controllers or processors; integrated circuit memories, programmable; cradle charger bases and cups (standard/ethernet); power supplies; lithium battery cells; lithium-ion batteries; parts and components of

Inventory data transmission devices—housing components, electrical components antennae, printed circuit board assemblies, scanner assemblies, flexible printed circuit assemblies; single loudspeakers; antenna filter kits; radio frequency antennas housing and mounting components; and, cartridge fuses (duty rate ranges from duty-free to 6.2%). The request indicates that helical spring lock washers is subject to an antidumping/countervailing duty (AD/CVD) order if imported from certain countries. The Board's regulations (15 CFR 400.14(e)) require that merchandise subject to AD/CVD orders, or items which would be otherwise subject to suspension of liquidation under AD/CVD procedures if they entered U.S. customs territory, be admitted to the zone in privileged foreign status (19 CFR 146.41). The request also indicates that certain components are subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 29, 2021.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov.*

Dated: November 15, 2021.

Camille R. Evans,

Acting Executive Secretary.

[FR Doc. 2021–25256 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–74–2021]

Foreign-Trade Zone (FTZ) 122—Corpus Christi, Texas, Notification of Proposed Production Activity, Gulf Coast Growth Ventures LLC (Ethylene, Polyethylene, Monoethylene Glycol and Related Co-Products), San Patricio County, Texas

Gulf Coast Growth Ventures LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in San Patricio County, Texas, within Subzone 122W. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on November 12, 2021.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material/component described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.* The proposed material/component would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed foreign-status material/component is metallocene catalyst, duty-free. The request indicates that metallocene catalyst is subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 29, 2021.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Diane Finver at *Diane.Finver@trade.gov.*

Dated: November 15, 2021.

Camille R. Evans,

Acting Executive Secretary.

[FR Doc. 2021–25255 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–086]

Steel Propane Cylinders From the People's Republic of China: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstance Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is initiating a changed circumstances review of the antidumping duty (AD) order on steel propane cylinders from the People's Republic of China (China). Further, Commerce preliminarily determines that Yi Jun Hong Kong Limited (Yi Jun) is the successor-in-interest to Hong Kong GSBF Company Limited (GSBF) and should be assigned the same AD cash deposit rates for purposes of determining AD liability. Interested parties are invited to comment on these preliminary results.

DATES: Effective November 19, 2021.

FOR FURTHER INFORMATION CONTACT: Katherine Sliney, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2437.

SUPPLEMENTARY INFORMATION:

Background

On August 15, 2019, Commerce published in the **Federal Register** the AD order on steel propane cylinders from China.[1] On September 30, 2021, Commerce received a request on behalf of Yi Jun for an expedited changed circumstances review, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.216(b), to establish Yi Jun as the successor-in-interest to GSBF, a Hong Kong trading company and exporter of steel propane cylinders from China produced by GSBF's affiliated producer, GSBF Tank, and thus, entitled to the AD cash deposit rate of GSBF.[2] We did not receive comments from other interested parties concerning this request.

Scope of the Order

The merchandise covered by the *Order* is steel cylinders for compressed or liquefied propane or other gases (steel propane cylinders) meeting the requirements of, or produced to meet the requirements of, U.S. Department of Transportation (USDOT) Specifications 4B, 4BA, or 4BW, or Transport Canada Specification 4BM, 4BAM, or 4BWM, or United Nations pressure receptacle standard ISO 4706 and otherwise meeting the description provided below. The scope includes steel propane cylinders regardless of whether they have been certified to these specifications before importation. Steel propane cylinders range from 2.5 pound nominal gas capacity (approximate 6 pound water capacity and approximate

[1] *See Steel Propane Cylinders from the People's Republic of China and Thailand: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Orders,* 84 FR 41703 (August 15, 2019) (*Order*).

[2] *See* Yi Jun's Letter, ''Steel Propane Cylinders from the People's Republic of China—Yi Jun/GSBF Changed Circumstances Review,'' dated September 30, 2021 (CCR Request).

4–6 pound tare weight) to 42 pound nominal gas capacity (approximate 100 pound water capacity and approximate 28–32 pound tare weight). Steel propane cylinders have two or fewer ports and may be imported assembled or unassembled (*i.e.,* welded or brazed before or after importation), with or without all components (including collars, valves, gauges, tanks, foot rings, and overfill prevention devices), and coated or uncoated. Also included within the scope are drawn cylinder halves, unfinished propane cylinders, collars, and foot rings for steel propane cylinders.

An ''unfinished'' or ''unassembled'' propane cylinder includes drawn cylinder halves that have not been welded into a cylinder, cylinders that have not had flanges welded into the port hole(s), cylinders that are otherwise complete but have not had collars or foot rings welded to them, otherwise complete cylinders without a valve assembly attached, and cylinders that are otherwise complete except for testing, certification, and/or marking.

The *Order* also covers steel propane cylinders that meet, are produced to meet, or are certified as meeting, other U.S. or Canadian government, international, or industry standards (including, for example, American Society of Mechanical Engineers (ASME), or American National Standard Institute (ANSI)), if they also meet, are produced to meet, or are certified as meeting USDOT Specification 4B, 4BA, or 4BW, or Transport Canada Specification 4BM, 4BAM, or 4BWM, or a United Nations pressure receptacle standard ISO 4706.

Subject merchandise also includes steel propane cylinders that have been further processed in a third country, including but not limited to, attachment of collars, foot rings, or handles by welding or brazing, heat treatment, painting, testing, certification, or any other processing that would not otherwise remove the merchandise from the scope of the *Order* if performed in the country of manufacture of the in-scope steel propane cylinders.

Specifically excluded are seamless steel propane cylinders and propane cylinders made from stainless steel (*i.e.,* steel containing at least 10.5 percent chromium by weight and less than 1.2 percent carbon by weight), aluminum, or composite fiber material. Composite fiber material is material consisting of the mechanical combination of two components: Fiber (typically glass, carbon, or aramid (synthetic polymer)) and a matrix material (typically polymer resin, ceramic, or metallic).

The merchandise subject to the *Order* is properly classified under statistical reporting numbers 7311.00.0060 and 7311.00.0090 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS statistical reporting numbers are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Initiation and Preliminary Results

Pursuant to section 751(b)(1) of the Act, Commerce will conduct a changed circumstances review upon receipt of information concerning, or a request from, an interested party for a review of an AD order which shows changed circumstances sufficient to warrant a review of the order. In the past, Commerce has used changed circumstances reviews to address the applicability of cash deposit rates after there have been changes in the name or structure of a respondent, such as a merger or spinoff ('successor-in-interest' or 'successorship' determinations).[3] Based on a review of the request from Yi Jun, and in accordance with section 751(b) of the Act and 19 CFR 351.216(d) and (e), we find that the information submitted in the CCR Request supporting Yi Jun's claim that it should be treated as the successor-in-interest to GSBF is sufficient to warrant such a review to determine whether Yi Jun is entitled to GSBF's AD cash deposit rate.

Section 351.221(c)(3)(ii) of Commerce's regulations permits Commerce to combine the notice of initiation of a changed circumstances review and the notice of preliminary results if Commerce concludes that expedited action is warranted.[4] In this instance, because the record contains information necessary to make a preliminary finding, we find that expedited action is warranted and have combined the notice of initiation and the notice of preliminary results.[5]

Accordingly, pursuant to section 751(b) of the Act, we have conducted a successor-in-interest analysis in response to Yi Jun's request. In making a successor-in-interest determination, Commerce examines several factors, including, but not limited to, changes in the following: (1) Management; (2) production facilities; (3) supplier relationships; and (4) customer base.[6] While no single factor or combination of factors will necessarily provide a dispositive indication of a successor-in-interest relationship, generally, Commerce will consider the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor.[7] Thus, if the evidence demonstrates that, with respect to the production and sales of the subject merchandise, the new company operates as essentially the same business entity as the former company, Commerce will accord the new company the same antidumping treatment as its predecessor.[8]

We preliminarily determine that Yi Jun supplied sufficient evidence to determine that Yi Jun is the successor-in-interest to GSBF. Specifically, Yi Jun provided documentation demonstrating approval of GSBF's name change by GSBF's shareholders[9] (which remained unchanged from the underlying investigation, as well as the shareholders of its affiliated supplier, GSBF Tank), noting that GSBF's shareholders decided to change the company name and start building their own brand. GSBF's shareholders approved of the name change in January 2020, but Yi Jun continued to do business as GSBF until its corporate bank account was changed to reflect the new name in September 2021.[10] Yi Jun asserts that the change in company name was cosmetic only, was made with the sole purpose of developing a distinct brand, and had no impact on the internal or external operation and

[3] *See, e.g., Diamond Sawblades and Parts Thereof from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 82 FR 51605, 51606 (November 7, 2017) (*Diamond Sawblades Preliminary*), unchanged in *Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review,* 82 FR 60177 (December 19, 2017) (*Diamond Sawblades Final*).

[4] *See* 19 CFR 351.221(c)(3)(ii); *see also Certain Pasta from Italy: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 80 FR 33480, 33480–41 (June 12, 2015) (*Pasta from Italy Preliminary Results*), unchanged in *Certain Pasta from Italy: Final Results of Changed Circumstances Review,* 80 FR 48807 (August 14, 2015) (*Pasta from Italy Final Results.*

[5] *See, e.g., Pasta from Italy Preliminary Results,* 80 FR at 33480–41, unchanged in *Pasta from Italy Final Results,* 80 FR at 48807.

[6] *See, e.g., Diamond Sawblades Final;* and *Certain Frozen Warmwater Shrimp from India: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 83 FR 37784 (August 2, 2018), unchanged in *Certain Frozen Warmwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 83 FR 49909 (October 3, 2018).

[7] *Id.*

[8] *See also, e.g., Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 64953 (October 24, 2012), unchanged in *Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 73619 (December 11, 2012).

[9] *See* CCR Request at Exhibit 1.

[10] *See* CCR Request at 4–5.

structure of the company.[11] As support, Yi Jun provides the name change certificate issued by the Hong Kong Registrar of Companies [12] and GSBF's business license before and after the change to Yi Jun which reflect a ''replacement'' business registration, which substantiates that there was no change in address or the material details of the registration.[13] Yi Jun also provided updated articles of association that reflect the name change, but are otherwise unchanged from the prior articles.[14] The lack of changes to the articles supports the claim that Yi Jun's operations with respect to the sales of subject merchandise have not materially changed as a result of its name change.

In addition, the record includes a list of company officials before and after the name change, supporting Yi Jun's assertion that the managing staff remained the same.[15] Further, Yi Jun notes that the subject merchandise sold to the U.S. by both GSBF and Yi Jun were all sourced from GSBF Tank, and that neither GSBF nor Yi Jun manufactures steel propane cylinders (*i.e.,* the company has been and will continue to only serve as an exporter).[16] Moreover, Yi Jun provided lists of both its suppliers and U.S. customers, before and after the name change to support its assertion that there have been no material changes to GSBF's suppliers [17] or its customer base following the name change. Yi Jun notes it has only added one U.S. customer through the normal course of business.[18]

Therefore, based on the aforementioned evidence on the record, we preliminarily determine that Yi Jun is the successor-in-interest to GSBF, as the change in the business' name was not accompanied by significant changes to its management and operations, supplier relationships, or customer base.[19] Thus, we preliminarily determine that Yi Jun operates as essentially the same business entity as GSBF, that Yi Jun is the successor-in-interest to GSBF, and that Yi Jun should receive the same AD cash deposit rate with respect to subject merchandise as its predecessor, GSBF.

Should our final results remain unchanged from these preliminary results, we will instruct U.S. Customs and Border Protection to assign entries of subject merchandise exported by Yi Jun the AD cash deposit rate applicable to GSBF. Commerce will issue its final results of the reviews in accordance with the time limits set forth in 19 CFR 351.216(e).

Public Comment

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 14 days of publication of this notice.[20] In accordance with 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 14 days after the date of publication of this notice.[21] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the case briefs, in accordance with 19 CFR 351.309(d). Parties who submit case or rebuttal briefs are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[22] All comments are to be filed electronically using ACCESS, available to registered users at *https://access.trade.gov,* and must also be served on interested parties. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the day it is due.[23] Note that Commerce has temporarily modified certain requirements for serving documents containing business proprietary information, until further notice.[24]

Consistent with 19 CFR 351.216(e), we will issue the final results of this changed circumstances review no later than 270 days after the date on which this review was initiated, or within 45 days if all parties agree to our preliminary finding.

Notification to Interested Parties

This notice is published in accordance with sections 751(b)(1) and 777(i) of the Act and 19 CFR 351.216(b), 351.221(b) and 351.221(c)(3).

Dated: November 15, 2021.

Ryan Majerus,

Deputy Assistant Secretaryfor Policy and Negotiations,Performing the Non-Exclusive Functions and Duties of theAssistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–25280 Filed 11–18–21; 8:45 am]

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[11] *Id.*

[12] *Id.* at Exhibit 2.

[13] *Id.* at Exhibit 3 and 4.

[14] *Id.* at Exhibit 5.

[15] *Id.* at Exhibit 6.

[16] *Id.* at 3.

[17] Yi Jun clarified that sales of subject merchandise between GSBF Tank and GSBF which were subsequently exported to the United States by GSBF during the underlying investigation were made through an unaffiliated Chinese trading company, and that though this trading company was listed as a supplier of GSBF, this was merely a paper transaction. However, GSBF Tank has since discontinued this relationship, and GSBF Tank now sells directly to GSBF/Yi Jun and no longer utilizes the unaffiliated trading company. *Id.* at 6–7.

[18] *Id.* at Exhibit 7 and 8.

[19] Yi Jun did not provide evidence concerning changes to production facilities, as neither the prior company GSBF, nor Yi Jun produces steel propane cylinders. As noted above, the company acts only as an exporter of the subject merchandise.

[20] Commerce is exercising its discretion under 19 CFR 351.310(c) to alter the time limit for requesting a hearing.

[21] Commerce is exercising its discretion under 19 CFR 351.309(c)(1)(ii) to alter the time limit for the filing of case briefs.

[22] *See* 19 CFR 351.309(c)(2).

[23] *See* 19 CFR 351.303(b).

[24] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–874]

Certain Hot-Rolled Steel Flat Products From Japan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Nippon Steel Corporation (NSC), producer and exporter of hot-rolled steel flat products (hot-rolled steel) from Japan, sold subject merchandise in the United States at prices below normal value during the period of review (POR) October 1, 2019, through September 30, 2020. In addition, Commerce preliminarily determines that Honda Trading Canada, Inc. (Honda) and Mitsui & CO., Ltd. (Mitsui) had no shipments during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jack Zhao, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1396.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on hot-rolled steel from Japan in accordance with section 751(a)(1)(B) of Tariff Act of 1930, as amended (the Act).[1] Commerce initiated this administrative review on

[1] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Australia, the Republic of Korea, and the Republic of Turkey and Antidumping Duty Orders,* 81 FR 67962 (October 3, 2016) (*Order*).

December 8, 2020 covering twenty-nine producers and/or exporters.[2] We selected NSC as mandatory respondent.[3] On June 28, 2021, we extended the deadline for the preliminary results of this review by an additional 118 days, in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), resulting in a deadline of October 29, 2021, for these preliminary results.[4] For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5]

Scope of the Order

The merchandise covered by the *Order* is hot-rolled steel from Japan. For a complete description of the scope of the *Order*, *see* the Preliminary Decision Memorandum.[6]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a) of the Act. Constructed export price and export price were calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Determination of No Shipments

Among the companies under review, Honda and Mitsui each properly filed a statement reporting that it had made no shipments of subject merchandise to the United States during the POR.[7] Commerce issued an instruction to the U.S. Customs and Border Protection (CBP) asking for any entry activity regarding Honda and Mitsui.[8] CBP subsequently confirmed that these two companies had no shipments.[9] Based on the certifications submitted by Honda and Mitsui, and our analysis of CBP information currently on the record, we preliminarily determine that Honda and Mitsui had no shipments during the POR. Consistent with its practice, Commerce finds that it is not appropriate to preliminarily rescind the review with respect to Honda and Mitsui, but rather to complete the review and issue appropriate instructions to CBP based on the final results of this review.

Rate for Non-Examined Companies

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we have preliminarily calculated a weighted-average dumping margin for NSC that is not zero, *de minimis,* or determined entirely on the basis of facts available. Accordingly, Commerce preliminarily has assigned to companies not individually examined a margin of 26.81 percent, which is NSC's calculated weighted-average dumping margin.

Preliminary Results

We preliminarily determine the following weighted-average dumping margins for the period October 1, 2019, through September 30, 2020:

Exporter/producer	Weighted-average dumping margin (percent)
Nippon Steel Corporation/Nippon Steel Nisshin Co., Ltd./Nippon Steel Trading Corporation[10]	26.81
Non-Examined Companies	
Hanwa Co., Ltd	26.81
Higuchi Manufacturing America, LLC	26.81

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 78990 (December 8, 2020).

[3] *See* Memorandum ''Respondent Selection for the 2019–2020 Antidumping Duty Administrative Review of Certain Hot-Rolled Steel Flat Products from Japan,'' dated June 29, 2021.

[4] *See* Memorandum, ''Certain Hot-Rolled Steel Flat Products from Japan: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review—2019–2020,'' dated June 28, 2021.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: Certain Hot-Rolled Steel Flat Products from Japan; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *Id.*

[7] *See* Honda's Letter, ''Administrative Review of Certain Hot-Rolled Steel Flat Products from Japan: Honda Trading Canada, Inc.'s No Shipment Certification,'' dated December 21, 2020; *see also* Mitsui's Letter, ''Antidumping Administrative Review of Certain Hot-Rolled Steel Flat Products from Japan: Mitsui No Shipment Notification,'' dated December 21, 2020.

[8] *See* No Shipment Inquiry to CBP, dated October 5, 2021.

[9] *See* Memoranda, ''Certain Hot-Rolled Steel Flat Products from Japan (A–588–874); No Shipment Inquiry for Honda Trading Canada, Inc. during the period 10/01/2019 through 09/30/2020,'' and ''Certain Hot-Rolled Steel Flat Products from Japan (A–588–874); No Shipment Inquiries for Mitsui & Co., Ltd. during the Period 10/01/2019 through 09/30/2020,'' both dated October 15, 2021.

[10] Commerce found in a changed circumstances review that NSC, Nippon Steel Nisshin Co., Ltd., and Nippon Steel Trading Corporation are affiliated companies that should be treated as a single entity and as the successor-in-interest to Nippon Steel & Sumitomo Metal Corporation, Nisshin Steel Co., Ltd., and Nippon Steel & Sumikin Bussan Corporation, respectively. *See Certain Hot-Rolled Steel Flat Products from Japan: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 46713 (September 5, 2019). Because there is no information on the record of this administrative review that would lead us to revisit this determination, we are continuing to treat these companies as part of a single entity for the purposes of this administrative review.

[11] We collapsed JFE Shoji Trade Corporation with JFE Steel Corporation in the underlying investigation. *See Certain Hot-Rolled Steel Flat Products from Japan: Preliminary Determination of Sales at Less than Fair Value and Postponement of Final Determination,* 81 FR 15222 (March 22, 2016), and accompanying Preliminary Decision Memorandum at 8–9.

Exporter/producer	Weighted-average dumping margin (percent)
Higuchi Seisakusho Co., Ltd	26.81
Hitachi Metals, Ltd	26.81
JFE Steel Corporation/JFE Shoji Trade Corporation [11]	26.81
JFE Shoji Trade America	26.81
Kanematsu Corporation	26.81
Kobe Steel, Ltd	26.81
Metal One Corporation	26.81
Miyama Industry Co., Ltd	26.81
Nakagawa Special Steel Inc	26.81
Nippon Steel & Sumikin Logistics Co., Ltd	26.81
Okaya & Co. Ltd	26.81
Panasonic Corporation	26.81
Saint-Gobain K.K	26.81
Shinsho Corporation	26.81
Sumitomo Corporation	26.81
Suzukaku Co., Ltd	26.81
Suzukaku Corporation	26.81
Tokyo Steel Manufacturing Co., Ltd	26.81
Toyota Tsusho Corporation Nagoya	26.81

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries. For any individually examined respondent whose weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review and the respondent reported reliable entered values, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the POR to each importer and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1). If the respondent has not reported reliable entered values, we will calculate a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total sales quantity associated with those transactions. Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). If a respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [12]

For entries of subject merchandise during the POR produced by NSC for which the producer did not know its merchandise was destined for the United States, or for any respondent for which we have a final determination of no shipments, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company (or companies) involved in the transaction.[13]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent, and therefore *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the underlying investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 5.58 percent, the all-others rate established in the less-than-fair-value investigation.[14] These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results of review to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, the content of which is limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[15] Parties who submit case briefs

[12] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

[13] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[14] *See Order.*

[15] *See* 19 CFR 351.309(d).

or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[16] Case and rebuttal briefs should be filed using ACCESS [17] and must be served on interested parties.[18] Executive summaries should be limited to five pages total, including footnotes.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed via ACCESS. An electronically filed request must be received successfully in its entirety by 5:00 p.m. Eastern Time within 30 days of the date of publication of this notice.[19] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[20] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any case or rebuttal briefs, no later than 120 days after the date of publication of this notice, unless extended.[21]

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

[16] *See* 19 CFR 351.309(c)(2) and (d)(2).

[17] *See generally* 19 CFR 351.303.

[18] *See* 19 CFR 351.303(f).

[19] *See* 19 CFR 351.310(c).

[20] *See* 19 CFR 351.310(d).

[21] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h).

Dated: October 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Preliminary Determination of No Shipments
V. Rates for Non-Examined Companies
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

[FR Doc. 2021–25257 Filed 11–18–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Intent To Conduct Scoping and To Prepare an Environmental Impact Statement for the Proposed Designation of a National Marine Sanctuary Within Papahānaumokuākea Marine National Monument

AGENCY: Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of Intent to prepare a draft environmental impact statement and hold public scoping meetings; request for comments.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), in cooperation with the U.S. Fish and Wildlife Service (USFWS), the State of Hawai'i, and the Office of Hawaiian Affairs (OHA), is initiating the process to consider designating marine portions of Papahānaumokuākea Marine National Monument as a national marine sanctuary. Per the requirements of the National Environmental Policy Act (NEPA) and National Marine Sanctuaries Act (NMSA), NOAA will prepare a draft environmental impact statement (DEIS) for the sanctuary designation process to evaluate potential environmental effects of this action. NOAA will also coordinate its responsibility under the National Historic Preservation Act with the NEPA process. NOAA is initiating the public scoping process to invite comments on the scope and significance of issues to be addressed in the environmental impact statement that are related to designating this area as a national marine sanctuary. The results of this scoping process will assist NOAA in moving forward with the designation process, including preparation and release of draft designation documents, and formulating alternatives for the DEIS.

DATES: Comments must be received by NOAA on or before January 31, 2022. NOAA will host virtual public scoping meetings and will allow for comments in both English and Hawaiian ('Ōlelo Hawai'i) at the following dates and times:

- Wednesday, December 8, 2021, 6 p.m. HST
- Saturday, December 11, 2021, 12 p.m. HST
- Tuesday, December 14, 2021, 6 p.m. HST
- Thursday, December 16, 2021, 3 p.m. HST

ADDRESSES: You may submit comments on this notice by any of the following methods:

Federal e-Rulemaking Portal: Go to *https://www.regulations.gov* and enter ''NOAA–NOS–2021–0114'' in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Mail: Send any hard copy public comments by mail to: PMNM-Sanctuary Designation, NOAA/ONMS, 1845 Wasp Blvd., Bldg 176, Honolulu, HI 96818.

Public Scoping Meetings: Provide oral comments during virtual public scoping meetings, as described under **DATES**. Webinar registration details and additional information about how to participate in these public scoping meetings is available at *https://sanctuaries.noaa.gov/papahanaumokuakea/*.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (for example: name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the commenter will be publicly accessible. NOAA will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Athline Clark, (808) 725–5800, *Athline.Clark@noaa.gov,* NOAA Superintendent Papahānaumokuākea Marine National Monument and

UNESCO World Heritage Site, address: 1845 Wasp Blvd., Bldg 176, Honolulu, Hawai'i 96818

SUPPLEMENTARY INFORMATION:

I. Papahānaumokuākea Marine National Monument

Papahānaumokuākea is considered a sacred area, from which Native Hawaiians believe all life springs, and to which spirits return to after death. The longest recorded traditional Hawaiian chant, the Kumulipo (source of deep darkness), is the history of how all life forms came and evolved from Papahānaumokuākea, beginning with the coral polyp—the building block for all life. This genealogy of Papahānaumokuākea tells the story of Native Hawaiians' ancestral connection with the gods who created those coral polyps, the Northwestern Hawaiian Islands or Kūpuna (respected elders) Islands, and everything else in the Hawaiian archipelago, including Native Hawaiians. Throughout the expanse of the Monument, there are many wahi pana (places of great cultural significance and practice) where Native Hawaiian cultural practitioners of today reconnect with their ancestors and gods.

Papahānaumokuākea Marine National Monument is one of the largest protected areas in the world. The original Papahānaumokuākea Marine National Monument and the Monument Expansion Area (collectively ''Papahānaumokuākea'' or ''Monument''), located around the Northwestern Hawaiian Islands, were established under the Antiquities Act through, respectively, Presidential Proclamation 8031 of June 15, 2006, as amended by Proclamation 8112 of February 28, 2007; and Proclamation 9478 of August 26, 2016. In 2006, the President established Papahānaumokuākea Marine National Monument to protect and preserve the marine area of the Northwestern Hawaiian Islands and certain lands as necessary for the care and management of the historic and scientific objects therein. The Federal land and interests in land reserved included approximately 139,793 square miles of emergent and submerged lands and waters of the Northwestern Hawaiian Islands. NOAA and USFWS promulgated implementing regulations for the original Papahānaumokuākea Marine National Monument on August 29, 2006 (71 FR 51134, 50 CFR part 404). These regulations codify the scope and purpose, boundary, definitions, prohibitions and regulated activities.

In 2016, Proclamation 9478 expanded the Monument into an adjacent area—the Monument Expansion Area—which includes the waters and submerged lands to the extent of the seaward limit of the United States Exclusive Economic Zone (U.S. EEZ) west of 163° West Longitude and covers an additional 442,781 square miles. Proclamation 9478 also directed the Secretary of Commerce to consider initiating the process to designate the Monument Expansion Area and the original Papahānaumokuākea Marine National Monument seaward of the Hawaiian Islands National Wildlife Refuge and Midway Atoll National Wildlife Refuge and Battle of Midway National Memorial as a national marine sanctuary to supplement and complement existing authorities. The area has a long history of being considered for national marine sanctuary designation, beginning with Executive Order 13178 in 2000, followed by Proclamation 9478 in 2016. Recently, the Senate Committee on Appropriations directed NOAA to initiate the process to designate Papahānaumokuākea Marine National Monument as a National Marine Sanctuary.

The Monument is administered jointly by four Co-Trustees—the Department of Commerce, the Department of the Interior, the State of Hawai'i, and the Office of Hawaiian Affairs. The Monument Co-Trustees currently operate the Monument guided by a 2008 Monument Management Plan for Papahānaumokuākea and the Presidential Proclamations designating the Monument. The Monument Co-Trustees will update the Monument Management Plan at a later date and will provide opportunities for public input for a new plan. Any draft sanctuary management plan would augment the overarching Monument Management Plan.

II. Background on Sanctuary Designation Process

The NMSA authorizes the Secretary of Commerce to designate and protect as national marine sanctuaries areas of the marine environment that are of special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archeological, educational, or esthetic qualities. Day-to-day management of national marine sanctuaries has been delegated by the Secretary of Commerce to NOAA's Office of National Marine Sanctuaries. The primary objective of the NMSA is to protect the resources of the National Marine Sanctuary System, including biological and cultural resources, such as coral reefs, marine animals, archaeological sites, historic structures and historic shipwrecks.

III. Purpose and Need for National Marine Sanctuary Designation

The purpose of the designation is to fulfill the purposes and policies outlined in Section 301(b) of the NMSA, 16 U.S.C. 1431(b), including to identify and designate as national marine sanctuaries areas of the marine environment which are of special national significance, provide authority for comprehensive and coordinated conservation and management of these marine areas, and to protect the resources of these areas. Additionally, the purpose of the designation is to implement the provisions of Executive Order 13178 and Presidential Proclamation 9478 that direct NOAA to consider initiating the sanctuary designation process.

The need for designation is to:

- Develop objectives and actions that ensure lasting protections consistent with the existing Monument proclamations and regulations;
- safeguard natural and cultural values of the marine environment of the Monument;
- strengthen the existing interagency management regulations (50 CFR 404);
- authorize NOAA to assess civil penalties for violations of sanctuary regulations or permits and to enforce provisions of the NMSA;
- prohibit destruction or loss of sanctuary resources and provide natural resource damage assessment authorities for loss of or injury to any sanctuary resource;
- require interagency consultation for any Federal agency action that is likely to destroy, cause the loss of, or injure any sanctuary resource;
- enhance the joint permitting system for activities in the Monument Expansion Area;
- augment existing authorities under the Antiquities Act; Presidential Proclamations 8031, 8112 and 9478; Executive Order 13178; and 50 CFR 404 to provide additional regulatory and non-regulatory tools for management and protection of Monument resources.

IV. Preliminary Description of Proposed Action and Alternatives

NOAA's proposed action is to consider designating the marine portions of the Monument as a national marine sanctuary, following the designation process in section 304 of the NMSA (16 U.S.C. 1434). As part of the sanctuary designation process, NOAA will develop designation materials including a draft sanctuary management plan, proposed sanctuary regulations, and proposed terms of designation. Each national marine sanctuary has

management programs developed with public input and crafted to meet the specific issues and resources found in that sanctuary.

The NEPA process will include preparation of a DEIS to consider alternatives and to describe potential effects of the proposed sanctuary designation on the human environment. The DEIS will evaluate a reasonable range of action alternatives that could include different options for management goals or actions, sanctuary regulations, and potential boundaries. The DEIS will also consider a No Action Alternative, wherein NOAA would not designate the proposed sanctuary. Any proposed sanctuary regulations would be separate from, but supplementary and complementary to, existing Monument regulations and management provisions from the establishing executive order and proclamations.

The results of this public scoping process will assist NOAA in moving forward with the designation process, including preparation and release of draft documents, and formulating alternatives for the DEIS. Reasonable alternatives that are identified during the scoping period will be evaluated in the DEIS.

V. Summary of Expected Impacts of Sanctuary Designation

The DEIS will identify and describe the potential effects of the proposed action, and reasonable alternatives, on the human environment. Potential impacts may include, but are not limited to, impacts on the Monument's:

- Marine resources, including habitats, plants, birds, sea turtles, marine mammals, and special status species;
- cultural and historic resources, including Traditional Cultural Properties and archaeological sites; and
- human uses and socioeconomics, including research, recreation, education, cultural practices, and fishing.

Based on a preliminary evaluation of the resources listed above, NOAA expects potential impacts of continued or enhanced long-term protection of the Monument's natural, cultural and historic resources; improved planning and coordination of research, monitoring, and management actions; reducing disturbance of special status species; reducing threats and stressors to Monument resources; and minimal disturbance during research or restoration actions.

VI. Process for Sanctuary Designation and Environmental Review

NOAA will undertake a process for the designation of a national marine sanctuary, as outlined below.

1. Public Scoping Process—Information collection and characterization, including the consideration of public comments received during scoping, coordination under section 304(a)(5) with Western Pacific Regional Fishery Management Council on any necessary draft fishing regulations for the proposed sanctuary;

2. Preparation of Draft Documents—Preparation and release of draft sanctuary designation documents, including: a DEIS, prepared pursuant to NEPA, a draft sanctuary management plan, and a notice of proposed rulemaking to define proposed sanctuary boundaries and regulations. Draft documents would be used to support consultations with Federal, State, or local agencies, the Office of Hawaiian Affairs, Native Hawaiian organizations, and other interested parties, as appropriate;

3. Public Comment—Through public meetings and in writing, allow for public review and comment on the DEIS, draft sanctuary management plan, and notice of proposed rulemaking;

4. Preparation of Final Documents—Preparation and release of a final environmental impact statement (FEIS), final sanctuary management plan, and a final rule and sanctuary regulations, including a response to public comments.

5. The sanctuary designation and regulations would take effect after the end of a review period of forty-five days of a continuous session of Congress. During this same period, should the designation include State waters, the Governor of the State has the opportunity to concurrently review the terms of designation including boundaries within State waters.

NEPA Lead and Cooperating Agency Roles

NOAA will serve as the lead Federal agency for the NEPA process for the proposed action. The USFWS, State of Hawai'i and OHA shall serve as cooperating agencies in this process, through agreement with the lead agency. NOAA may invite other Federal, Tribal, or State and local government agencies to become cooperating agencies in the preparation of this EIS. NEPA regulations specify that a cooperating agency means any Federal agency (and a State, Tribal, or local agency with agreement of the lead agency) that has jurisdiction by law or special expertise with respect to any environmental impact involved in a proposal (or a reasonable alternative) (40 CFR 1508.1(e)).

Schedule for the Decision-Making Process

NOAA expects to make the DEIS and other draft sanctuary designation documents available to the public in approximately January 2023. NOAA expects to make the FEIS for sanctuary designation available to the public in Fall 2023. A Record of Decision and the final sanctuary management plan and final rule will be completed no sooner than 30 days after the FEIS is made available to the public, in accordance with 40 CFR 1506.11.

VII. Anticipated Permits, Authorizations, and Consultations

Federal, State, and local permits, authorizations or consultations may be required for the proposed action, including consultation under the Endangered Species Act, 16 U.S.C. 1531 *et seq.,* Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.,* National Historic Preservation Act, 54 U.S.C. 300101 *et seq.,* consistency review under the Coastal Zone Management Act, 16 U.S.C. 1451 *et seq.,* and possibly reviews under other laws and regulations determined to be applicable to the proposed action. To the fullest extent possible, NOAA will prepare the DEIS concurrently with and integrated with analyses required by other Federal environmental review requirements, and the DEIS will list all Federal permits, licenses, and other authorizations that must be obtained in implementing the proposed action, in accordance with 40 CFR 1502.24.

Consultation Under Section 106 of the National Historic Preservation Act

This notice confirms that NOAA will coordinate its responsibilities under section 106 of the National Historic Preservation Act (NHPA) during the sanctuary designation process and is soliciting public and stakeholder input to meet section 106 compliance requirements. The section 106 consultation process specifically applies to any Federal agency undertaking that may affect historic properties. Pursuant to 36 CFR 800.16(l)(1), historic properties include: ''any prehistoric or historic district, site, building, structure or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. The term includes artifacts, records, and remains that are related to and located within

such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria.''

The NHPA requires that Federal decision makers consider historic properties during project planning. Section 106 of the NHPA requires agencies to take into account the effects of such undertakings they carry out, assist, fund, or permit on historic properties. NEPA mandates that Federal agencies assess a proposed Federal action's environmental impacts, including impacts on historic and cultural resources. As part of section 106 consultation, it is the agency's responsibility to provide consulting parties a reasonable opportunity to identify their concerns about historic properties, advise on the identification and evaluation of historic properties, including those of traditional religious and cultural importance, articulate their views on the undertaking's effects on such properties, and participate in the resolution of any adverse effects (if identified).

The following parties may have consultative roles in the section 106 process: State historic preservation officer, Native Hawaiian organizations, the Advisory Council on Historic Preservation, representatives of local government, and additional consulting parties. Certain individuals and organizations may also participate as consulting parties due to the nature of their legal or economic relation to the undertaking or affected properties, or their concern with the action's effects on historic properties. As part of this public scoping process, NOAA seeks public input on potential effects on historic properties in the area of potential effects (the entire Monument area). NOAA will invite consulting party participation via letters of invitation.

VIII. Public Scoping Process

With this notice, NOAA is initiating a public scoping process to gather input from individuals, organizations, Native Hawaiian Organizations, and Federal, State, and local agencies on the proposed sanctuary designation. NOAA intends to use this process to determine the scope and significant issues to be analyzed in depth in the DEIS, with consideration of the scoping factors and responsibilities provided in 40 CFR 1501.9. NOAA specifically request comments on the following topics, including the identification of potential alternatives, information, and analyses relevant to the proposed action:

- The proposed designation of marine waters of the Monument as a national marine sanctuary, including the spatial extent of the proposed sanctuary and boundary alternatives NOAA should consider;
- the location, nature, and value of resources that would be protected by a sanctuary;
- management measures for the sanctuary and any additional regulations that should be added under the NMSA authority to protect Monument resources;
- the potential socioeconomic, cultural, and biological impacts of sanctuary designation;
- information regarding historic properties in the entire Monument area and the potential effects to those historic properties to support National Historic Preservation Act compliance under section 106; and
- other information relevant to the designation and management of a national marine sanctuary.

Comments may be submitted to NOAA by *January 31, 2022* using the methods described above in **ADDRESSES**. NOAA will host public scoping meetings during the public comment period, as described above under **DATES**.

Authority: 16 U.S.C. 1431 *et seq.;* 42 U.S.C. 4321 *et seq.;* 40 CFR 1500–1508 (NEPA Implementing Regulations); Companion Manual for NOAA Administrative Order 216–6A;

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2021–25207 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB594]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Executive Committee, including joint sessions with the Atlantic States Marine Fisheries Commission's Bluefish and Summer Flounder, Scup, and Black Sea Bass Boards.

DATES: The meetings will be held Monday, December 13, 2021 through Thursday, December 16, 2021. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: This meeting will be conducted in a hybrid format, with options for both in person and webinar participation. The meeting will be held at the Westin Annapolis, 100 Westgate Circle, Annapolis, MD 21401, telephone: (410) 972–4300. Webinar registration details will be available on the Council's website at *https://www.mafmc.org/briefing/december-2021.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's website, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, although agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Monday, December 13, 2021

Executive Committee (Closed Session)

Ricks E Savage Award

Wind Updates

Consider revisions to the Council's policy on offshore wind energy develop

Updates from the Bureau of Ocean Energy Management

Update on Kitty Howk Wind Project (Rick Robbins)

Update from US Wind

Omega Net Mesh Measurement Gauge

(Spencer Talmage, Greater Atlantic Regional Fisheries OfficeLCDR Matthew Kahley, USCG)

Presentation on the current status of the rulemaking process regarding the use of this device

Council Meeting With the Atlantic States Marine Fisheries Commission's Bluefish Board

2022–23 Bluefish Recreational Measures

Review Monitoring Committee recommendations

Adopt recommendations for 2022–23 federal waters recreational management measures

Tuesday, December 14, 2021

Council Meeting With the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Board

Ecosystem Approach to Fisheries Management (EAFM) Recreational Summer Flounder Management Strategy Evaluation (MSE)
Review outcomes and recommendations from November 8–9 core stakeholder group workshop
Update on project timeline and tasks
2022 Summer Flounder Recreational Measures
Review Advisory Panel and Monitoring Committee recommendations
Recommend conservation equivalency or coastwide management and associated measures for 2022
2022 Scup Recreational Measures
Review Advisory Panel and Monitoring Committee recommendations
Recommend 2022 recreational management measures for federal waters
2022 Black Sea Bass Recreational Measures
Review Advisory Panel and Monitoring Committee recommendations
Recommend conservation equivalency or coastwide management and associated measures for 2022
Final Action on Summer Flounder, Scup, and Black Sea Bass Commercial/Recreational Allocation Amendment
Review alternatives
Review staff recommendations
Consider final action

Wednesday, December 15, 2021

Biennial Review of 2020–24 Research Priorities Document
Review proposed research priority changes and Research Steering Committee recommendations
Approved updated research priorities document
Surfclam and Ocean Quahog Species Separation Requirements
Review white paper and identify next steps
Climate Change Scenario Planning
Summary of scoping input and update on next steps
Ocean City, Maryland Video Project
Update on data collection and next
Habitat Activities
Update from Greater Atlantic Regional Fisheries Office Habitat Conservation Division on activities of interest (aquaculture, other projects) in the region
Sea Turtle Bycatch in Trawl Fisheries
(Carrie Upite, Greater Atlantic Regional Fisheries Office, Sea Turtle Recovery Coordinator)
GARFO presentation on outreach process for development of bycatch reduction measures to reduce takes of sea turtles in trawl fisheries
Acknowledgements and Awards

Thursday, December 16, 2021

2022 Implementation Plan
Review and approve 2022 Implementation Plan
Business Session
Committee Reports (SSC, Research Steering Committee, Executive Committee); Executive Director's Report; Organization Reports; and Liaison Reports
Other Business and General Public Comment

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c).

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: November 16, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–25279 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Recreational Angler Survey of Sea Turtle Interactions

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 19, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Recreational Angler Survey of Sea Turtle Interactions.

OMB Control Number: 0648–0774.

Form Number(s): None.

Type of Request: Regular (extension of a current information collection).

Number of Respondents: 20,000.

Average Time per Response: 10 minutes for the Angler Intercept Survey, 5 minutes for the Sea Turtle Incidental Capture Form.

Total Annual Burden Hours: 1,153 hours.

Needs and Uses: NOAA's National Marine Fisheries Service (NOAA Fisheries) proposes to extend a current information collection designed to assess the extent of hook and line interactions between recreational anglers on piers and other shore-based fishing locations and sea turtles. The collection comprises an Angler Intercept Survey, a Fishing Site Characterization Form, a Survey Cover Sheet, and a Sea Turtle Incidental Capture Form. The Angler Intercept Survey will be verbally administered on piers and shore-based fishing locations within NOAA Fisheries Greater Atlantic Region and Southeast Region, and will be administered to approximately 20,000 individual recreational fishermen. The respondents will be verbally asked a series of questions about their fishing practices and observations of sea turtles and the interviewer will record their answers. The survey will also assess the feasibility of an intercept survey for this purpose in terms of response rates and data collection. The Fishing Site Characterization Form will be completed by the survey administrator at each fishing location and collects information on the structure and operation of the pier or shore-based fishing location. The Site Characterization Sheet will be completed by the survey administrator during each survey period and collects

information on the environmental conditions for that particular day, the number of anglers fishing, number of lines in the water, and the number of surveys completed. Sea Turtle Incidental Capture Form will be filled out by a Sea Turtle Stranding and Salvage Network participant when a turtle is incidentally captured, regardless of if the capture occurs during a specific survey period, and collects information on the specific interaction with fishing gear. This information is necessary to compare to the angler survey data, to identify if certain factors or fishing practices influence the rate of interactions. In this extension, minor revisions will be made to the Sea Turtle Incidental Capture Form to eliminate duplication with other sea turtle stranding data collection efforts.

Affected Public: Individuals or households.

Frequency: Once.

Respondent's Obligation: Voluntary.

Legal Authority: Collection of these data on sea turtle interactions in the shore-based recreational fishing sector is necessary to fulfill statutory requirements of the Endangered Species Act (16 U.S.C. 1531 et. seq.).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0774.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–25313 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB516]

Atlantic Highly Migratory Species; Atlantic Shark Management Measures; 2022 Research Fishery

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

ACTION: Notice of intent; request for applications.

SUMMARY: NMFS announces its request for applications for the 2022 shark research fishery from commercial shark fishermen with directed or incidental shark limited access permits. The shark research fishery allows for the collection of fishery-dependent and biological data for future stock assessments and to meet the research objectives of the Agency. The only commercial vessels authorized to land sandbar sharks are those participating in the shark research fishery. Shark research fishery permittees may also land other large coastal sharks (LCS), small coastal sharks (SCS), smoothhound, and pelagic sharks. Commercial shark fishermen who are interested in participating in the shark research fishery need to submit a completed Shark Research Fishery Permit Application to be considered.

DATES: Shark Research Fishery Applications must be received no later than December 20, 2021.

ADDRESSES: Please submit completed applications via email to *NMFS.Research.Fishery@noaa.gov.*

For copies of the Shark Research Fishery Permit Application, please email a request to *NMFS.Research.Fishery@noaa.gov.* Copies of the Shark Research Fishery Application are also available at the HMS website at *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-highly-migratory-species-exempted-fishing-permits.* Additionally, please be advised that your application may be released under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Karyl Brewster-Geisz, at (301) 427–8503 (phone) or Delisse Ortiz at (202) 930–1304 or email *NMFS.research.fishery@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Atlantic shark fisheries are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP), as amended, is implemented by regulations at 50 CFR part 635. Specifics regarding the commercial shark quotas and the shark research fishery can be found at §§ 635.27(b) and 635.32(f).

The shark research fishery was established, in part, to maintain time series data for stock assessments and to meet NMFS' research objectives. Since the shark research fishery was established in 2008, it has allowed for: The collection of fishery-dependent data for current and future stock assessments; the operation of cooperative research to meet NMFS' ongoing research objectives; the collection of updated life-history information used in the sandbar shark (and other species) stock assessment; the collection of data on habitat preferences that might help reduce fishery interactions through bycatch mitigation; evaluation of the utility of the mid-Atlantic closed area on the recovery of dusky sharks and collection of hook-timer and pop-up satellite archival tag information to determine at-vessel and post-release mortality of dusky sharks; and collection of sharks to determine the weight conversion factor from dressed weight to whole weight.

The shark research fishery allows selected commercial fishermen the opportunity to earn revenue from selling additional sharks, including sandbar sharks. Only the commercial shark fishermen selected to participate in the shark research fishery are authorized to land sandbar sharks subject to the sandbar quota available each year. The base quota for sandbar sharks is 90.7 metric tons (mt) dressed weight (dw) per year, although this number may be reduced in the event of overharvests. The selected shark research fishery permittees will also be allowed to land other LCS, SCS, smoothhound, and pelagic sharks consistent with any restrictions established on their shark research fishery permit. Generally, the shark research fishery permits are valid only for the calendar year for which they are issued.

One hundred percent observer coverage is required on shark research fishery trips. The specific 2022 trip limits and number of trips per month will depend on the availability of funding, number of selected vessels, the availability of observers, the available quota, and the objectives of the research fishery, and will be included in the permit terms at time of issuance. The number of participants in the research fishery changes each year. In 2021, four fishermen were chosen to participate. From 2008 through 2021, there has been

an average of six participants each year with the range from 4 to 11. The number of trips allowed per month can change, but in the last few years participating vessels on average have been able to take one trip per month. The number of trips taken per month are limited by the scientific and research needs of the Agency and the number of NMFS-approved observers available. Participants are also limited on the amount of gear they can deploy on a given set (*e.g.,* number of hooks and sets, soak times, length of longline). These limits may change both between years and during the year depending on research goals and bycatch limits.

In 2021, NMFS split 90 percent of the sandbar and LCS research fishery quotas equally among selected participants, with 20.4 mt dw (44,973 lb dw) of sandbar shark research fishery quota and 11.3 mt dw (24,911 lb dw) of other LCS research fishery quota available to each vessel. The remaining quota was held in reserve to ensure the overall sandbar and LCS research fishery quotas were not exceeded. It is likely NMFS will use this process again for the quota in 2022.

In 2021, NMFS continued to implement a regional dusky bycatch limit, which was first established in 2013, in the shark research fishery, applicable to four regions across the Gulf of Mexico and Atlantic. Under this limit, when four or more dusky sharks have been brought to the vessel dead in a region, shark research fishery permit holders in that region were prohibited from soaking their gear for longer than 3 hours. If, after the change in soak time, three additional dusky shark interactions (alive or dead) were observed, shark research fishery permit holders were prohibited from making a trip in that region for the remainder of the year, unless otherwise permitted by NMFS. Slightly different measures were established for shark research fishery participants in the mid-Atlantic shark closed area in order to allow NMFS observers to place satellite archival tags on dusky sharks and collect other scientific information on dusky sharks while also minimizing any dusky shark mortality.

Previously, shark research fishery permit holders were required to land any dead sharks, except for prohibited species. However, in 2021, shark research fishery permit holders were provided more flexibility and allowed to retain or discard any shark, regardless of condition. All prohibited species were required to be released, unless the observer requested that the shark be retained for research purposes. If the regional non-blacknose SCS, blacknose, and/or pelagic shark commercial management group quotas were closed, then any shark research fishery permit holder fishing in the region was required to discard all of the species from the closed management groups, regardless of condition. All other sharks, except prohibited species, caught and brought to the vessel could be released alive or landed. The vessels participating in the shark research fishery averaged 12 trips in 2021, but the timing, and number of the trips varied based on seasonal availability of certain species and quota available.

To participate in the shark research fishery, commercial shark fishermen need to submit a completed Shark Research Fishery Application by the deadline noted above (see **DATES**) showing that the vessel and owner(s) meet the specific criteria outlined below.

Research Objectives

Each year, the research objectives are developed by a shark board, which is comprised of representatives within NMFS, including representatives from the Southeast Fisheries Science Center (SEFSC) Panama City Laboratory, the Southeast Regional Office Protected Resources Division, and the HMS Management Division. The research objectives for 2022 are based on various documents, including the 2020 Biological Opinion of the Atlantic Shark Fisheries Except Pelagic Longline, as well as recent stock assessments for the U.S. South Atlantic blacknose, U.S. Gulf of Mexico blacknose, U.S. Gulf of Mexico blacktip, sandbar, and dusky sharks (all these stock assessments can be found at *http://sedarweb.org/*). The 2022 research objectives are:

- Collect reproductive, length, sex, and age data from sandbar and other sharks throughout the calendar year for species-specific stock assessments;
- Monitor the size distribution of sandbar sharks and other species captured in the fishery;
- Continue on-going tagging shark programs for identification of migration corridors and stock structure using dart and/or spaghetti tags;
- Maintain time-series of abundance from previously derived indices for the shark bottom longline observer program;
- Acquire fin-clip samples of all shark and other species for genetic analysis;
- Attach satellite archival tags to endangered smalltooth sawfish to provide information on critical habitat, preferred depth and post-release mortality, consistent with the requirements listed in the take permit issued under section 10 of the Endangered Species Act to the SEFSC Observer Program;
- Attach satellite archival tags to prohibited dusky and other sharks, as needed, to provide information on daily and seasonal movement patterns, and preferred depth;
- Evaluate hooking mortality and post-release survivorship of dusky, hammerhead, blacktip, and other sharks using hook-timers and temperature-depth recorders;
- Evaluate the effects of controlled gear experiments to determine the effects of potential hook changes to prohibited species interactions and fishery yields;
- Examine the size distribution of sandbar and other sharks captured throughout the fishery including in the Mid-Atlantic shark time/area closure off the coast of North Carolina from January 1 through July 31;
- Develop allometric and weight relationships of selected species of sharks (*e.g.,* hammerhead, sandbar, blacktip shark); and
- Collect samples such as liver and muscle plugs for stable isotope analysis as a part of a trophic level-based ecosystem study.

Selection Criteria

Shark Research Fishery Permit Applications will only be accepted from commercial shark fishermen who hold a current directed or incidental shark limited access permit. While incidental permit holders are welcome to submit an application, to ensure that an appropriate number of sharks are landed to meet the research objectives for this year, NMFS will give priority to directed permit holders as recommended by the shark board. As such, qualified incidental permit holders will be selected only if there are not enough qualified directed permit holders to meet research objectives.

The Shark Research Fishery Permit Application includes, but is not limited to, a request for the following information: Type of commercial shark permit possessed; past participation and availability in the commercial shark fishery (not including sharks caught for display); past involvement and compliance with HMS observer programs per 50 CFR 635.7; past compliance with HMS regulations at 50 CFR part 635; past and present availability to participate in the shark research fishery year-round; ability to fish in the regions and seasons requested; ability to attend necessary meetings regarding the objectives and research protocols of the shark research fishery; and ability to carry out the research objectives of the Agency.

Preference will be given to those applicants who are willing and available to fish year-round and who affirmatively state that they intend to do so, to ensure the timely and accurate data collection NMFS needs to meet this year's research objectives. An applicant who has been charged criminally or civilly (*e.g.,* issued a Notice of Violation and Assessment (NOVA) or Notice of Permit Sanction) for any HMS-related violation will not be considered for participation in the shark research fishery. In addition, applicants who were selected to carry an observer in the previous two years for any HMS fishery, but failed to contact NMFS to arrange the placement of an observer as required per § 635.7, will not be considered for participation in the 2022 shark research fishery. Applicants who were selected to carry an observer in the previous two years for any HMS fishery and failed to comply with all the observer regulations per § 635.7 will also not be considered. Exceptions will be made for vessels that were selected for HMS observer coverage but did not fish in the quarter when selected and thus did not require an observer. Applicants who do not possess a valid USCG safety inspection decal when the application is submitted will not be considered. Applicants who have been non-compliant with any of the HMS observer program regulations in the previous two years, as described above, may be eligible for future participation in shark research fishery activities by demonstrating two subsequent years of compliance with observer regulations at § 635.7.

Selection Process

The HMS Management Division will review all submitted applications and develop a list of qualified applicants from those applications that are deemed complete. A qualified applicant is an applicant that has submitted a complete application by the deadline (see **DATES**) and has met the selection criteria listed above. Qualified applicants are eligible to be selected to participate in the 2022 shark research fishery. The HMS Management Division will provide the list of qualified applicants without identifying information to the SEFSC. The SEFSC will then evaluate the list of qualified applicants and, based on the temporal and spatial needs of the research objectives, the availability of observers, the availability of qualified applicants, and the available quota for a given year, will randomly select qualified applicants to conduct the prescribed research. Where there are multiple qualified applicants that meet the criteria, permittees will be randomly selected through a lottery system. If a public meeting is deemed necessary, NMFS will announce details of a public selection meeting in a subsequent **Federal Register** notice.

Once the selection process is complete, NMFS will notify the selected applicants and issue the shark research fishery permits. The shark research fishery permits will be valid through December 31, 2022, unless otherwise specified. If needed, NMFS will communicate with the shark research fishery permit holders to arrange a captain's meeting to discuss the research objectives and protocols. NMFS usually holds mandatory captain's meetings before observers are placed on vessels and may hold one for the 2022 shark research fishery in early 2022. Once the fishery starts, the shark research fishery permit holders must contact NMFS or the NMFS-designee to arrange the placement of a NMFS-approved observer for each shark research trip. Selected applicants are required to allow observers the opportunity to perform their duties and assist observers as necessary.

A shark research fishery permit will only be valid for the vessel and owner(s) and terms and conditions listed on the permit, and, thus, cannot be transferred to another vessel or owner(s). Shark research fishery permit holders must carry a NMFS-approved observer on shark research fishery trips. Issuance of a shark research permit does not guarantee that the permit holder will be assigned a NMFS-approved observer on any particular trip. Rather, issuance indicates that a vessel may be issued a NMFS-approved observer for a particular trip, and on such trips, may be allowed to harvest Atlantic sharks, including sandbar sharks, in excess of the retention limits described in § 635.24(a). Applicable retention limits will be based on available quota, number of vessels participating in the 2022 shark research fishery, the research objectives set forth by the shark board, the extent of other restrictions placed on the vessel, and may vary by vessel and/or location. When not operating under the auspices of the shark research fishery, the vessel would still be able to land LCS, SCS, and pelagic sharks subject to existing retention limits on trips without a NMFS-approved observer.

NMFS annually invites commercial shark permit holders (directed and incidental) to submit an application to participate in the shark research fishery. Permit applications can be found on the HMS Management Division's website at *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-highly-migratory-species-permits-and-reporting-forms* or by calling (301) 427–8503. Final decisions on the issuance of a shark research fishery permit will depend on the submission of all required information by the deadline (see **DATES**), and NMFS' review of applicant information as outlined above. The 2022 shark research fishery will start after the opening of the shark fishery and under available quotas as published in a separate **Federal Register** final rule.

Dated: November 16, 2021.

Ngagne Jafnar Gueye,

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

[FR Doc. 2021–25314 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for a meeting of the Science Advisory Board (SAB). The members will discuss issues outlined in the section on Matters to be considered.

DATES: The meeting is scheduled for December 7, 2021 from 1:00 p.m. to 5:00 p.m. Eastern Standard Time (EST) and December 8, 2021 from 1:00 p.m. to 5:00 p.m. Eastern Standard Time (EST). This time and the agenda topics described below are subject to change. For the latest agenda, please refer to the SAB website: *https://sab.noaa.gov/index.php/sab-meetings/.*

ADDRESSES: This is a virtual meeting. The webinar registration links for the December 7 and December 8, 2021 meeting may be found on the website at *http://sab.noaa.gov/SABMeetings.aspx.*

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, SSMC3, Room 11230, 1315 East-West Hwy., Silver Spring, MD 20910; Phone Number: 301–734–1156; Email: *Cynthia.Decker@noaa.gov;* or visit the SAB website at *http://sab.noaa.gov/SABMeetings.aspx.*

SUPPLEMENTARY INFORMATION: The NOAA Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for

Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Status: The December 7, 2021 meeting will be open to public participation with a 15-minute public comment period at 4:45 p.m., EST. The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three minutes. Written comments for the December 7 and December 8, 2021 meeting should be received by the SAB Executive Director's Office by November 29, 2021 to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after these dates will be distributed to the SAB, but may not be reviewed prior to the meeting date.

Special Accommodations: This meeting is physically accessible to people with disabilities. Requests for special accommodations may be directed to the Executive Director no later than 12 p.m. on November 29, 2021.

Matters To Be Considered: The meeting on December 7–8, 2021 will consider (1) NOAA Update; (2) NOAA Science Update; (3) NOAA Response to the SAB Environmental Information Services Working Group: Statement Concerning the Ongoing NWS Data Dissemination Challenges; (4) Priorities of Weather Research (PWR) Final Report; (5) Tsunami Science & Technology Advisory Panel Final Report; (6) NOAA Response to SAB Environmental Information Services Working Group Report: Recommendations to the NOAA Concerning the Hurricane Forecast Improvement Program; (7) Review of the Draft 2021 Report to the United States Congress from the Environmental Information Services Working Group (EISWG); (8) NOAA Response to SAB Climate Working Group Report (CWG): Precipitation Prediction Grand Challenge Strategic Plan Review. The full agenda will be published on the SAB website. Meeting materials, including work products, will be available on the SAB website: *http://sab.noaa.gov/SABMeetings.aspx.*

Eric Locklear,

Acting Chief Financial Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2021–25250 Filed 11–18–21; 8:45 am]

BILLING CODE 3510–KD–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete product(s) that were on the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Comments must be received on or before:* December 19, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
2520–01–398–4589—Parts Kit, Hydraulic Transmission, Utility Trucks
2590–00–299–0739—Valve, Poppet, Hull Drain
2520–01–211–6702—Parts Kit, Transmission Oil Filter
Designated Source of Supply: Goodwill Industries—Knoxville, Inc., Knoxville, TN
Contracting Activity: DLA LAND AND MARITIME, COLUMBUS, OH
NSN(s)—Product Name(s): 8465–00–656–0816—Bag, Laundry, Self-Closing, Ropeless
Designated Source of Supply: Ability Building Center, Inc., Rochester, MN
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA
NSN(s)—Product Name(s): 7520–01–484–5256—Pen, Ball Point, Retractable, Ergonomic, MD Ergo Grip, Blue Barrel, Blue Ink, Medium Point
Designated Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

Michael R. Jurkowski,

Acting Deputy Director, Business Operations.

[FR Doc. 2021–25262 Filed 11–18–21; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds product(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* December 19, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 2/12/2021, 3/12/2021, 3/19/2021, 4/30/2021, 5/7/2021, 5/21/2021, and 5/28/2021, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product(s) and service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the product(s) and service(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product(s) and service(s) to the Government.

2. The action will result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product(s) are added to the Procurement List:

Product(s)

NSN(s)—Product Name(s):
MR 13087—Set, Cookie Sheet, 3 Piece
MR 10796—Dish Rack, Compact, Includes Shipper 20796
MR 11136—Tablecloth, 3 Pack
MR 10792—Twin Juicer, Includes Shipper 20792
MR 10794—Mini Garden Colander, Includes Shipper 20794
MR 10788—Super Sifter, Includes Shipper 20788
MR 16400—Sunglasses, Women's Fashion
MR 16401—Sunglasses, Women's Aviator
MR 16402—Sunglasses, Polarized Assorted
MR 16403—Sunglasses, Metal Assorted
MR 16404—Sunglasses, Sport Assorted
MR 10809—Onion Saver, Includes Shipper 20809
MR 10798—Headlamp, Includes Shipper 20798
Designated Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Defense Commissary Agency
Mandatory For: The requirements of military commissaries and exchanges in accordance with the 41 CFR 51–6.4
Distribution: C-List

NSN(s)—Product Name(s):
MR 1194—Cleaning Cloth, DuraFresh, 2 Pack
MR 863—Lint Roller
MR 864—Lint Roller Refill
Designated Source of Supply: Alphapointe, Kansas City, MO
Contracting Activity: Defense Commissary Agency
Mandatory For: The requirements of military commissaries and exchanges in accordance with the 41 CFR 51–6.4
Distribution: C-List

NSN(s)—Product Name(s):
MR 11480—Dust Remover, Compressed Gas, 10 oz
Designated Source of Supply: The Lighthouse for the Blind, St. Louis, MO
Contracting Activity: Defense Commissary Agency
Mandatory For: The requirements of military commissaries and exchanges in accordance with the 41 CFR 51–6.4
Distribution: C-List

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2021–25266 Filed 11–18–21; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the U.S. Naval Academy Board of Visitors

AGENCY: Department of the Navy, U.S. Department of Defense (DoD).

ACTION: Notice of partially closed meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the U.S. Naval Academy Board of Visitors, hereafter ''Board,'' will take place.

DATES: Open to the public, December 6, 2021, from 9 a.m. to 11 a.m. Closed to the public, December 6, 2021, from 11 a.m. to noon (12 p.m.).

ADDRESSES: This meeting will be held at the United States Naval Academy in Annapolis, Maryland. Pending prevailing health directives, the meeting will be handicap accessible. Escort is required.

FOR FURTHER INFORMATION CONTACT: Major Raphael Thalakottur, USMC, Executive Secretary to the Board of Visitors, Office of the Superintendent, U.S. Naval Academy, Annapolis, MD 21402–5000, 410–293–1503, *thalakot@usna.edu,* or visit *https://www.usna.edu/PAO/Superintendent/bov.php.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), the General Services Administration's (GSA) Federal Advisory Committee Management Final Rule (41 CFR part 102–3).

Purpose of Meeting: The U.S. Naval Academy Board of Visitors will meet to make such inquiry, as the Board deems necessary, into the state of morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, and academic methods of the Naval Academy.

Agenda: Proposed meeting agenda for December 6, 2021.

0830–0900 Members Assemble
0900 Call to Order (Open to Public)
0900–1055 Business Session (Open to Public)
1055–1100 Break (Open to Public)
1100–1200 Executive Session (Closed to Public)

Current details on the board of visitors may be found at *https://www.usna.edu/PAO/Superintendent/bov.php.*

The executive session of the meeting from 11:00 a.m. to 12:00 p.m. on December 6, 2021, will consist of discussions of new and pending administrative or minor disciplinary infractions and non-judicial punishments involving midshipmen attending the Naval Academy to include but not limited to, individual honor or conduct violations within the Brigade, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. For this reason, the executive session of this meeting will be closed to the public, as the discussion of such information cannot be adequately segregated from other topics, which precludes opening the executive session of this meeting to the public. Accordingly, the Secretary of the Navy, in consultation with the Department of the Navy General Counsel, has determined in writing that the meeting shall be partially closed to the public because the discussions during the executive session from 11 a.m. to noon (12 p.m.) will be concerned with matters protected under sections 552b(c) (5), (6), and (7) of title 5, United States Code (U.S.C.).

Authority: 5 U.S.C. 552b.

Meeting Accessibility: Pursuant to FACA and 41 CFR 102–3.140, this meeting is open to the public. Any public attendance at the meeting will be governed by prevailing health directives at the United States Naval Academy. Please contact the Executive Secretary five business days prior the meeting to coordinate access to the meeting.

Written Statements: Per Section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration at any time, but should be received by the Designated Federal Officer at least 15 business days prior to the meeting date so that the comments may be made available to the Board for their consideration prior to the meeting. Written statements should be submitted via mail to Board of

Visitors, 121 Blake Rd., Annapolis, MD 21402. Please note that since the Board operates under the provisions of the FACA, as amended, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the board website. If, and only if, prevailing medical directives require the employment of a virtual meeting, the virtual meeting will be broadcasted live from the United States Naval Academy. The broadcast will be close captioned for the duration of the public portion of the meeting. The link to view the meeting will be posted at *https://www.usna.edu/PAO/Superintendent/bov.php* forty-eight hours prior to the meeting. A virtual event will preclude accommodation of the public to attend the meeting in person.

Dated: November 15, 2021.

J.M. Pike,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2021–25275 Filed 11–18–21; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Rural Postsecondary and Economic Development Grant Program; Corrections

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice; corrections.

SUMMARY: On November 5, 2021, the Department of Education (Department) published in the **Federal Register** a notice inviting applications (NIA) for new awards for fiscal year (FY) 2021 for the Rural Postsecondary and Economic Development (RPED) Grant Program, Assistance Listing Number 84.116W. We are amending the NIA to include as eligible applicants public and private non-profit organizations and agencies that partner with institutions of higher education (IHEs) and to make associated changes to performance measure 2. In addition, we are extending the deadline for transmittal of applications until December 13, 2021.

DATES: *Deadline for Transmittal of Applications:* December 13, 2021.

FOR FURTHER INFORMATION CONTACT: Kurrinn Abrams, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–4260. Telephone: (202) 453–7906. Email: *kurrinn.abrams2@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On November 5, 2021, we published in the **Federal Register** the NIA for the FY 2021 RPED Grant Program (86 FR 61193). The application deadline in the NIA was December 6, 2021. We are amending the NIA to include as eligible applicants public and private non-profit organizations and agencies that partner with IHEs and to make corresponding changes to performance measure 2. In addition, we are extending the deadline for transmittal of applications until December 13, 2021. All other requirements and conditions stated in the NIA remain the same.

Corrections

In FR Document 2021–24361 appearing on page 61193 of the **Federal Register** of November 5, 2021, we make the following amendments:

1. On page 61193, in the second column, under the **DATES** caption and following the heading ''Deadline for Transmittal of Applications'', remove ''December 6, 2021'' and add in its place ''December 13, 2021''.

2. On page 61195, in the second column, in the ''Eligiblity Information'' section, at the end of the paragraph following the heading ''Eligible Applicants'', add '', and public and private non-profit organizations and agencies that partner with such IHEs''.

3. On page 61197, in the third column, in the second line of the second paragraph, add ''and/or partner'' after ''grantee''.

Program Authority: 20 U.S.C. 1138–1138d; Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2021, H.R. 7614, 116th Congress (2020); the explanatory statement accompanying H.R. 133 (Pub. L. 116–260).

Accessible Format: On request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document, the NIA, and a copy of the application in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Michele Asha Cooper,

Deputy Assistant Secretary for Higher Education Programs, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2021–25332 Filed 11–18–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2021–SCC–0131]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) Kindergarten and First-Grade Field Test Data Collection, National Sampling, and National Recruitment

AGENCY: Institute of Educational Science (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before December 20, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, 202–245–6347.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) Kindergarten and First-Grade Field Test Data Collection, National Sampling, and National Recruitment.

OMB Control Number: 1850–0750.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 20,895.

Total Estimated Number of Annual Burden Hours: 15,599.

Abstract: The Early Childhood Longitudinal Study (ECLS) program, conducted by the National Center for Education Statistics (NCES) within the Institute of Education Sciences (IES) of the U.S. Department of Education (ED), draws together information from multiple sources to provide rich, descriptive data on child development, early learning, and school progress. The ECLS program studies deliver national data on children's status at birth and at various points thereafter; children's transitions to non-parental care, early care and education programs, and school; and children's experiences and growth through the elementary grades. The Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) is the fourth cohort in the series of early childhood longitudinal studies that began with the Early Childhood Longitudinal Study, Kindergarten Class of 1998–99 (ECLS–K) and continued with the Early Childhood Longitudinal Study, Birth Cohort (ECLS–B), and the Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS–K:2011).

In preparation for the ECLS–K:2024 data collections, several OMB packages have been cleared or have been planned for submission. Prior to the field test collection of data from parents of preschool-aged children, in-person focus groups with parents of preschoolers and usability testing of the preschool parent survey instruments were conducted in 2019 (OMB 1850–0803 v.246 and OMB 1850–0803 v.253, respectively). The field test with preschool parents was conducted in the spring of 2020 (OMB 1850–0750 v.19). In order to test recruitment messages and materials for the field test and national data collections, online focus groups with school administrators, teachers, and parents were conducted in fall 2019 and spring 2020 (OMB 1850–0803 v.255 & v.264). Additionally, usability testing of the kindergarten and first-grade field test instruments was conducted in early 2021 (OMB 1850–0803 v.280).

This current request is to conduct a field test of the ECLS–K:2024 kindergarten and first-grade data collection activities to evaluate the design of the national study's kindergarten and first-grade surveys and child assessments, as well as the operational procedures (that is, sampling and recruitment) for the national kindergarten and first-grade data collections in the fall 2023, spring 2024, and spring 2025. This data collection to evaluate the kindergarten and first-grade instruments and procedures is referred to throughout the remainder of this package as the K–1 field test. District and school sampling and recruitment activities for the K–1 field test will occur in spring 2022, while student sampling will occur in August and September 2022. From September through November 2022, trained study field staff will visit the participating schools to conduct in-person, one-on-one child assessments. Parents, teachers, and school administrators will also be asked to complete web surveys. As testing and development continues, it is anticipated that changes to the surveys, website language, and respondent materials will be necessary; a change request describing these changes will be submitted in spring 2022 prior to the K–1 field test data collection. Furthermore, this package also includes a request to conduct national district and school sampling and recruitment from fall 2022 to spring 2023. These recruitment activities will closely mimic what will be done in the K–1 field test but will occur over a much longer period of time.

Dated: November 16, 2021.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–25307 Filed 11–18–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0163]

Agency Information Collection Activities; Comment Request; Grantee Reporting Form—Rehabilitation Services Administration (RSA) Annual Payback Report

AGENCY: Office of Special Education and Rehabilitation Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before January 18, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2021–SCC–0163. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be

addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208C, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Karen Holliday, 202–245–7318.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Grantee Reporting Form—Rehabilitation Services Administration (RSA) Annual Payback Report.

OMB Control Number: 1820–0617.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Individuals and Households; Private Sector.

Total Estimated Number of Annual Responses: 11,790.

Total Estimated Number of Annual Burden Hours: 4,858.

Abstract: Public Law 114–95, section 302(b) of the Rehabilitation Act of 1973, as amended by the Workforce Innovation and Opportunity Act (WIOA), the Rehabilitation Services Administration (RSA) provides Long-Term Training grants to academic institutions to support scholarship assistance to students. Students who receive scholarships under this program are required to work within the public rehabilitation program, such as with a state vocational rehabilitation agency, or an agency or organization that has a service arrangement with a state vocational rehabilitation agency. The student is expected to work two years in such settings for every year of full-time scholarship support. The program regulations at 34 CFR 386.33–386.35 and 386.40–386.43 detail the payback provisions and the RSA scholars' requirements to comply with them.

Section 302(b)(2)(C) of the Act requires tracking of scholars' employment status and location of former scholars supported under the grants in order to ensure that students are meeting the payback requirement. Scholars must provide requested information necessary to meet the exit certification requirements.

In addition to meeting the requirement that all scholars be tracked, the information collected will provide performance data relevant to the rehabilitation fields and degrees pursued by RSA scholars, as well as the funds owed and the rehabilitation work completed by them. These data are used to assess program effectiveness and efficiency, and to meet the reporting requirements of Public Law 103–62 section 4 of the Government Performance and Results Act (GPRA).

RSA is requesting an extension of the currently approved collection for grantees (Institutions of Higher Education), scholars, and employers to submit data electronically through the online RSA Payback Information Management System (PIMS). There is no substantial change in the proposed data collected, nor estimated burden required to report data using the PIMS system.

Dated: November 16, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–25304 Filed 11–18–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0158]

Agency Information Collection Activities; Comment Request; Mandatory Civil Rights Data Collection

AGENCY: Office for Civil Rights (OCR), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision to an existing information collection.

DATES: Interested persons are invited to submit comments on or before January 18, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2021–SCC–0158. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of Strategic Collections and Clearance, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 6W201, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to the collection activities, please contact Rosa Olmeda at *Rosa.Olmeda@ed.gov* or (202) 245–7264.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection

necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Mandatory Civil Rights Data Collection.

OMB Control Number: 1870–0504.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, or Tribal Governments.

Total Estimated Number of Annual Responses: 17,884.

Total Estimated Number of Annual Burden Hours: 2,165,918.

Abstract: The collection, use, and reporting of education data is an integral component of the mission of the U.S. Department of Education (ED). ED has collected civil rights data about the nation's public schools via the Civil Rights Data Collection (CRDC) since 1968. For school years 2009–10 and 2011–12, the Office of Management and Budget (OMB) approved the CRDC part of the EDFacts information collection (1875–0240). EDFacts, an ED initiative to put performance data at the center of ED's policy, management, and budget decision-making processes for all preschool-grade 12 education programs, has transformed the way in which ED collects and uses data. For school years 2013–14, 2015–16, 2017–18, and 2020–21, the Office for Civil Rights (OCR) cleared the CRDC as a separate collection from EDFacts while maintaining its transformative data collection policies and practices. As with previous CRDC collections, the purpose of the 2021–22 CRDC is to obtain vital data related to the civil rights laws' requirement that public local educational agencies (LEAs) and elementary and secondary schools provide equal educational opportunity. ED has analyzed the uses of many data elements collected in the 2015–16 and 2017–18 CRDCs and sought advice from experts across ED to refine, improve, and where appropriate, add or remove data elements from the collection. ED also made the CRDC data definitions and metrics consistent with other mandatory collections across ED wherever possible. ED seeks OMB approval under the Paperwork Reduction Act to collect from LEAs the elementary and secondary education data described in the sections of Attachment A. In addition to reviewing and commenting on the proposed changes (detailed in Supporting Statement A and Attachments A–1, A–2, A–3, and A–4), ED requests that LEAs and other stakeholders respond to the directed questions found in Attachment A–5.

Dated: November 16, 2021.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of the Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–25246 Filed 11–18–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–243–D]

Application To Export Electric Energy; Tenaska Power Services Co.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Tenaska Power Services Co. (Applicant or TPS) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 20, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On November 3, 2021, TPS filed an application with DOE (Application or App.) to ''transmit electric energy from the United States to Canada for a period of five years.'' App. at 1. TPS states that it ''is a Nebraska corporation and an indirect, wholly owned subsidiary of Tenaska Energy, Inc. ('Tenaska').'' *Id.* TPS further states that its ''parent company, Tenaska, is a privately held corporation organized and existing under the laws of Delaware.'' *Id.* at 2. TPS represents that it ''does not currently own or control electric generation or transmission facilities, and does not have a power supply of its own in the United States that would cause its electricity exports to have a reliability, fuel use, or system stability impact.'' *Id.* at 3.

TPS further claims that it would ''purchase the electricity may export . . . from wholesale generators, electric utilities, federal power marketing agencies and affiliates through negotiated agreements that have been voluntarily executed by the selling parties after considering their own need for any such electricity.'' App. at 3. TPS contends that its ''proposed electricity exports will not impair or tend to impede the sufficiency of electric power supplies in the United States or the regional coordination of electric utility planning or operations.'' *Id.* at 3–4.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning TPS's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–243–D. Additional copies are to be provided directly to Norma Rosner Iacovo, 300 East John Carpenter Freeway, Suite 100, Irving, TX 75062, *niacovo@tnsk.com;* and Neil L. Levy, 500 North Capitol Street NW, Washington, DC 20001, *nlevy@mwe.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *https://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 12, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–25247 Filed 11–18–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–433–A]

Application To Export Electric Energy; SociVolta, Inc.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: SociVolta, Inc. (Applicant or SociVolta) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 20, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On October 29, 2021, SociVolta filed an application with DOE (Application or App.) to ''transmit electric energy from the United States to Canada for a period of five (5) years.'' App. at 1. SociVolta states that it ''is a Canadian company with its principal place of business in Montreal, Quebec,'' adding that it ''was incorporated in Quebec under a Canadian federal chart.'' *Id.* at 2. SociVolta represents that it ''does not have any affiliates or upstream owners that possess any ownership interest or involvement in any other company that is a traditional utility or that owns, operates, or controls any electric generation, transmission or distribution facilities, nor do they have any direct involvement with the energy industry other than through the ownership of SociVolta.'' *Id.*

SociVolta further claims that it would ''purchase power to be exported from a variety of sources such as power marketers, independent power producers, or U.S. electric utilities and federal power marketing entities as those terms are defined in Sections 3(22) and 3(19) of the [Federal Power Act].'' App. at 3. SociVolta contends that its proposed exports would be ''surplus to the system of the generator and, therefore, the electric power that [it would] export on either a firm or interruptible basis [would] not impair the sufficiency of the electric power supply within the U.S.'' *Id.* SociVolta adds that its proposed exports would ''not impair or tend to impede the sufficiency of electric supplies in the U.S. or the regional coordination of electric utility planning or operations.'' *Id.* at 4.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning SociVolta's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–433–A. Additional copies are to be provided directly to Ruta Kalvaitis Skučas, 1601 K St. NW, Washington, DC 20006, *rskucas@piercewood.com*; and Daniel Doyon, 5455 De Gaspe Ave, Suite 710, Montreal, Quebec H2T 3B3, Canada, *info@socivolta.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *https://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 12, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–25248 Filed 11–18–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Department of Energy Final Decision and Reasoning Response to Defense Nuclear Facilities Safety Board Recommendation 2020–1, Nuclear Safety Requirements

AGENCY: Office of Environment, Health, Safety and Security, Department of Energy.

ACTION: Notice.

SUMMARY: On June 1, 2021, the Defense Nuclear Facilities Safety Board issued the reaffirmation and revision of Recommendation 2020–1, *Nuclear Safety Requirements,* to the Department of Energy. In accordance with the Atomic Energy Act of 1954 the following represents the Secretary of Energy's final decision and the reasoning for such decision on the recommendation.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Do, Office of the Departmental Representative to the Defense Nuclear Facilities Safety Board, Office of Environment, Health, Safety and Security, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, or telephone number (301) 903–6460, or email *Mark.Do@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On June 1, 2021, the Defense Nuclear Facilities Safety Board issued the reaffirmation and revision of Recommendation 2020–1, *Nuclear Safety Requirements,* to the Department of Energy. In accordance with section 315 of the Atomic Energy Act of 1954 (42 U.S.C. 2286d(e)), the Secretary of Energy's final decision and the reasoning for such decision pertaining to Recommendation 2020–1 are printed in full at the conclusion of this notice.

Signing Authority

This document of the Department of Energy was signed on November 15, 2021, by Joe Olencz, Departmental

Representative to the Defense Nuclear Facilities Safety Board, Office of Environment, Health, Safety and Security, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 16, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

Summary: This notice, together with its attachments, memorializes the Secretary of Energy's final decision and reasoning for such decision pertaining to Defense Nuclear Facilities Safety Board (DNFSB or Board) Recommendation 2020–1, *Nuclear Safety Requirements.*

Discussion: The Board issued Recommendation 2020–1 on February 21, 2020. The Recommendation was published in the **Federal Register** on March 13, 2020 (85 FR 14658). The Secretary of Energy responded to the DNFSB in the letter dated June 11, 2020, indicating that the Department of Energy (DOE) partially accepted Recommendation 2020–1. DOE's response was published in the **Federal Register** on June 19, 2020 (85 FR 37086).

In response to DOE's partial acceptance, the DNFSB revised and reaffirmed Recommendation 2020–1 on June 1, 2021. In this revision and reaffirmation, the Board acknowledged DOE's completion of the rulemaking for 10 Code of Federal Regulations (CFR) Part 830, *Nuclear Safety Management,* and made a number of revisions to specific sub-recommendations within Recommendation 2020–1.

In a letter to the DNFSB dated September 8, 2021, the Secretary of Energy accepted Recommendation 2020–1, and provided details of the reasoning for this acceptance. This response constitutes the Secretary's final decision for the Recommendation. The Secretary of Energy's final decision and reasoning are included as attachments to this notice.

This notice is in accordance with 42 United States Code (U.S.C.) Section 2286d paragraph (e), which states:

If the Secretary of Energy, in a response under subsection (c)(1), rejects (in whole or part) any recommendation made by the Board under section 2286a of this title, the Board shall either reaffirm its original recommendation or make a revised recommendation and shall notify the Secretary of its action. Within 30 days after receiving the notice of the Board's action under this subsection, the Secretary shall consider the Board's action and make a final decision on whether to implement all or part of the Board's recommendations. Subject to subsection (i), the Secretary shall publish the final decision and the reasoning for such decision in the **Federal Register** and shall transmit to the Committees on Armed Services, Appropriations, and Energy and Commerce of the House of Representatives and the Committees on Armed Services, Appropriations, and Energy and Natural Resources of the Senate a written report containing that decision and reasoning.

Attachment 1

September 8, 2021

The Honorable Joyce Connery
Chair, Defense Nuclear Facilities Safety Board
625 Indiana NW, Suite 700
Washington, DC 20004

Dear Chair Connery:

The Department of Energy (DOE) acknowledges receipt of your letter dated June 1, 2021, which both reaffirms and revises Defense Nuclear Facilities Safety Board (DNFSB) Recommendation 2020–1, *Nuclear Safety Requirements.* The initial issuance of Recommendation 2020–1, dated February 21, 2020, asserted that DOE's August 2018 proposed revisions to Title 10 Code of Federal Regulations (CFR) Part 830, *Nuclear Safety Management,* would erode DOE's nuclear safety regulatory framework. In its June 11, 2020, response which states that ''the changes to 10 CFR part 830 will improve the effectiveness and efficiency of DOE's nuclear safety framework while continuing to ensure adequate protection of public and worker health and safety across the DOE complex,'' DOE disagreed with the DNFSB's assertions. On October 19, 2020, DOE published the Final Rule amending 10 CFR part 830, addressing and incorporating comments from the DNFSB and members of the public as part of the formal rulemaking process. (85 FR 66201).

Following our recent evaluation of your updated Recommendation 2020–1, the Department continues to conclude that its current regulatory framework, as revised by the October 2020 rulemaking, provides adequate protection of public and worker health and safety across the DOE complex. However, I accept Recommendation 2020–1, as detailed in the enclosure, which constitutes my Final Decision for this Recommendation. DOE agrees with addressing the technical concerns raised by the Board, but DOE cannot commit to a specific outcome in a future rulemaking and will perform a regulatory analysis to evaluate whether any changes to 10 CFR part 830 should be proposed through a future rulemaking process.

The enclosure updates DOE's June 11, 2020, response for several sub-recommendations to reflect revisions to Recommendation 2020–1. We believe DOE's implementation plan will meet the safety improvement objectives of the DNFSB's Recommendation.

DOE appreciates the Board's advice and will continue working closely with the Board and its staff to continuously improve DOE's nuclear safety regulatory framework in a manner that meets our shared objective to ensure the continued safe, effective, and efficient execution of DOE's mission.

To ensure that our implementation plan will meet the underlying safety improvement objectives of the DNFSB's Recommendation, DOE will engage in frequent staff level interactions during the preparation of the plan. The Board cited these constructive interactions during the most recent preparation of an implementation plan as a potential best practice, and we look forward to enhancing and improving our interactions during this process as well.

If you have any questions, please contact Mr. Matthew Moury, Associate Under Secretary for Environment, Health, Safety and Security, at 202–586–1285.

Sincerely,

Jennifer Granholm

Enclosure

Attachment 2

Enclosure—Department of Energy Response to DNFSB Recommendation 2020–1, Nuclear Safety Requirements

The Department of Energy (DOE or Department) has evaluated the reaffirmed and revised Defense Nuclear Facilities Safety Board (DNFSB or Board) Recommendation 2020–1, dated June 1, 2021. The following discussion presents a detailed response for each DNFSB sub-recommendation, which reflects the Department's acceptance of Recommendation 2020–1, and constitutes the Secretary's Final Decision for this Recommendation.

As described in DOE's June 11, 2020, initial response to Recommendation 2020–1, DOE disagreed with the DNFSB's assertion that the revisions proposed in the August 8, 2018, Notice

of Proposed Rulemaking (NOPR) for 10 CFR part 830, *Nuclear Safety Management,* will erode DOE's nuclear safety regulatory framework. Rather, DOE believes that these proposed changes will improve the effectiveness and efficiency of the framework while continuing to ensure adequate protection of environment, public, and worker health and safety at DOE defense nuclear facilities. On October 19, 2020, DOE published the Final Rule amending 10 CFR part 830, addressing and incorporating comments from the DNFSB and members of the public as part of the formal rulemaking process. (85 FR 66201).

The DNFSB's June 1, 2021, letter both revises and reaffirms DNFSB Recommendation 2020–1, *Nuclear Safety Requirements,* in response to DOE's June 11, 2020, response and to DOE's completion of the rulemaking. Given the revisions made to the Recommendation, the following reflects DOE's revised response.

While accepting Recommendation 2020–1, DOE accepts sub-recommendations 3.c, 5.d, and 5.e with the understanding that DOE cannot commit to a specific outcome in a future rulemaking as doing so would be inconsistent with its requirements under the Administrative Procedure Act. DOE will perform a regulatory analysis to evaluate whether changes to 10 CFR part 830 should be pursued through a future rulemaking effort.

Sub-Recommendation 1: Aging Infrastructure

Sub-Recommendation 1.a. *Develop and implement an integrated approach—including requirements—for the management of aging infrastructure that includes formal processes to identify and perform infrastructure upgrades necessary to ensure facilities and structures, systems, and components can perform their safety functions.*

DOE accepts this sub-recommendation. DOE believes its nuclear safety regulatory framework has requirements in place to ensure facilities and safety structures, systems, and components (SSCs), both active and passive, perform their safety functions. In the Department's December 17, 2019, response to the Draft Recommendation, the Department included an extensive discussion regarding DOE's expectations for the performance of safety SSCs within DOE's policy documents. At the highest level, compliance with 10 CFR part 830, including the requirement in 10 CFR 830.204(b)(4) to ''. . . demonstrate the adequacy of these [hazard] controls to eliminate, limit, or mitigate identified hazards . . .'', is required for all Hazard Category (HC) 1, 2, and 3 nuclear facilities, and applies to new and existing facilities.

DOE will benchmark existing successful aging management processes, such as the Extended Life Program at Y–12, and infrastructure upgrade programming systems, such as Science-based Infrastructure Stewardship, to enhance its processes to identify, prioritize, and plan safety-related infrastructure upgrades at Defense Nuclear Facilities. DOE will ensure funding necessary to complete upgrades designated through these evaluation and prioritization processes is clearly identified as part of the federal budgeting process. Given the multiple government-wide priorities that are considered as part of the budgeting process, DOE recognizes that not all upgrades are likely to be able to be funded in any given budgeting cycle. DOE will continue its risk-based budgeting prioritization approach and will continue taking other mitigating steps, as appropriate, to continue to maintain adequate safety. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 2: Hazard Categories

Sub-Recommendation 2.a. *Revise DOE Standard 1027–2018 to address the deficiencies noted in the Board's letter dated January 19, 2021.*

DOE accepts this sub-recommendation. During the DNFSB staff's recent 2020 review of the content and technical basis of DOE Standard 1027–2018, Change Notice 1, *Hazard Categorization of DOE Nuclear Facilities,* DOE and the DNFSB staff had multiple meetings to discuss the DNFSB staff's questions and concerns. The DNFSB staff's outstanding issues were identified in the Board's letter dated January 19, 2021. The letter was provided to DOE for information. DOE has reviewed this letter and will work with the Board staff to further understand these concerns as part of future work on DOE Standard 1027 (as described in response to sub-Recommendation 2.b, below). Further, it should be noted that as a result of the Board's review of hazard categorization, NNSA Supplemental Directive (SD) Guide (G)-1027, Admin Change 2, was issued on May 10, 2021, that clarified the use of the calculated threshold quantities and provided additional historical perspective on use of International Commission for Radiation Protection (ICRP) guidance. DOE believes that the changes address some of the Board's concerns identified in the letter.

Sub-Recommendation 2.b. *Mandate use of the updated version of DOE Standard 1027 when performing facility hazard categorization of new defense nuclear facilities.*

DOE accepts this sub-recommendation. DOE plans future work on DOE Standard 1027, including an evaluation of DOE–STD–1027–2018, a potential revision of the Standard, and a potential revision to 10 CFR part 830 to incorporate Standard(s) used by the Department for hazard categorization. This work will inform any requirements to be considered for the future. As part of this effort DOE will perform a regulatory analysis to evaluate potential changes to the Rule.

DOE's current approach is consistent with 10 CFR part 830, which allows updates to DOE–STD–1027, such as in DOE–STD–1027–2018, that are consistent with the methodology of DOE–STD–1027–92, Change Notice 1. In DOE's June 11, 2020 response, we noted that if DOE were to propose a new methodology for categorization, DOE would need to undertake a new rulemaking effort that would include proposing the revised methodology for public comment and reference the new Standard that includes the methodology. This remains the case. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 2.c. *Review existing hazard category 3 and below hazard category 3 defense nuclear facilities to confirm they are appropriately categorized.*

DOE accepts this sub-recommendation. The DNFSB's review does not provide sufficient data, nor has DOE's oversight indicated that use of the hazard categorization standards has led to under categorization that would necessitate additional reviews. However, concurrent with DOE's resolution to sub-Recommendation 2.b, DOE will evaluate the nuclear safety management framework (*i.e.,* DOE directives and technical standards) to determine the best approach to establish requirements that would provide greater confidence that defense nuclear facilities, including below hazard category 3 facilities, are appropriately categorized. The Implementation Plan will identify the specific steps that will be taken to address this sub-recommendation.

Sub-Recommendation 3: DOE Approvals

Sub-Recommendation 3.a. *Establish requirements in DOE Standard 1104 for timely periodic DOE reviews of facility safety bases to ensure they meet the requirements of 10 CFR 830.*

DOE accepts this sub-recommendation. DOE commits to evaluating DOE Standard 1104 or other DOE directive(s) and revising directives and technical standards, as necessary, to incorporate DOE's expectations for the review of facility safety bases to ensure they meet the requirements of 10 CFR part 830. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 3.b. *Establish clear requirements in DOE Standard 1104 for DOE approval of JCOs and ESSs for PISAs that result in a positive USQ determination.*

DOE accepts this sub-recommendation. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 3.c. *Update 10 CFR 830 to incorporate the requirements established per items 3.a and 3.b.*

DOE accepts this sub-recommendation with the understanding that while the Department has accepted sub-recommendations 3.a and 3.b, any future resulting requirements can be implemented in several policy documents (*i.e.,* DOE rules, directives, or technical standards) and DOE cannot commit to a specific outcome in a future rulemaking. However, DOE will perform a regulatory analysis to evaluate whether any changes to 10 CFR part 830 should be proposed through a future rulemaking process.

Sub-Recommendation 4: Evaluation of DSA Preparation and Review Processes

Sub-Recommendation 4.a. *Conduct an independent review of contractor and federal processes to identify and evaluate the underlying issues that prevented the annual submittal and approval of high-quality safety basis documents, and use the findings to improve the relevant processes.*

DOE accepts this sub-Recommendation. This sub-Recommendation is related to the Board's concerns with the deletion of the requirement for review and approval of the annual updates to the DSA in the recent 10 CFR part 830 Rulemaking (final Rule published October 19, 2020, 85 FR 66201). DOE's acceptance of this sub-Recommendation does not constitute its agreement that there is a safety concern associated with the October 19, 2020, final Rule, nor that there were underlying safety issues with the annual submittal and approval of high-quality safety basis documents. However, DOE is committed to continuous improvement and will conduct an independent review of the current safety basis development processes to determine whether improvements may be made for future submittals.

Sub-Recommendation 5: Safety Basis Process and Requirements

Sub-Recommendation 5.a. *Establish clear requirements for USQs and JCOs in an order or invoked standard, including elevation of key concepts and guidance from DOE Guide 424.1–1. While developing these requirements, address issues discussed in the Board's letter dated July 10, 2020.*

DOE accepts this sub-recommendation. DOE will evaluate the nuclear safety management framework (*i.e.,* DOE directives and technical standards) to determine the best approach to establish requirements for USQs and JCOs. The Board's July 10, 2020, letter will be considered as part of this effort. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 5.b. *Establish clear requirements for TSRs in an order or invoked standard, including elevation of key concepts and guidance from DOE Guide 423.1–1. While developing these requirements, address issues discussed in DNFSB Technical Report 45, Violations of the Nuclear Safety Basis.*

DOE accepts this sub-recommendation. DOE will evaluate the nuclear safety management framework (*i.e.,* DOE directives and technical standards) to determine the best approach to establish requirements for Technical Safety Requirements. The Board's Technical Report 45 will be considered as part of this effort. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 5.c. *Establish requirements for SACs by invoking DOE Standard 1186 in an appropriate DOE order.*

DOE accepts this sub-recommendation. DOE will evaluate the nuclear safety management framework (*i.e.,* DOE directives and technical standards) to determine the best approach to establish requirements for Specific Administrative Controls. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 5.d. *Update 10 CFR 830 to incorporate the requirements established per items 5.a through 5.c.*

DOE accepts this sub-recommendation with the understanding that while the Department has accepted sub-recommendations 5.a through 5.c, any future resulting requirements can be implemented in several policy documents (*i.e.,* DOE rules, directives, or technical standards) and DOE cannot commit to a specific outcome in a future rulemaking effort. However, DOE will perform a regulatory analysis to evaluate whether any changes to 10 CFR part 830 should be proposed through an additional rulemaking process.

Sub-Recommendation 5.e. *Establish requirements in 10 CFR 830 regarding the concept of defense-in-depth.*

DOE accepts this sub-recommendation with the understanding that while the Department agrees to evaluate the need for additional requirements regarding the concept of defense-in-depth, DOE cannot commit to a specific outcome in a future rulemaking process. However, DOE will perform a regulatory analysis to evaluate whether any changes to 10 CFR part 830 should be proposed through an additional rulemaking process.

[FR Doc. 2021–25269 Filed 11–18–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–223–000.
Applicants: Kern River Gas Transmission Company.
Description: Compliance filing: 2021 NAESB 3.2 to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5078.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–224–000.
Applicants: Northwest Pipeline LLC.
Description: Compliance filing: NAESB 3.2 Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5096.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–225–000.

Applicants: Gulf Shore Energy Partners, LP.
Description: Compliance filing: Gulf Shore Energy Partners LP Order No. 587–Y NAESB Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5100.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–226–000.
Applicants: Honeoye Storage Corporation.
Description: Compliance filing: Compliance Filing Adoption of NAESB Version 3.2 to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5102.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–227–000.
Applicants: RH energytrans, LLC.
Description: Compliance filing: RH energytrans, LLC Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5108.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–228–000.
Applicants: Great Basin Gas Transmission Company.
Description: Compliance filing: NAESB Version 3.2 to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5127.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–229–000.
Applicants: Florida Southeast Connection, LLC.
Description: Compliance filing: Florida Southeast Connection, LLC Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5150.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–230–000.
Applicants: Cameron Interstate Pipeline, LLC.
Description: Compliance filing: Cameron Interstate Pipeline, LLC Compliance Filing—FERC Order 587–Z NAESB 3.2 to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5151.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–231–000.
Applicants: LA Storage, LLC.
Description: Compliance filing: LA Storage, LLC Complianec Filing—FERC Order 587–Z NAESB 3.2 to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5153.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–232–000.
Applicants: MarkWest New Mexico, L.L.C.
Description: Compliance filing: Order No. 587–Z Compliance to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5155.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–233–000.
Applicants: MarkWest Pioneer, L.L.C.
Description: Compliance filing: Order No. 587–Z Compliance to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5158.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–234–000.
Applicants: Rendezvous Pipeline Company, LLC.
Description: Compliance filing: Order No. 587–Z Compliance to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5164.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–235–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5202.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–236–000.
Applicants: Cadeville Gas Storage LLC.
Description: Compliance filing: Cadeville Gas Storage submits Order No. 587–Z Compliance be effective 6/1/2022 to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5203.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–237–000.
Applicants: Mojave Pipeline Company, L.L.C.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5204.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–238–000.
Applicants: Blue Lake Gas Storage Company.
Description: Compliance filing: Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5205.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–239–000.
Applicants: Cheyenne Plains Gas Pipeline Company, L.L.C.
Description: Compliance filing: Order 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5206.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–240–000.
Applicants: Sierrita Gas Pipeline LLC.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5207.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–241–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: Compliance filing: Order 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5210.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–242–000.
Applicants: Ruby Pipeline, L.L.C.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5212.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–243–000.
Applicants: TransColorado Gas Transmission Company LLC.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5213.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–244–000.
Applicants: Colorado Interstate Gas Company, L.L.C.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5217.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–245–000.
Applicants: Young Gas Storage Company, Ltd.
Description: Compliance filing: Order 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5228.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–246–000.
Applicants: Monroe Gas Storage Company, LLC.
Description: Compliance filing: MGS submits Order No. 587–Z Compliance be effective 6/1/2022 to be effective 6/1/2022.
Filed Date: 11/10/21.
Accession Number: 20211110–5233.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: RP22–247–000.
Applicants: Pine Prairie Energy Center, LLC.

Description: Compliance filing: PPEC submits Order No. 587–Z Compliance be effective 6/1/2022 to be effective 11/10/2021.

Filed Date: 11/10/21.

Accession Number: 20211110–5234.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–248–000.

Applicants: SG Resources Mississippi, L.L.C.

Description: Compliance filing: SGRM submits Order No. 587–Z Compliance be effective 6/1/2022 to be effective 6/1/2022.

Filed Date: 11/10/21.

Accession Number: 20211110–5236.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–249–000.

Applicants: Perryville Gas Storage LLC.

Description: Compliance filing: PGS submits Order No. 587–Z Compliance be effective 6/1/2022 to be effective 6/1/2022.

Filed Date: 11/10/21.

Accession Number: 20211110–5237.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: RP22–250–000.

Applicants: Crossroads Pipeline Company.

Description: Compliance filing: Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5000.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–251–000.

Applicants: Tuscarora Gas Transmission Company.

Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5002.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–252–000.

Applicants: Nautilus Pipeline Company, L.L.C.

Description: Compliance filing: NPC Order 587–Z (Docket RM96–1–042) Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5005.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–253–000.

Applicants: Texas Eastern Transmission, LP.

Description: Compliance filing: TETLP Order 587–Z (Docket RM96–1–042) Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5006.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–254–000.

Applicants: Columbia Gas Transmission, LLC.

Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5008.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–255–000.

Applicants: Portland Natural Gas Transmission System.

Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5009.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–256–000.

Applicants: Northern Border Pipeline Company.

Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5010.

Comment Date: 5 p.m. ET 11/24/21.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP20–614–006.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Refund Report: Cash Out Refund Report Docket Nos. RP20–614 & RP20–618 to be effective N/A.

Filed Date: 11/10/21.

Accession Number: 20211110–5055.

Comment Date: 5 p.m. ET 11/22/21.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 15, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–25251 Filed 11–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Privacy Act of 1974; System of Records

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Energy Regulatory Commission (FERC) is publishing notice of modifications to an existing FERC system of records, FERC–24 titled *Commission Miscellaneous Investigation File.* This notice adds 11 new routine uses, including two prescribed by the Office of Management and Budget (OMB) Memorandum M–17–12, *Preparing for and Responding to a Breach of Personally Identifiable Information,* January 3, 2017, that will permit FERC to disclose information as necessary in response to an actual or suspected breach of its own records or to assist another agency in its efforts to respond to a breach. This System of Records Notice (SORN) also describes the Commission's systems manager and location change.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records notice is effective upon publication, with the exception of the routine uses, which will go into effect on December 20, 2021, unless comments have been received from interested members of the public requiring modification and republication of the notice. Please submit any comments by December 20, 2021.

ADDRESSES: Any person interested in commenting on the establishment of this modified system of records may do so by submitting comments electronically to: *Privacy@ferc.gov* (Include reference to ''Commission Miscellaneous Investigation File'' in the subject line of the message.)

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Room 4A–05, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy

Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Director, Workforce Relations, Chief Human Capital Officer, Office of the Executive Director, 888 First Street NE, Washington, DC 20426, (202) 502–6475.

SUPPLEMENTARY INFORMATION: The Commission Miscellaneous Investigation File notice is being modified. The notice includes 11 new routine uses, including two prescribed routine uses that will permit FERC to disclose information as necessary in response to an actual or suspected breach of its own records or to assist another agency in its efforts to respond to a breach. This notice also addresses the system's manager and location change, while also providing additional specificity on the category of employees and employee matters contained in the system of records.

SYSTEM NAME AND NUMBER:

Commission Miscellaneous Investigation File: FERC–24.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Federal Energy Regulatory Commission, Office of the Executive Director, Workforce Relations Division (CHCO), 888 First Street NE, Washington, DC 20426.

SYSTEM MANAGER(S):

Director, Workforce Relations Division, Chief Human Capital Officer, Office of the Executive Director, 888 First Street NE, Washington, DC 20426, (202) 502–6475.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Rehabilitation Act, 29 U.S.C. 791 *et. seq.*

Title VII of the Civil Rights Act, 42 U.S.C. 2000e *et. seq.*

Executive Order No. 13164.

Executive Order No. 13991.

29 CFR part 1614—*Federal Sector Equal Employment Opportunity.*

5 CFR part 735—*Employee responsibilities and conduct.*

PURPOSE(S) OF THE SYSTEM:

To maintain documentation on employee matters that are not part of a formal grievance process require collection of employee information by management in order to process request and/or render decisions in accordance with applicable law, rule or regulation preserve and maintain confidentiality. This may include, among other considerations, requests for reasonable accommodation, medical or religious accommodation, religious compensatory time off, or anti-harassment allegations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

For matters that do not involve a formal grievance or appeal process, or formal Department of Energy Inspector General inquiry, which may include among other matters: (1) Employees requesting exception to agency policy, adjustment to the job or adjustment to the work environment under applicable law, rules or regulations; and (2) employees petitioning for informal inquiry into allegations of workplace harassment not that are not covered under Title VII.

CATEGORIES OF RECORDS IN THE SYSTEM:

Formal reports of inquiry and supporting documentation; records of actions taken resulting from the inquiry and supporting documentation for the inquiry and the response; medical forms, medical documents, documentation from healthcare providers, religious affiliation information, and other related supporting documents; and decision documents.

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the individual to whom it applies; is derived from information supplied by that individual; or created by management officials to summarize findings and/or develop recommendations for action.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, information maintained in this system may be disclosed to authorized entities outside FERC for purposes determined to be relevant and necessary as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) FERC suspects or has confirmed that there has been a breach of the system of records; (2) FERC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To another Federal agency or Federal entity, when FERC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

3. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

4. To the Equal Employment Opportunity Commission (EEOC) when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law or regulation.

5. To the Federal Labor Relations Authority or its General Counsel when requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel.

6. To disclose information to another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, where the record is relevant and necessary to the proceeding and the Government is a party to the judicial or administrative proceeding. In those cases where the Government is not a party to the proceeding, records may be disclosed if a subpoena has been signed by a judge.

7. To the Department of Justice (DOJ) for its use in providing legal advice to FERC or in representing FERC in a proceeding before a court, adjudicative body, or other administrative body, where the use of such information by the DOJ is deemed by FERC to be relevant and necessary to the advice or proceeding, and such proceeding names as a party in interest: (a) FERC; (b) any employee of FERC in his or her official capacity; (c) any employee of FERC in his or her individual capacity where DOJ has agreed to represent the employee; or (d) the United States, where FERC determines that litigation is likely to affect FERC or any of its components.

8. To non-Federal Personnel, such as contractors, agents, or other authorized individuals performing work on a contract, service, cooperative agreement, job, or other activity on behalf of FERC or Federal Government and who have a

need to access the information in the performance of their duties or activities.

9. To the National Archives and Records Administration in records management inspections and its role as Archivist, as permitted by 44 U.S.C. 2904 and 2906.

10. To the Merit Systems Protection Board or the Board's Office of the Special Counsel, when relevant information is requested in connection with appeals, special studies of the civil service and other merit systems, review of Office of Personnel Management (OPM) rules and regulations, and investigations of alleged or possible prohibited personnel practices.

11. To appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the record indicates a violation or potential violation of civil or criminal law, rule, regulation, order.

12. To serve as a data source for OPM or Government Accountability Office (GAO) during the course of on-site inspections or audits.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper (assorted documents) or electronic media. Data center buildings are guarded and monitored by security personnel, cameras, ID checks, and other physical security measures. Physical access to the server rooms is limited to authorized personnel only. Records are maintained in lockable file cabinets in a lockable room with access limited to those employees whose official duties require access; servers are stored in secured facilities in cipher locked server rooms. Computer data is secured by password. The system is secured with the safeguards required by FedRAMP and NIST SP 800–53.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by employee's name or employee ID number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained under the National Archives and Records Administration's General Records Schedule 2.3. Destroy 3 years after being superseded, but longer retention is authorized if required for business use. Destroy 3 years after employee separation from the agency or all matters are concluded, whichever is later, but longer retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All FERC employees and contractors with authorized access have undergone a thorough background security investigation. Data access is restricted to agency personnel or contractors whose responsibilities require access. Access to electronic records is controlled by ''User ID'' and password combination and/or other network access or security controls (*e.g.,* firewalls). The system is secured with the safeguards required by FedRAMP and NIST SP 800–53. Physical access to FERC is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort.

RECORD ACCESS PROCEDURES:

Submit a Privacy Act Request:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended. Privacy requests follow FERC's *Freedom of Information Act (FOIA) request process.* You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.* Written request for access to records should be directed to:

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

CONTESTING RECORD PROCEDURES:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended. Privacy requests follow FERC's *Freedom of Information Act (FOIA) request process.* You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

For questions: Contact the FOIA Service Center at 202–502–6088 or by email at *foia-ceii@ferc.gov.*

Written request for access to records should be directed to:

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

NOTIFICATION PROCEDURES:

The Privacy Act permits access to records about yourself that are maintained by FERC in a Privacy Act system of records. In addition, you may request that incorrect or incomplete information be changed or amended.

Privacy requests follow FERC's *Freedom of Information Act (FOIA) request process.* You may access the FOIA website at *https://www.ferc.gov/freedom-information-act-foia-and-privacy-act.*

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Written request for access to records should be directed to:

For United States Postal Service-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

For hand-delivered or courier-delivered mail: Director, Office of External Affairs, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

FERC–24 Commission Miscellaneous Investigation File was last published at **Federal Register** Vol. 65, No. 79, Monday, April 24, 2000.

Dated: November 16, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–25285 Filed 11–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–15–000.

Applicants: RE Gaskell West LLC, RE Gaskell West 2 LLC, RE Gaskell West 3 LLC.

Description: Joint Application for Authorization Under Section 203 of the

Federal Power Act of RE Gaskell West LLC, et al.

Filed Date: 11/12/21.

Accession Number: 20211112–5373.

Comment Date: 5 p.m. ET 12/3/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4423–003.

Applicants: Lockport Energy Associates, L.P.

Description: Notice of Non-Material Change in Status of Lockport Energy Associates, L.P.

Filed Date: 11/12/21.

Accession Number: 20211112–5387.

Comment Date: 5 p.m. ET 12/3/21.

Docket Numbers: ER20–378–002.

Applicants: Pacific Gas and Electric Company.

Description: Compliance filing: CCSF Calaveras Compliance Filing WDT SA 275 to be effective N/A.

Filed Date: 11/15/21.

Accession Number: 20211115–5145.

Comment Date: 5 p.m. ET 12/6/21.

Docket Numbers: ER22–335–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2021–11–04_SA 3616 Entergy Louisiana-St. Jacques Solar 1st Rev GIA (J1076) to be effective 10/29/2021.

Filed Date: 11/4/21.

Accession Number: 20211104–5073.

Comment Date: 5 p.m. ET 11/26/21.

Docket Numbers: ER22–404–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2021–11–12_Schedule 49 Cost Allocation Filing to be effective 2/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5327.

Comment Date: 5 p.m. ET 12/13/21.

Docket Numbers: ER22–405–000.

Applicants: Midcontinent Independent System Operator, Inc., Michigan Electric Transmission Company, LLC.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 2021–11–15_SA 3746 METC-Cereal City Solar E&P (J1430) to be effective 11/11/2021.

Filed Date: 11/15/21.

Accession Number: 20211115–5081.

Comment Date: 5 p.m. ET 12/6/21.

Docket Numbers: ER22–406–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2021–11–15_SA 3739 NSP-Walleye Wind FSA (J569) to be effective 1/15/2022.

Filed Date: 11/15/21.

Accession Number: 20211115–5083.

Comment Date: 5 p.m. ET 12/6/21.

Docket Numbers: ER22–409–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA, Service Agreement No. 6230; Queue No. AG1–315 to be effective 10/18/2021.

Filed Date: 11/15/21.

Accession Number: 20211115–5149.

Comment Date: 5 p.m. ET 12/6/21.

Docket Numbers: ER22–410–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: UAMPS Const Agmt Lehi North Substation to be effective 1/15/2022.

Filed Date: 11/15/21.

Accession Number: 20211115–5150.

Comment Date: 5 p.m. ET 12/6/21.

Docket Numbers: ER22–411–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Lincoln Electric System Formula Rate Revisions to be effective 1/1/2022.

Filed Date: 11/15/21.

Accession Number: 20211115–5195.

Comment Date: 5 p.m. ET 12/6/21.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH22–1–000.

Applicants: EDF Renewables, Inc.

Description: EDF Renewables, Inc., submits FERC 65–B Notice of Change in Fact and Withdrawal of Waiver Notification.

Filed Date: 11/10/21.

Accession Number: 20211110–5267.

Comment Date: 5 p.m. ET 12/1/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 15, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–25254 Filed 11–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #3

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–291–000.

Applicants: Black Marlin Pipeline LLC.

Description: Compliance filing: Petition for Temporary Exemption from Tariff Revision Filing—Order 587–Z to be effective N/A.

Filed Date: 11/12/21.

Accession Number: 20211112–5116.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–292–000.

Applicants: Trunkline Gas Company, LLC.

Description: Compliance filing: Annual Interruptible Storage Revenue Credit filed 11–12–21 to be effective N/A.

Filed Date: 11/12/21.

Accession Number: 20211112–5126.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–293–000.

Applicants: Cheniere Creole Trail Pipeline, L.P.

Description: Compliance filing: Cheniere Creole Trail Pipeline NAESB 3.2 Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5127.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–294–000.

Applicants: Cheniere Corpus Christi Pipeline, LP.

Description: Compliance filing: Cheniere Corpus Christi Pipeline NAESB 3.2 Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5128.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–295–000.

Applicants: Midship Pipeline Company, LLC.

Description: Compliance filing: Midship Pipeline Company NAESB 3.2 Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5130.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–296–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Order No. 587–Z Compliance (NAESB 3.2) to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5165.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–297–000.
Applicants: Bluewater Gas Storage, LLC.
Description: Compliance filing: Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5170.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–298–000.
Applicants: Stingray Pipeline Company, L.L.C.
Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5175.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–299–000.
Applicants: Empire Pipeline, Inc.
Description: Compliance filing: Empire NAESB v3.2 (Order 587–Z) to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5180.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–300–000.
Applicants: Pine Needle LNG Company, LLC.
Description: § 4(d) Rate Filing: Pine Needle Order No. 587–Z Compliance (NAESB 3.2) to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5184.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–301–000.
Applicants: PPG Shawville Pipeline, LLC.
Description: Compliance filing: NAESB 3.2 standards 2022 to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5186.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–302–000.
Applicants: National Fuel Gas Supply Corporation.
Description: Compliance filing: National Fuel NAESB Version 3.2 (Order No. 587–Z) to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5191.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–303–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Compliance filing: NAESB 3.2 to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5206.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–304–000.
Applicants: Southern Natural Gas Company, L.L.C.
Description: Compliance filing: SNG Operational Transactions Filing to be effective N/A.
Filed Date: 11/12/21.
Accession Number: 20211112–5207.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–305–000.
Applicants: WestGas InterState, Inc.
Description: Compliance filing: RP22–XXXX 587–Z Compliance to be effective 11/12/2021.
Filed Date: 11/12/21.
Accession Number: 20211112–5219.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–306–000.
Applicants: TransCameron Pipeline, LLC.
Description: Compliance filing: Compliance Filing 2022 to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5220.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–307–000.
Applicants: Millennium Pipeline Company, LLC.
Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5221.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–308–000.
Applicants: Kinetica Energy Express, LLC.
Description: Compliance filing: Compliance Filing—FERC Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5256.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–309–000.
Applicants: Kinetica Deepwater Express, LLC.
Description: Compliance filing: Compliance Filing—FERC Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5258.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–310–000.
Applicants: Spire STL Pipeline LLC.
Description: Compliance filing: STL Order 587–Y NAESB Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5262.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–311–000.
Applicants: Freebird Gas Storage, L.L.C.
Description: Compliance filing: Freebird Gas Storage NAESB Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5283.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–312–000.
Applicants: Mississippi Hub, LLC.
Description: Compliance filing: Mississippi Hubs NAESB Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5304.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–313–000.
Applicants: Caledonia Energy Partners, L.L.C.
Description: Compliance filing: Caledonia Energy Partners LLC NAESB Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5306.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–314–000.
Applicants: WTG Hugoton, LP.
Description: Compliance filing: Order No. 587–Z Compliance (NAESB Version 3.2) to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5307.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–315–000.
Applicants: East Cheyenne Gas Storage, LLC.
Description: Compliance filing: East Cheyennes NAESB Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5308.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–316–000.
Applicants: Western Gas Interstate Company.
Description: Compliance filing: Order No. 587–Z Compliance (NAESB Version 3.2) to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5313.
Comment Date: 5 p.m. ET 11/24/21.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/*

docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 15, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–25252 Filed 11–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–257–000.
Applicants: Leaf River Energy Center LLC.
Description: Compliance filing: Leaf River Order No. 587–Z Compliance Filing 11–11–21 to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5012.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–258–000.
Applicants: Spire Storage West LLC.
Description: Compliance filing: Spire Storage West LLC Order No. 587–Z Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5015.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–259–000.
Applicants: Adelphia Gateway, LLC.
Description: Compliance filing: Adelphia Order No. 587–Z Compliance Filing 11–12–21 to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5016.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–260–000.
Applicants: Golden Triangle Storage, Inc.
Description: Compliance filing: Proposed Revisions to FERC Gas Tariff to Comply With Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5021.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–261–000.
Applicants: Kinder Morgan Louisiana Pipeline LLC.
Description: Compliance filing: V2 KMLP NAESB 3.2 to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5022.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–262–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: Compliance filing: Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5023.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–263–000.
Applicants: Cheyenne Connector, LLC.
Description: Compliance filing: CC 2021–11–12 NAESB 3.2 Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5026.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–264–000.
Applicants: Portland General Electric Company.
Description: Compliance filing: NAESB 3.2 Standards Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5027.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–265–000.
Applicants: Rockies Express Pipeline LLC.
Description: Compliance filing: REX 2021–11–12 NAESB 3.2 Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5028.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–266–000.
Applicants: Tallgrass Interstate Gas Transmission, LLC.
Description: Compliance filing: TIGT 2021–11–12 NAESB 3.2 Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5029.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–267–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Compliance filing: TPC 2021–11–12 NAESB Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5030.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–268–000.
Applicants: ANR Pipeline Company.
Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5032.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–269–000.
Applicants: Vector Pipeline L.P.
Description: Compliance filing: NAESB 3.2 Compliance Filing to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5033.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–270–000.
Applicants: Kinder Morgan Illinois Pipeline LLC.
Description: Compliance filing: V2 NAESB 3.2 to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5034.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–271–000.
Applicants: North Baja Pipeline, LLC.
Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5036.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–272–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Compliance Filing Pursuant to Order 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5039.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–273–000.
Applicants: Horizon Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Compliance Filing Pursuant to Order 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5040.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–274–000.
Applicants: Great Lakes Gas Transmission Limited Partnership.
Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5043.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–275–000.
Applicants: Gas Transmission Northwest LLC.
Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5045.
Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–276–000.
Applicants: Hardy Storage Company, LLC.
Description: Compliance filing: NAESB 3.2—Compliance to RM96–1–042—Order No. 587–Z to be effective 6/1/2022.
Filed Date: 11/12/21.
Accession Number: 20211112–5046.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–277–000.

Applicants: Gulfstream Natural Gas System, L.L.C.

Description: Compliance filing: Gulfstream Order 587–Z (Docket RM96–1–042) Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5067.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–278–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: Compliance filing: NAESB Order 587–Z Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5069.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–279–000.

Applicants: Texas Gas Transmission, LLC.

Description: Compliance filing: NAESB Order 587–Z Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5070.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–280–000.

Applicants: Boardwalk Storage Company, LLC.

Description: Compliance filing: NAESB Order 587–Z Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5071.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–281–000.

Applicants: High Island Offshore System, L.L.C.

Description: Compliance filing: NAESB v. 5.0 Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5078.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–282–000.

Applicants: MIGC LLC.

Description: Compliance filing: NAESB V3.2 (Order No. 587–Z) Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5089.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–283–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: Compliance filing: 11.12.21 FERC Order 587–Z (NAESB) v3.2 Compliance Filing to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5095.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–284–000.

Applicants: DBM Pipeline, LLC.

Description: Compliance filing: Order No. 587–Z Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5098.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–285–000.

Applicants: ETC Tiger Pipeline, LLC.

Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5099.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–286–000.

Applicants: Fayetteville Express Pipeline LLC.

Description: Compliance filing: Fayetteville Express Pipeline LLC submits tariff filing per 154.203: NAESB 3.2 Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5103.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–287–000.

Applicants: Transwestern Pipeline Company, LLC.

Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5107.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–288–000.

Applicants: Southwest Gas Storage Company.

Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5108.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–289–000.

Applicants: Gulf States Transmission LLC.

Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5110.

Comment Date: 5 p.m. ET 11/24/21.

Docket Numbers: RP22–290–000.

Applicants: Florida Gas Transmission Company, LLC.

Description: Compliance filing: NAESB 3.2 Compliance to be effective 6/1/2022.

Filed Date: 11/12/21.

Accession Number: 20211112–5114.

Comment Date: 5 p.m. ET 11/24/21.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

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eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 15, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–25253 Filed 11–18–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0466; FRL–9272–01–OCSPP]

Spirodiclofen; Product Cancellation Order for Certain Pesticide Registrations; Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA issued a notice in the **Federal Register** on December 21, 2020 to amend the effective date of cancellation for the two spirodiclofen registrations listed in Table 1B of the cancellation order published in the **Federal Register** on April 13, 2018. The affected registrations for that cancellation order, EPA Registration Nos. 264–830 and 264–831 were registered to Bayer CropScience. The December 21, 2020, notice in the **Federal Register** was issued to amend the cancellation order, as requested by Bayer, by amending the effective date of the cancellation and the existing stocks provision for the two spirodiclofen registrations until December 31, 2021. Subsequent to the issuance of this cancellation order, the two registrations were transferred to the Gowan Company and Gowan has requested that the cancellation order be rescinded. EPA is extending the effective date of cancellation to June 30, 2022 while considering Gowan's request. The cancellation of these two registrations would terminate the last spirodiclofen products registered for use in the United States. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The **Federal Register** of December 21, 2020, announced the voluntary cancellation of two

spirodiclofen registrations (EPA Registration Nos. 264–830 and 264–831) as requested by the registrant, effective December 31, 2021. The Agency is now amending the effective date of cancellation to June 30, 2022.

FOR FURTHER INFORMATION CONTACT: Veronica Dutch, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; telephone number: (202) 566–2352; email address: *dutch.veronica@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0466, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice is being issued to amend the effective date for cancellation the two spirodiclofen registrations (now EPA Registration Nos. 10163–382 and 10163–383) as published in the **Federal Register** on December 21, 2020 (85 FR 83078) (FRL 10017–47). The transfer of these spirodiclofen products to Gowan became effective on March 18, 2021. Gowan committed to develop required data with the intention of maintaining these spirodiclofen registrations in a letter dated October 8, 2020. With this notice, EPA is hereby amending the effective date for cancellation of EPA Registration Nos. 10163–382 and 10163–383 to June 30, 2022. Although Gowan submitted data and waiver requests to EPA as they had committed to do, EPA recently completed draft ecological and human health risk assessments as part of registration review which identified potential cancer dietary (water and food) risks of concern, along with potential ecological risks of concern for certain taxa, including mammals and honeybees. Changes to the spirodiclofen labels are necessary to adequately mitigate those risks. EPA is extending the effective date of cancellation to further consider Gowan's request to rescind the cancellation order. Consistent with the previous cancellation order, the registrant would be prohibited from producing, selling, or distributing existing stocks of products containing spirodiclofen following the cancellation effective date. Other entities would be permitted to sell, distribute, and use stocks of spirodiclofen until stocks are exhausted. The cancellation of these two registrations would terminate the last spirodiclofen products registered for use in the United States.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 15, 2021.

Mary Reaves,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2021–25214 Filed 11–18–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[CERCLA–04–2021–2504; FRL–9143–01–R4]

Horton Iron and Metal Superfund Site, Wilmington, North Carolina, Proposed Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement.

SUMMARY: Under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency is proposing to enter into a settlement with W.R. Grace & Co. Conn concerning the Horton Iron and Metal Superfund Site located in Wilmington, North Carolina. The proposed settlement addresses recovery of CERCLA costs for a cleanup that will be performed at the Site and costs incurred by EPA.

DATES: The Agency will consider public comments on the proposed settlement until December 20, 2021. The Agency will consider all comments received and may modify or withdraw its consent to the proposed settlement if comments received disclose facts or considerations which indicate that the proposed settlement is inappropriate, improper, or inadequate.

ADDRESSES: Copies of the proposed settlement are available from the Agency by contacting Ms. Paula V. Painter, Program Analyst, using the contact information provided in this notice. Comments may also be submitted by referencing the Site's name through one of the following methods:

Internet: https://www.epa.gov/aboutepa/about-epa-region-4-southeast#r4-public-notices

Email: Painter.Paula@epa.gov

FOR FURTHER INFORMATION CONTACT: Paula V. Painter at 404 562–8887.

Maurice Horsey,

Chief, Enforcement Branch, Superfund & Emergency Management Division.

[FR Doc. 2021–25245 Filed 11–18–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9059–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed November 5, 2021 10 a.m. EST Through November 15, 2021 10 a.m. EST

Pursuant to 40 CFR 1506.9

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20210173, Draft Supplement, USACE, WA, Howard A. Hanson Dam Additional Water Storage Project, Section 902 Post Authorization Change Validation Study—Fish Passage, Draft Integrated Validation Report and Supplemental Environmental Impact Statement, Comment Period Ends: 01/04/2022, Contact: Nancy Gleason 206–764–6577.

EIS No. 20210174, Final, FERC, NY, Enhancement by Compression Project, Review Period Ends: 12/20/2021, Contact: Office of External Affairs 866–208–3372.

EIS No. 20210175, Final, WAPA, WY, Rail Tie Wind Project, Review Period Ends: 12/20/2021, Contact: Mark Wieringa 720–962–7448.

EIS No. 20210176, Draft, USFS, UT, Ashley National Forest Plan Revision, Comment Period Ends: 02/17/2022, Contact: Anastasia Allen 406–270–9241.

Dated: November 15, 2021.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2021–25263 Filed 11–18–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2021–0736; FRL–9261–01–OW]

Proposed Information Collection Request; Comment Request; Meat and Poultry Products Industry Data Collection

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''U.S. Environmental Protection Agency Meat and Poultry Products Industry Data Collection'' (EPA ICR No. 2701.01, OMB Control No. 2040–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a request for approval of a new collection. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before January 18, 2022.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OW–2021–0736, online using *www.regulations.gov* (our preferred method), by email to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Stephen Whitlock, Engineering and Analysis Division, Office of Science and Technology, (4303T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–566–1541; email address: *Whitlock.Steve@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA (44 U.S.C. 3501 *et seq*), EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Under the Clean Water Act (CWA), EPA develops effluent limitations guidelines (ELGs) to limit pollutants discharged from industrial point source categories. EPA initially promulgated ELGs for the Meat and Poultry Products (MPP) category in 1974 and amended the regulations in 2004. The current regulation covers wastewater directly discharged by meat and poultry slaughterhouses and further processors as well as independent renderers. Small facilities and indirect dischargers are not included in the current rule.

In EPA's cross-industry review of nutrients in industrial wastewater, the MPP category ranked among the top two industrial categories based on 2018 data, and EPA announced a detailed study of the MPP category in 2020. During the detailed study, EPA collected publicly available data and met with industry trade associations. Based on the detailed study, EPA found that there are existing, affordable technologies that can reduce nutrient concentrations in MPP wastewater. As part of the detailed study, EPA also found that pretreatment standards may be needed as publicly available data shows that pollutants from MPP facilities may passthrough and cause interference for some POTWs.

Publicly available data on MPP facilities is limited. To identify the base population of approximately 7,000 MPP facilities, EPA collected data from the US Department of Agriculture (USDA) Food Safety Inspection Service (FSIS). Using this base population, EPA attempted to find data on MPP wastewater, effluent limits, and treatment technologies by collecting publicly available facility permits and consulting the Integrated Compliance Information System (ICIS) dataset. Available data was limited to only those facilities directly discharging wastewater or individual states that require pretreatment permits to be reported, leaving a large data gap. Thus, a survey of the current MPP industry will be an essential portion of the rulemaking process, necessary for EPA to determine if the current regulations remain appropriate.

The data collection activities described in this Information Collection Request (ICR) will provide a robust dataset that characterizes wastewater generation, treatment, and discharge from MPP facilities. A short questionnaire will be administered as a census of the industry to confirm general information on the type and size (both production and employees) of the facility and gather information on wastewater generation and treatment. To reduce burden on the industry, a statistically representative subset of MPP facilities will complete a detailed survey collecting additional details on processing operations, types and amount of wastewater generated by operation, wastewater treatment details, and economic data. A small number of MPP facilities will also be asked to collect and analyze wastewater samples to characterize raw waste streams,

wastewater treatment systems, and treated effluent for pollutants of interest.

The MPP industry has approximately 7,000 facilities across the country. The current rule contains 11 subparts, as the industry engages in a wide range of activities. Facilities range in size from very small (less than 10 employees) to large (over 500 employees). For EPA to complete the detailed technical and economic analysis for the entire industry necessary for the rulemaking process, the short questionnaire, detailed questionnaire, and sampling activities are essential.

Confidential Business Information (CBI) may be collected. In accordance with 40 CFR part 2, subpart B, section 2.203, the MPP Surveys inform respondents of their right to claim information as confidential. Each survey provides instructions for claiming confidentiality and informs respondents of the terms and rules governing the protection of CBI under the Clean Water Act and 40 CFR 2.203. Survey respondents are able to and are requested to mark any claimed confidential responses as CBI. EPA and its contractors will follow EAD's existing procedures to protect data labeled as CBI.

Form Numbers: None.

Respondents/affected entities: All Meat and Poultry Products facilities in the U.S., which includes facilities with the following NAICS codes: 311611, 311612, 311613, 311615, 311111, 311119, 311999. 1,633 facilities will receive the detailed questionnaire, 5,367 facilities will receive the short questionnaire, and no more than 20 facilities will be asked to conduct specific wastewater sampling events.

Respondent's obligation to respond: Mandatory (Clean Water Act section 308) (citing authority).

Estimated number of respondents: 7,000 (total).

Frequency of response: One-time data collection.

Total estimated respondent burden: 70,807 hours. Burden is defined at 5 CFR 1320.03(b).

Total estimated respondent cost: $3,219,484 one-time cost.

Changes in Estimates: This is a new data collection request and is a one-time temporary increase to the Agency's burden.

Deborah Nagle,

Director, Office of Science and Technology, Office of Water.

[FR Doc. 2021–25295 Filed 11–18–21; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

Sunshine Act Meetings

Notice of Open Meeting of the Advisory Committee of the Export-Import Bank of the United States (EXIM).

TIME AND DATE: Thursday, November 18th, 2021 from 1:30–4:00 p.m. EDT.

PLACE: The meeting will be held virtually.

STATUS: Public Participation: The meeting will be open to public participation and time will be allotted for questions or comments submitted online. Members of the public may also file written statements before or after the meeting to *external@exim.gov.* Interested parties may register below for the meeting.

https://teams.microsoft.com/registration/PAFTuZHHMk2Zb1GDkIVFJw,5M1LfonJMEi2VFUgYRv6oQ,i145n2l9vkmDj5btNlkuGw,6pffizIY90ejfY7ZxOQxYA,rpZ5FoIsIUSTq6hUxDUGrQ,ALPUR1YOwUOm02kL5pavxw?mode=read&tenantId=b953013c-c791-4d32-996f-518390854527.

MATTERS TO BE CONSIDERED: Discussion of EXIM policies and programs to provide competitive financing to expand United States exports and comments for inclusion in EXIM's Report to the U.S. Congress on Global Export Credit Competition.

CONTACT PERSON FOR MORE INFORMATION: For further information, contact India Walker, External Enagagement Specialist, at 202–480–0062 or at *india.walker@exim.gov.*

Joyce B. Stone,

Assistant Corporate Secretary.

[FR Doc. 2021–25385 Filed 11–17–21; 11:15 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2021–6045]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received on or before December 20, 2021 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* (EIB 95–09) or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20038 Attn: OMB 3048–EIB 95–09. The form can be reviewed at *https://www.exim.gov/sites/default/files/pub/pending/95-09-li.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Donna Schneider <*donna.schneider@exim.gov*>, 202–565–3612.

SUPPLEMENTARY INFORMATION: The Letter of Interest (LI) is an indication of Export-Import (EXIM) Bank's willingness to consider financing a given export transaction. EXIM uses the requested information to determine the applicability of the proposed export transaction and determines whether or not to consider financing that transaction.

Title and Form Number: EIB 95–09 Letter of Interest Application.

OMB Number: 3048–0005.

Type of Review: Regular.

Need and Use: The Letter of Interest (LI) is an indication of Export-Import (EXIM) Bank's willingness to consider financing a given export transaction. EXIM uses the requested information to determine the applicability of the proposed export transaction system prompts and determines whether or not to consider financing that transaction.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 400.

Estimated Time per Respondent: 0.75 hours.

Annual Burden Hours: 300.

Frequency of Reporting of Use: On occasion.

Government Expenses:

Reviewing Time per Year: 400.

Average Wages per Hour: $42.50.

Average Cost per Year: $17,000 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $20,400.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–25237 Filed 11–18–21; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on the Annual Report for Fiscal Year 2021 and Three-Year Plan

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued its *Annual Report for Fiscal Year 2021 and Three-Year Plan.* Respondents are encouraged to comment on the content of the annual report and FASAB's project priorities for the next three years. Written comments are requested by January 18, 2022, and should be sent to *fasab@fasab.gov* or Ms. Monica R. Valentine, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW, Suite 1155, Washington, DC 20548.

ADDRESSES: *The Annual Report for Fiscal Year 2021 and Three-Year Plan* is available on the FASAB website at *https://www.fasab.gov/our-annual-reports/*. Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. app.), and the FASAB Rules of Procedure, as amended in October 2010.

Dated: November 15, 2021.

Monica R. Valentine,

Executive Director.

[FR Doc. 2021–25305 Filed 11–18–21; 8:45 am]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0261 and OMB 3060–0270; FR ID 58121]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it can further reduce the information collection burden for small business concerns with fewer than 25 employees.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before December 20, 2021.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0261.

Title: Section 90.215, Transmitter Measurements.

Form No.: Not applicable.

Frequency of Response: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions and state, local or tribal Government.

Number of Respondents: 150,081 respondents; 234,439 responses.

Estimated Time per Response: .033 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in *47 U.S.C. 303(f)* of the Communications Act of 1934, as amended.

Total Annual Burden: 7,727 hours.

Total Annual Cost: No cost.

Needs and Uses: The information collection requirements contained in Section 90.215 require station licensees to measure the carrier frequency, output power, and modulation of each transmitter authorized to operate with power in excel of two watts when the transmitter is initially installed and when any changes are made which would likely affect the modulation characteristics. Such measurements, which help ensure proper operation of transmitters, are to be made by a qualified engineering measurement service, and are required to be retained in the station records, along with the name and address of the engineering measurement service, and the name of

the person making the measurements. The information is normally used by the licensee to ensure that equipment is operating within prescribed tolerances. Prior technical operation of transmitters helps limit interference to other users and provides the licensee with the maximum possible utilization of equipment.

OMB Control No.: 3060–0270.

Title: Section 90.443, Content of Station Records.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 166,658 respondents; 166,658 responses.

Estimated Time per Response: .25 hours.

Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in *47 U.S.C. Section 303(j),* as amended.

Total Annual Burden: 61,665 hours.

Annual Cost Burden: No cost.

Needs and Uses: The information collection requirements contained under Section 90.443(b) require that each licensee of a station shall maintain records for all stations by providing the dates and pertinent details of any maintenance performed on station equipment, along with the name and address of the service technician who did the work. If all maintenance is performed by the same technician or service company, the name and address need be entered only once in the station records.

The information collection requirements under Section 90.443(c) require that at least one licensee participating in the cost arrangement must maintain cost sharing records.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–25222 Filed 11–18–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1214; FR ID 58561]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before January 18, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1214.

Title: Direct Access to Numbers Order, FCC 15–70, Conditions.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 30 respondents; 30 responses.

Estimated Time per Response: 10–20 hours.

Frequency of Response: One-time; on-going and bi-annual reporting requirements.

Obligation to Respond: Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. 251(e)(1).

Total Annual Burden: 1,200 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: If respondents submit information which respondents believe is confidential, respondents may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules, 47 CFR 0.459.

Needs and Uses: In a June 2015 Report and Order (FCC 15–70), the Commission established the Numbering Authorization Application process, which allows interconnected VoIP providers to apply for a blanket authorization from the FCC that, once granted, will allow them to demonstrate that they have the authority to provide service in specific areas, thus enabling them to request numbers directly from the Numbering Administrator. This collection covers the information and certifications that applicants must submit in order to comply with the Numbering Authorization Application process. The data, information, and documents acquired through this collection will allow interconnected VoIP providers to obtain numbers with minimal burden or delay while also preventing providers from obtaining numbers without first demonstrating that they can deploy and properly utilize such resources. This information will also help the Federal Communications Commission (FCC) protect against number exhaust while promoting competitive neutrality among traditional telecommunications carriers and interconnected VoIP providers by allowing both entities to obtain numbers directly from the Numbering Administrator. It will further help the FCC to maintain efficient utilization of numbering resources and ensure that telephone numbers are not being stranded.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–25221 Filed 11–18–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Thursday, December 2, 2021 at 10:00 a.m.

PLACE: Virtual hearing. Note: Because of the COVID–19 pandemic, we will conduct the hearing virtually. If you would like to access the hearing, see the instructions below.

STATUS: This hearing will be open to the public. To access the virtual hearing, go to the commission's website *www.fec.gov* and click on the banner to be taken to the hearing page.

MATTERS TO BE CONSIDERED: Audit Hearing: Democracy Engine, Inc. PAC.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer; Telephone: (202) 694–1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2021–25395 Filed 11–17–21; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 6, 2021.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Maria Blanca del Valle Perochena and Maria de Guadalupe del Valle Perochena, both of Mexico City, Mexico;* to become limited partners in MBG Investors I, L.P., Ontario, Canada, and thereby indirectly acquire voting shares of Byline Bancorp, Inc. and Byline Bank, both of Chicago, Illinois.

B. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *The Jerome Hageman Stock Trust 2020, Stephen Hageman, as trustee, both of Watertown, South Dakota;* to join the Hageman Family Control Group, a group acting in concert, to retain voting shares of Plains Commerce Financial, Inc., and thereby indirectly retain shares of Plains Commerce Bank, both of Hoven, South Dakota.

2. *Pamela J. Bjerke, Rice, Minnesota;* to acquire control of the voting shares of Stearns Financial Services, Inc. (Stearns), by becoming a co-trustee of the Stearns Financial Services, Inc. Employee Stock Ownership Plan and Trust, both of St. Cloud, Minnesota, which owns Stearns, and thereby indirectly owns Stearns Bank N.A., St. Cloud, Minnesota; Stearns Bank of Upsala, N.A., Upsala, Minnesota; and Stearns Bank of Holdingford, N.A., Holdingford, Minnesota.

Board of Governors of the Federal Reserve System, November 16, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–25312 Filed 11–18–21; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice–PCSCOTUS–2021–01; Docket No. PCSCOTUS–2021–0001; Sequence No. 6]

Office of Asset and Transportation Management; Presidential Commission on the Supreme Court of the United States; Notification of Upcoming Public Virtual Meeting and Request for Public Comment

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Request for public comment; meeting notice.

SUMMARY: GSA is accepting written public comments on the work of the Presidential Commission on the Supreme Court of the United States (Commission). Further, GSA is providing notice of an open public virtual meeting of the Commission in accordance with the requirements of the Federal Advisory Committee Act. The purpose of this meeting is for the Commissioners to review the draft Commission Report and vote on its submission to the President pursuant to Executive Order 14023. This meeting is open to the public and will be live-streamed at *www.whitehouse.gov/pcscotus/.* Materials relevant to the public meeting will be posted at *www.whitehouse.gov/pcscotus/* prior to the meeting.

DATES: The Commission will hold a public virtual meeting on December 7, 2021 from 3:00 p.m. to 4:30 p.m., Eastern Standard Time (EST).

ADDRESSES: This meeting will be conducted virtually on the internet. Interested individuals must register to attend as instructed below.

Procedures for Attendance and Public Comment

Attendance. This meeting is open to the public and the Commission encourages the public's attendance. To attend this public virtual meeting, please send an email with the Subject: Registration. In the body of the email, provide your full name, organization (if applicable), email address, and phone number to the Designated Federal Officer, at *info@pcscotus.gov.* Registration requests must be received by 5:00 p.m. EST, on December 3, 2021. Registrations received after this day/time may not be processed.

Public Comments. Written public comments are being accepted via *http://www.regulations.gov,* the Federal eRulemaking portal through December 15, 2021. No comments will be accepted after December 15, 2021.

To submit a written public comment, go to *http://www.regulations.gov* and search for PCSCOTUS–2021–0001. Then, click on the ''Comment'' button that shows up in the search results. Select the link ''Comment'' that corresponds with this notice. Follow the instructions provided on the screen. Please include your name, company name (if applicable), and ''PCSCOTUS–2021–0001, Notification of Upcoming Public Virtual Meeting and Request for Public Comment'' on your attached document (if applicable). Public comments meeting our public comment policy, included under **SUPPLEMENTARY INFORMATION**, will be shared on *Regulations.gov.* Comments provided by 5:00 p.m. EST, on December 3, 2021

will be provided to the Commission members in advance of the December 7 public meeting. Comments submitted after this date will still be provided to the Commission members, but please be advised that Commission members may not have adequate time to consider the comments prior to the meeting.

Special accommodations. For information on services for individuals with disabilities, or to request accommodation of a disability, please contact the Designated Federal Officer at least 10 business days prior to the meeting to give GSA as much time as possible to process the request.

FOR FURTHER INFORMATION CONTACT: For information on the public virtual meeting, contact Dana Fowler, Designated Federal Officer, Office of Government-wide Policy, General Services Administration, at *info@pcscotus.gov,* 202–501–1777.

SUPPLEMENTARY INFORMATION:

Background

The Administrator of GSA established the Commission under the Federal Advisory Committee Act on April 26, 2021 pursuant to *Executive Order 14023, Establishment of the Presidential Commission on the Supreme Court of the United States,* issued on April 9, 2021. Per the Executive Order, the Commission shall produce a report for the President that includes the following:

(i) An account of the contemporary commentary and debate about the role and operation of the Supreme Court in our constitutional system and about the functioning of the constitutional process by which the President nominates and, by and with the advice and consent of the Senate, appoints Justices to the Supreme Court;

(ii) The historical background of other periods in the Nation's history when the Supreme Court's role and the nominations and advice-and-consent process were subject to critical assessment and prompted proposals for reform; and

(iii) An analysis of the principal arguments in the contemporary public debate for and against Supreme Court reform, including an appraisal of the merits and legality of particular reform proposals.

Public Comment Policy

The Commission asks that written public comments be respectful and relevant to the work of the Commission. All comments are reviewed before they are shared with the Commission or posted online. Comments that include the following will not be shared on *Regulations.gov:*

- Vulgar, obscene, profane, threatening, or abusive language; personal attacks of any kind.
- Discriminatory language (including hate speech) based on race, national origin, age, gender, sexual orientation, religion, or disability.
- Endorsements of commercial products, services, organizations, or other entities.
- Repetitive posts (for example, if you submit the same material multiple times).
- Spam or undecipherable language (gratuitous links will be viewed as spam).
- Copyrighted material.
- Links to external sites.
- Images or videos.
- Solicitation of funds.
- Procurement-sensitive information.
- Surveys, polls, and questionnaires subject to the Office of Management and Budget Paperwork Reduction Act clearance.
- Personally Identifiable Information (PII) or Sensitive Information (SI).
- Off-topic posts.
- Media inquiries.

Thank you for your interest in the Presidential Commission on the Supreme Court of the United States. We look forward to hearing from you.

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2021–25315 Filed 11–18–21; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0106; NIOSH–344]

Interventions To Prevent Work-Related Stress and Support Health Worker Mental Health; Request for Information; Extension of Public Comment Period.

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Extension of public comment period.

SUMMARY: On September 27, 2021, the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), published a notice announcing an opportunity for the public to provide information and comments on current evidence-based, workplace and occupational safety and health interventions to prevent work-associated stress, support stress reduction, and foster positive mental health and well-being among the nation's health workers. Written and electronic comments were to be received on or before November 26, 2021. NIOSH has decided to extend the comment period to January 25, 2022.

DATES: Comments must be received on or before January 25, 2022.

ADDRESSES: Comments may be submitted through either of the following two methods:

- *Federal eRulemaking Portal: http://www.regulations.gov* (follow the instructions for submitting comments), or
- *By Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS C–34, 1090 Tusculum Avenue, Cincinnati, Ohio 45226–1998.

Instructions: All written submissions received in response to this notice must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC–2021–0106; NIOSH–344) for this action. All relevant comments, including any personal information provided, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst; 1090 Tusculum Ave., MS: C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the American Rescue Plan Act of 2021 (Pub. L. 117–2, sec. 2704), CDC is charged with educating health workers and first responders on primary prevention of mental health conditions and substance use disorders and encouraging these professionals to identify and seek support for their own mental health or substance use concerns. Accordingly, on September 27, 2021, CDC's National Institute for Occupational Safety and Health (NIOSH) announced an opportunity for the public to provide information and comments on evidence-based workplace and occupational safety and health interventions, policies, or other activities relevant to health care professionals and first responders, including those at the population, organizational, or individual levels (86 FR 53306). Information and comments were requested on related interventions under development and research in progress. NIOSH also sought information on related best practices, promising practices, or successful programs related to providing stress prevention and mental health services

to health workers. The September 27, 2021 request for information is available in docket CDC–2021–0106, which can be found by searching *www.regulations.gov.*

NIOSH believes it is appropriate to allow additional time for public comment. Accordingly, the public comment period for the request for information is extended to January 25, 2022.

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2021–25235 Filed 11–18–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC); Notice of Charter Renewal

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 5, 2023.

FOR FURTHER INFORMATION CONTACT: Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341, Telephone: (770) 488–1279; Email address: *AGreenspan@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–25290 Filed 11–18–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Center for Preparedness and Response (BSC, CPR); Notice of Charter Renewal

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, Center for Preparedness and Response (BSC, CPR), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 5, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lochner, ScD, Designated Federal Officer, BSC, CPR, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road NE, Mailstop H21–6, Atlanta, Georgia 30329–4027, Telephone: (404) 718–3420; Email address: *KLochner@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–25293 Filed 11–18–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Center for Preparedness and Response, (BSC, CPR)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, Center for Preparedness and Response, (BSC, CPR). This is a virtual meeting that is open to the public, limited only by the number of internet conference accesses available, which is 500. Pre-registration is required by accessing the link in the addresses section.

DATES: The meeting will be held on December 16, 2021, from 1:00 p.m. to 2:00 p.m., EST.

ADDRESSES: Zoom Virtual Meeting. If you wish to attend the virtual meeting, please pre-register by accessing the link at: *https://cdc.zoomgov.com/webinar/register/WN_-FzSni59TTS2AnYR4x1a7w.* Instructions to access the Zoom virtual meeting will be provided in the link following registration.

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Office of Science and Public Health Practice, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop–H21–6, Atlanta, Georgia 30329–4027, Telephone: (404) 639–7450; Facsimile: (678) 669–1667; Email: *DOuisley@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Center for Preparedness and Response (CPR), concerning strategies and goals for the programs and research within CPR, monitoring the overall strategic direction and focus of the CPR Divisions and Offices, and administration and oversight of peer review for CPR scientific programs. For additional information about the Board, please visit: *https://www.cdc.gov/cpr/bsc/index.htm.*

Matters To Be Considered: The agenda will include: Strategic Capacity

Building and Innovation Program: Update and Program Review Working Group deliberation. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–25288 Filed 11–18–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID); Notice of Charter Renewal

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, Deputy Director for Infectious Diseases (BSC, DDID), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through October 31, 2023.

FOR FURTHER INFORMATION CONTACT: Hilary Eiring, MPH, Designated Federal Officer, BSC, DDID, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road NE, Mailstop H24–12, Atlanta, Georgia 30329–4027, Telephone: (770) 488–3901; Email address: *HEiring@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–25289 Filed 11–18–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0125]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on November 19, 2021, from 12:00 p.m. to 3:00 p.m., EST (times subject to change). The public may submit written comments from November 19, 2021 through November 22, 2021.

ADDRESSES: You may submit comments identified by Docket No. CDC–2021–0125 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027, Attn: ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

Written public comments submitted up to 72 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, Georgia 30329–4027; Telephone: (404) 639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: *http://www.cdc.gov/vaccines/acip/index.html.* In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be Considered: The agenda will include discussions on COVID–19 vaccine booster doses. A vote on COVID–19 booster doses is scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or

supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on November 19, 2021. Written comments must be received on or before November 22, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the November 19, 2021 ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EST, November 18, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 9:00 a.m., EST, on November 19, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–25387 Filed 11–17–21; 11:15 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10157]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 18, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10157—The HIPAA Eligibility Transaction System (HETS)

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The HIPAA Eligibility Transaction System (HETS); *Use:* CMS created the HETS application to provide Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant 270/271 health care

eligibility inquiries (270) and responses (271) on a real-time basis. In creating the HETS application, federal law requires that CMS take precautions to minimize the security risk to federal information systems. Accordingly, CMS is requiring that trading partners who wish to connect to the HETS 270/271 application via the CMS Extranet and/or internet agree to specific trading partner terms as a condition of receiving access to Medicare eligibility information. Applicants will complete the entire Trading Partner Agreement form to indicate agreement with CMS trading partner terms and provide sufficient information to establish connectivity to the service and assure that those entities that access the Medicare eligibility information are aware of applicable provisions and penalties for the misuse of information.

CMS uses the Trading Partner Agreement Form to capture certain information whereby a person certifies that they are fully aware of any and all penalties related to the use of PHI and their access to this data from the HETS application. The information is an attestation by the authorized representative of an entity that wishes to access the Medicare eligibility information to conduct real-time eligibility transactions. The authorized representative is a person responsible for business decisions on behalf of the Organization who is submitting the access request. The data captured includes the authorized representative's name, title contact number and the name of the submitting entity. Other data captured is the submitter's National Provider Identifier (NPI), business name, billing address, physical address, and telephone number. *Form Number:* CMS–10157 (OMB control number: 0938–0960); *Frequency:* Annually; *Affected Public:* Private Sector, Businesses or other for-profits; *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 250. (For policy questions regarding this collection contact Rupinder Singh at 410–786–7484.)

Dated: November 16, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–25318 Filed 11–18–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10341 and CMS–10653]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 20, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428; *Use:* This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. *Form Number:* CMS–10341 (OMB control number: 0938–1162); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 48; *Total Annual Responses:* 403; *Total Annual Hours:* 41,847. (For policy questions regarding this collection contact Tonya Moore at 410–786–0019.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Coverage of Certain Preventive Services Under the Affordable Care Act; *Use:* The 2018 final regulations titled ''Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (83 FR 57536) and ''Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the

Affordable Care Act'' (83 FR 57592) expand exemptions for religious beliefs and moral convictions for certain entities or individuals whose health plans may otherwise be subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. The final regulations extend the exemption to health insurance issuers that hold religious or moral objections in certain circumstances, as well as to additional categories of group health plan sponsors.

The 2018 final regulations also leave the accommodation process in place as an optional process for objecting entities who wish to use it, and expand the categories of group health plan sponsors that may avail themselves of the accommodation. To avoid contracting, arranging, paying, or referring for contraceptive coverage, an organization seeking to be treated as an eligible organization may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization. The eligible organization must provide a copy of its self-certification to each health insurance issuer that would otherwise provide such coverage in connection with the health plan (for insured group health plans or student health insurance coverage). The issuer that receives the self-certification must provide separate payments for contraceptive services for plan participants and beneficiaries (or students and dependents). For a self-insured group health plan, the self-certification must be provided to its third party administrator. An eligible organization may submit a notification to HHS as an alternative to submitting EBSA Form 700 to the eligible organization's health insurance issuer or third party administrator. A health insurance issuer or third party administrator providing or arranging payments for contraceptive services for participants and beneficiaries in plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations must provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

Under the 2018 final regulations, eligible organizations can revoke the accommodation process if participants and beneficiaries (or student enrollees and covered dependents) receive written notice of such revocation from the issuer or third party administrator, and such revocation will be effective on the first day of the first plan year that begins on or after thirty days after the date of revocation. Final regulations were published in the **Federal Register** on July 14, 2015 (80 FR 41318) under which qualifying closely held, for-profit entities may avail themselves of the accommodation. Previously, this accommodation had been available only to non-profit eligible organizations. The 2015 final regulations also finalized the 2014 interim final regulations that permit an eligible organization to notify HHS directly that it will not contract, arrange, pay, or refer for all or a subset of contraceptive services. These information collection requirements (ICRs) are intended for use under whichever accommodation process is in effect at the time an entity avails of it (for example, the 2018 final regulations, or the 2015 final regulations). HHS will only implement the ICRs under regulations that are legally in effect at the time the ICRs are used. *Form Number:* CMS–10653 (OMB Control number 0938–1344); *Frequency:* On Occasion; *Affected Public:* Private Sector; *Number of Respondents:* 60; *Number of Responses:* 595,312; *Total Annual Hours:* 72. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410–786–6650.)

Dated: November 16, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–25316 Filed 11–18–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 20, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0728. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

OMB Control Number 0910–0728—Extension

The definition of ''food'' under the Federal Food, Drug, and Cosmetic Act (FD&C Act (21 U.S.C. 321(f))) includes ''articles used for food or drink'' and thus includes alcoholic beverages. As such, alcoholic beverages are subject to the FD&C Act's adulteration and misbranding provisions and implementing regulations related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the registration of food facilities requirements in 21 CFR part 1 and to the good manufacturing practice regulations in 21 CFR part 110. There are also certain requirements for nutrition labeling on menus, menu boards, and other written materials for alcohol beverages served in restaurants or similar retail food establishments in 21 CFR part 101. However, as reflected in a 1987 Memorandum of Understanding between FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB), TTB is responsible for the dissemination and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages issued in the Federal Alcohol Administration Act (the FAA Act). In TTB Ruling 2008–3, dated July 7, 2008, TTB clarified that certain beers, which are not made from both malted

barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice, or wheat) or are made without hops, do not meet the definition of a ''malt beverage'' under the FAA Act. Accordingly, TTB stated in its ruling that such products (other than saké, which is classified as a wine under the FAA Act), are not subject to the labeling, advertising, or other provisions of TTB regulations issued under the FAA Act.

In cases where an alcoholic beverage is not covered by the labeling provisions of the FAA Act, the product is subject to ingredient and other labeling requirements under the FD&C Act and the implementing regulations that we administer. In addition, as provided for under the Fair Packaging and Labeling Act (FPLA), alcoholic beverages that are not covered by the labeling provisions of the FAA Act are subject to the provisions of the FPLA, which we administer.

Therefore, the beers described in TTB's ruling as not being a ''malt beverage'' are subject to the labeling requirements under the FD&C Act and FPLA, and our implementing regulations. In general, we require that food products under our jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act, the FPLA, and FDA's regulations. Furthermore, some TTB labeling requirements, such as the Government Health Warning Statement under the Alcoholic Beverage Labeling Act and certain marking requirements under the Internal Revenue Code, continue to apply to these products.

Persons with access to the internet may obtain the guidance entitled ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration,'' located at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-labeling-certain-beers-subject-labeling-jurisdiction-food-and-drug-administration.* This guidance is intended to assist manufacturers on how to label bottled or otherwise packaged beers that are subject to our labeling laws and regulations.

Our food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the FPLA (15 U.S.C. 1453, 1454, and 1455) and under sections 201, 301, 402, 403, 409, 411, 701, and 721 of the FD&C Act (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the FD&C Act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the FD&C Act and the FPLA.

The primary user of the information to be disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to assist them in making choices concerning their purchase of a food product, including choices related to substances that the consumer must avoid to prevent adverse reactions. This information also enables the consumer to determine the role of the food product in a healthful diet. Additionally, FDA intends to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory and regulatory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403 of the FD&C Act and parts 101, 102, 104, and 105 of FDA's food labeling regulations may result in a product being misbranded under the FD&C Act, subjecting the firm and product to regulatory action.

Description of Respondents: The respondents to this collection of information are manufacturers of beers that are subject to our labeling laws and regulations.

In the **Federal Register** of May 21, 2021 (86 FR 27631), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received two comments pertaining to the necessity and practical utility of the information being collected and the accuracy of our burden estimate.

(Comment 1) One comment questioned the necessity and practical utility of treating beer as a ''food'' making it subject to food labeling regulations. A related comment questioned the need to label beer at all.

(Response) As stated in the guidance as well in the above-referenced 60-day notice, the definition of ''food'' under the FD&C Act (see 21 U.S.C. 321(f)), includes ''articles used for food or drink'' and thus includes alcoholic beverages. In cases where an alcoholic beverage is not covered by the labeling provisions of the FAA Act, the product is subject to ingredient and other labeling requirements under the FD&C Act and the implementing regulations that are administered by FDA. In addition, as provided for under the FPLA, alcoholic beverages that are not covered by the labeling provisions of the FAA Act are subject to the provisions of the FPLA, which is administered by FDA.

Therefore, the beers described in the TTB's Ruling as not being a ''malt beverage'' are subject to the labeling requirements under the FD&C Act and FPLA, and FDA's implementing regulations. In general, FDA requires that food products under its jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act, the FPLA, and FDA's regulations.

The primary user of the information to be disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to assist them in making choices concerning their purchase of a food product, including choices related to substances that the consumer must avoid to prevent adverse reactions. This information also enables the consumer to determine the role of the food product in a healthful diet.

(Comment 2) One comment argued that the burden estimate underestimated the number of respondents affected by this collection.

(Response) This collection of information applies to alcoholic beverages not covered by the labeling provisions of the FAA Act. Our estimate of the number of respondents is based on the number of regulatory submissions to TTB for beers that do not meet the definition of a ''malt beverage'' under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTB estimates the annual number of respondents to be 12.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
101.3 and 101.22; statement of identity labeling requirements	12	2	24	0.5 (30 minutes)	12
101.4; ingredient labeling requirements	12	2	24	1	24
101.5; requirement to specify the name and place of business of the manufacturer, packer, or distributor.	12	2	24	0.25 (15 minutes)	6
101.9; labeling requirements for disclosure of nutrition information	12	2	24	4	96
101.7; declaration of net quantity of contents	12	2	24	0.5 (30 minutes)	12
Section 403(w)(1) of the FD&C Act; declaration of food allergens	12	2	24	1	24
Guidance document entitled ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration''.	12	1	12	1	12
Total					186

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimate of the number of respondents is based on the number of regulatory submissions to TTB for beers that do not meet the definition of a ''malt beverage'' under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTB estimates the annual number of respondents to be 12 and the annual number of disclosures to be 24.

Our estimates of the average burden per disclosure for each collection provision are based on our experience with food labeling under the Agency's jurisdiction. The estimated average burden per disclosure for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.7 (21 CFR 101.3, 101.4, 101.5, 101.9, 101.22, and 101.7) are equal to, and based upon, the estimated average burden per disclosure approved by OMB control number 0910–0381. We further estimate that the labeling burden of section 403(w)(1) of the FD&C Act, which specifies requirements for the declaration of food allergens, will be 1 hour based upon the similarity of the requirements to that of § 101.4. Finally, we estimate that a respondent will spend 1 hour reading the guidance.

The guidance also refers to previously approved collections of information found in our regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.7 have been approved under OMB control number 0910–0381. Allergen labeling of these beers under section 403(w)(1) of the FD&C Act, which was added by the Food Allergen Labeling and Consumer Protection Act of 2004, has been approved under OMB control number 0910–0792.

Dated: November 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25300 Filed 11–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1192]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with provisions of the notification procedure for substances generally recognized as safe (GRAS).

DATES: Submit either electronic or written comments on the collection of information by January 18, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as

well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–1192 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170, Subpart E and 21 CFR 570, Subpart E

OMB Control Number 0910–0342—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all food additives (as defined by section 201(s) (21 U.S.C. 321(s)) be approved by FDA before they are marketed. Section 409 of the FD&C Act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives.'' Section 201(s) of the FD&C Act provides an exclusion to the definition of food additive and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in 21 CFR part 170 (part 170) and 21 CFR part 570 (part 570) for human food and animal food, respectively. Part 170, subpart E and part 570, subpart E provide a standard format for the submission of a notice. This collection utilizes a voluntary administrative procedure for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human food or animal food. The information submitted to us in a GRAS notice is necessary to allow us to administer efficiently the FD&C Act's various provisions that apply to the use of substances added to food, specifically with regard to whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review. We use the information collected through the GRAS notification procedures to complete our evaluation within specific timelines.

To assist respondents with submissions to the Center for Food Safety and Applied Nutrition, we offer Form FDA 3667 entitled ''Generally Recognized as Safe Notice'' (*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM350015.pdf*). The form, and elements prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (*https://www.fda.gov/industry/electronic-submissions-gateway*), or may be submitted in paper format, or as electronic files on physical media with paper signature page. While we do not expect Form FDA 3667 to reduce reporting time for respondents, use of the form helps to expedite our review of the information being submitted. For submissions to the Center for Veterinary Medicine, respondents may continue to send GRAS notices in letter format to the Agency, as instructed in the **Federal Register** of June 4, 2010 (75 FR 31800).

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in human food and animal food and feed.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food; 170.210–170.280 (part 170, subpart E)	100	1	100	170	17,000
GRAS notification procedure for animal food and animal feed; 570.210–570.280 (part 570, subpart E)	25	1	25	170	4,250
Total			125		21,250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years, which has remained constant.

Dated: November 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25302 Filed 11–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3404]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA's Generic Drug User Fee Program.

DATES: Submit either electronic or written comments on the collection of information by January 18, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3404 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://*

www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Drug User Fee Program

OMB Control Number 0910–0727—Revision

This information collection supports implementation of FDA's Generic Drug User Fee program. The Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title 111) were enacted to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA authorizes FDA to assess user fees to fund critical and measurable enhancements to the performance of FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. GDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. For more information regarding GDUFA and ongoing implementation, we invite you to visit our website at *https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments.*

GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry intended to address continuing regulatory challenges. GDUFA reflects input received during an open process that includes regular public meetings, posting of meeting minutes, and consideration of comments from a public docket. We are revising the information collection to include the current GDUFA agreement, or ''goals letter,'' as reflected in the document ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022,'' available for download from our website at *https://www.fda.gov/media/101052/download.* The performance goals and program enhancements specified in the goals letter apply to aspects of the generic drug review program that are important for facilitating timely access to quality, affordable generic medicines. FDA is committed to meeting the performance goals specified in the goals letter and to continuous improvement of its performance.

Included among the performance goals is the issuance of topic-specific guidance documents. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-document.* In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We have developed Form FDA 3794, the Generic Drug User Fee Cover Sheet, available at *https://www.ipqpubs.com/wp-content/uploads/2012/09/GDUFA-cover-sheet.pdf,* which requests the minimum necessary information from generic drug applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete and submit the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA's web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct fiscal year user fee assessment that is due for the submission or program. FDA requests that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, as well as other additional GDUFA fees, so FDA can verify that the applicant has paid the correct user fee and their account is current.

Respondents to the information collection are potential or actual generic drug application holders or related active pharmaceutical ingredient and finished dosage form manufacturers. Companies with multiple user fee obligations may submit a cover sheet for each user fee obligation.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA 3794	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic Drug User Fee Cover Sheet	500	7.616	3,808	0.5 (30 minutes)	1,904

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Based on a review of the information collection, we have retained the currently approved burden estimate.

Dated: November 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25294 Filed 11–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5389]

Determination of Regulatory Review Period for Purposes of Patent Extension; SUNOSI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SUNOSI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 18, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 18, 2022. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–E–5389 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SUNOSI.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, SUNOSI (solriamfetol hydrochloride) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Subsequent to this approval, the USPTO received a patent term restoration application for SUNOSI (U.S. Patent No. 8,440,715) from JAZZ Pharmaceutials, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 26, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SUNOSI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SUNOSI is 8,209 days. Of this time, 7,664 days occurred during the testing phase of the regulatory review period, while 545 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 27, 1996. The applicant claims that December 17, 2009, is the date the investigational new drug application (IND) 107203 became effective. However, FDA's records indicate that the effective date was December 27, 1996, which was 30 days after FDA receipt of the applicant's earlier IND 52082.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 20, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for SUNOSI (NDA 211230) was initially submitted on December 20, 2017.

3. *The date the application was approved or the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act:* June 17, 2019. FDA has verified the applicant's claim that NDA 211230 was approved on March 20, 2019, and that the Drug Enforcement Administration issued an interim final rule controlling the product on June 17, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,386 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25297 Filed 11–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3031]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products.

DATES: Submit either electronic or written comments on the collection of information by January 18, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3031 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

OMB Control Number 0910–0749—Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

FDA issued a final rule on May 10, 2016 (81 FR 28707) that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the FD&C Act (*https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10688.pdf*). FDA expanded its authority over tobacco products by issuing another final rule entitled ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (Deeming rule; May 10, 2016, 81 FR 28974), deeming all products that meet the statutory definition of ''tobacco product,'' except accessories of the newly deemed tobacco products, to be subject to the FD&C Act (*https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf*). The Deeming rule, among other things,

subjected domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act's user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, the user fee final rule requires the submission of the information needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA.

As noted, FDA issued a final rule that requires domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the FD&C Act. The U.S. Department of Agriculture (USDA) had been collecting this information and provided FDA with the data the Agency needed to calculate the amount of user fees assessed to tobacco product manufacturers and importers. USDA ceased collecting this information in fiscal year 2015 (October 2014). USDA's information collection did not require OMB approval, per an exemption by Public Law 108–357, section 642(b)(3). Consistent with the requirements of the FD&C Act, FDA requires the submission of this information to FDA now instead of USDA. FDA took this action to ensure that the Agency continues to have the information needed to calculate, assess, and collect user fees from domestic manufacturers and importers of tobacco products.

Section 919(a) of the FD&C Act (21 U.S.C. 387s(a)) requires FDA to ''assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of the FD&C Act (chapter IX of the FD&C Act). The total amount of user fees to be collected for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and under section 919(a) FDA is to assess and collect a proportionate amount each quarter of the fiscal year. The FD&C Act provides for the total assessment to be allocated among the classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco product removed into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its share of the market for that tobacco product class.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1150.5(a), (b)(1), and (b)(2), and Form FDA 3852; General identifying information provided by manufacturers and importers of FDA regulated tobacco products and identification and removal information (monthly)	711	12	8,532	3	25,596
1150.5(b)(3); Certified copies (monthly)	711	12	8,532	1	8,532
1150.13; Submission of user fee information (identifying information, fee amount, etc.) (quarterly)	355	4	1,420	1	1,420
1150.15(a); Submission of user fee dispute (annually)	5	1	5	10	50
1150.15(d); Submission of request for further review of dispute of user fee (annually)	3	1	3	10	30
Total					35,628

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 711 entities will submit tobacco product user fees. The entity count was derived from aggregate data provided by the Alcohol and Tobacco Tax and Trade Bureau (TTB) and reflects that in 2021 there were 233 total permitted manufacturers and 478 permitted importers over all tobacco product types for which TTB assesses excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco).

The estimate of 711 respondents to provide the information requested from § 1150.5(a), (b)(1), and (b)(2) (21 CFR 1150.5(a), (b)(1), and (b)(2)), and Form FDA 3852 reflects both reports of no removal of tobacco products into domestic commerce and reports of removal of tobacco product into domestic commerce. FDA estimates it will take 3 hours for each of these submission types for a total of 25,596 hours. Under § 1150.5(b)(3), these respondents are also expected to provide monthly certified copies of the returns and forms that relate to the removal of tobacco products into domestic commerce and the payment of Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986 to FDA. We estimate that each monthly report will take 1 hour for a total of 8,532 hours. The estimate of 355 respondents to submit payment of user fee information under § 1150.13 (21 CFR 1150.13) reflects an average of half the number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. FDA estimates the quarterly submission will take approximately 1 hour for a total of 1,420 hours.

FDA estimates that five of those respondents assessed user fees will dispute the amounts under § 1150.15(a) (21 CFR 1150.15(a)), for a total amount of 50 hours. FDA also estimates that three respondents who dispute their user fees will ask for further review by FDA under § 1150.15(d), for a total amount of 30 hours. FDA has received nine dispute submissions since fiscal year 2015. Based on this data, the Agency does not believe we will receive more than five disputes and three requests for further reviews in the next 3 years.

FDA estimates the total annual burden for this collection of information is 35,628 hours. The estimated burden for the information collection reflects an overall increase of 2,648 hours. We attribute this adjustment to an increase in the number of entities submitting tobacco user fee information to FDA.

Dated: November 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25306 Filed 11–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Notice to Public of Website Location of Center for Devices and Radiological Health Fiscal Year 2022 Proposed Guidance Development

Correction

In notice document 2021–23392, appearing on pages 59399 through 59401 in the issue of Wednesday, October 27, 2021, make the following correction:

On page 59399, in the second column, in the **DATES** section, on the second and third lines, ''November 26, 2021'' should read, ''December 27, 2021''.

[FR Doc. C1–2021–23392 Filed 11–18–21; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality (Formerly the Advisory Committee on Infant Mortality)

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant and Maternal Mortality (ACIMM) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES: December 14, 2021, 12:00 p.m.–4:00 p.m. Eastern Time and December 15, 2021, 12:00 p.m.–4:00 p.m. Eastern Time.

ADDRESSES: This meeting will be held via webinar. *The webinar link and log-in information will be available at the ACIMM website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301–443–0543; or *SACIM@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. app. 2), which sets forth standards for the formation and use of Advisory Committees.

The ACIMM advises the Secretary of Health and Human Services (Secretary) on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, and maternal health, as well as influence similar efforts in the private and voluntary sectors. The Committee provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The agenda for the December 14–15, 2021, meeting is being finalized and may include the following topics: Federal program updates; COVID–19 updates; health of indigenous mothers and infants; birth defects and congenital anomalies; the impact of housing and eviction on birth outcomes; and state/community projects to improve maternal and infant health. Agenda items are subject to change as priorities dictate. Refer to the ACIMM website listed above for any updated information concerning the meeting.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to ACIMM should be sent to Vanessa Lee, using the email address above at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing *SACIM@hrsa.gov.* Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or some reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–25272 Filed 11–18–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Extension of the Deadline for Nomination of Delegates; Center for Indigenous Innovation and Health Equity Tribal Advisory Committee; Solicitation of Nominations for Delegates

AGENCY: Office of Minority Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice of solicitation of nominations for delegates for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee.

SUMMARY: On October 1, 2021, the U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) published a notice in the **Federal Register** inviting nominations of qualified candidates to serve as primary and alternate delegates for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee (CIIHE TAC), including a submission deadline of October 29, 2021. This notice extends the deadline date for submission of nominations to January 7, 2022 at 11:59 p.m. EST.

DATES: Nomination letters for the CIIHE TAC must be sent to the address noted below no later than 11:59 p.m. EST on January 7, 2022.

ADDRESSES: All nominations should be emailed to: Violet Woo, Designated Federal Officer for the CIIHE TAC, at *Violet.Woo@hhs.gov.* Please use the subject line ''OMH CIIHE Tribal Advisory Committee''.

FOR FURTHER INFORMATION CONTACT: For information and guidance about the nomination process for CIIHE TAC delegates, please contact Violet Woo, Designated Federal Officer at *Violet.Woo@hhs.gov.* CIIHE TAC nomination guidance and sample nomination letters also are available on the OMH website's Tribal Leader Letters section: *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62#tribal-leader-letters.*

SUPPLEMENTARY INFORMATION: On October 1, 2021, the notice of solicitation of nominations for delegates for the CIIHE TAC was published in the **Federal Register** (86 FR 54462: Available at *https://www.federalregister.gov/documents/2021/10/01/2021-21253/center-for-indigenous-innovation-and-health-equity-tribal-advisory-committee-solicitation-of*). The deadline for submission of nomination letters is being extended to January 7, 2022.

Note: All information in the notice of solicitation of nominations for delegates for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee remain the same, except for the deadline for the submission of nominations and the date the nominees will be notified of the status of delegate selection.

Authorized under Section 1707 of the Public Health Service Act, 42 U.S.C. 300u–6, as amended, the mission of OMH is to improve the health of racial and ethnic minority populations through the development of health policies and programs that help eliminate health disparities. OMH awards and other activities are intended to support the identification of effective policies, programs, and practices for improving health outcomes and to promote the sustainability and dissemination of these approaches.

Under the authority of Public Law 116–260 (2021 Consolidated Appropriations Act), Congress directed OMH to create a CIIHE to support research, education, service, and policy development advancing Indigenous solutions that ultimately address health disparities in American Indian/Alaska Native (AI/AN) and Native Hawaiian and Pacific Islander (NHPI) populations. OMH is establishing the CIIHE TAC to ensure that Tribal Leaders have meaningful and timely input in the development of the priorities and activities established to address the focus areas of the CIIHE. The CIIHE TAC shall support, but not supplant, government-to-government consultation activities that OMH undertakes.

TAC Membership: The CIIHE TAC will consist of 16 delegate positions: One from each of the 12 geographic areas served by the Indian Health Service and four National At-Large Member positions.

Alaska Area
Albuquerque Area
Bemidji Area
Billings Area
California Area
Great Plains Area
Nashville Area
Navajo Area
Oklahoma Area
Phoenix Area
Portland Area
Tucson Area
National At-Large Members (4)

OMH recommends a two (2) year term length for each delegate, but delegates' term length will be established by the TAC's charter.

Eligibility: The CIIHE TAC delegates must be: (1) Elected tribal officials from a federally recognized tribe acting in their official capacity as elected officials of their tribe, with authority to act on behalf of the tribe; or (2) individuals designated by an elected tribal official. Designees must have the authority to act on behalf of the tribal official and the tribe and be qualified to represent the views of the AI/AN tribes in the area from which they are nominated. No delegate of the CIIHE TAC may be an employee of the federal government.

Nomination Procedures: CIIHE TAC candidates must be nominated by an elected tribal leader. The nomination letter must be on tribal letterhead and signed by an elected tribal leader, and must include the following information:

- Name of the nominee
- Nominee's official title
- Name of the nominee's tribe
- Date of nominee's election to official tribal position and term length
- Nominee's contact information (mailing address, phone, and email)
- Nominee's expertise that is relevant to the CIIHE TAC
- Name of tribal leader submitting the nomination
- Official title of tribal leader submitting the nomination
- Contact information for tribal leader submitting the nomination and/or administrative office for tribal government

CIIHE TAC nomination guidance and sample nomination letters are available on the OMH website's Tribal Leader Letters section: *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62#tribal-leader-letters.*

Selection Process: OMH is responsible for selecting and finalizing CIIHE TAC members. Eligible nominees will be considered in the following priority order:

1. Tribal President/Chairperson/Governor
2. Tribal Vice-President/Vice-Chairperson/Lt. Governor
3. Elected or Appointed Tribal Official
4. Designated Tribal Official with authority to act on behalf of Tribal leader

In the event that there is more than one nomination for a given IHS area, OMH will make a determination of representation based on submitted nomination materials.

Nominees will be notified of the status of delegate selection in February 2022.

Dated: November 9, 2021.

Violet Woo,

Designated Federal Officer, Center for Indigenous Innovation and Health Equity Tribal Advisory Committee.

[FR Doc. 2021–25292 Filed 11–18–21; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; RFA Review: Data Archives for the BRAIN Initiative (R24 Clinical Trial Optional).

Date: December 14, 2021.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center/Room 6150/MSC 9606, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, *nick.gaiano@nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 16, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25267 Filed 11–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Exploiting in Vivo or in Situ Imaging Approaches to Understand HIV-Relevant Processes in the Context of Substance Use Disorders (R61/R33 Clinical Trials Optional).

Date: December 15, 2021.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sheila Pirooznia, Ph.D., Scientific Review Officer, Division of Extramural Review, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 496–9350, *sheila.pirooznia@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 15, 2021.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25208 Filed 11–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity PAR.

Date: December 9, 2021.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 16, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25319 Filed 11–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Societal and Ethical Issues in Research.

Date: December 9, 2021.

Time: 11:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maribeth Champoux, Ph.D., BA, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 594–3163, *champoum@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 15, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25211 Filed 11–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Muscular Dystrophy Coordinating Committee (MDCC).

The meeting will be open to the public. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: December 20, 2021.

Time: 1:00 p.m. to 5:00 p.m. EST

Agenda: The purpose of this meeting is to bring together committee members, representing government agencies, patient advocacy groups, other voluntary health

organizations, and patients and their families to update one another on progress relevant to the Action Plan for the Muscular Dystrophies and to coordinate activities and discuss gaps and opportunities leading to better understanding of the muscular dystrophies, advances in treatments, and improvements in patients' and their families' lives. The agenda for this meeting is available on the MDCC website: *https://www.mdcc.nih.gov/.*

Registration: To register, please go to: *https://roseliassociates.zoomgov.com/webinar/register/WN_E2_Swp8wQjWtnZFgls2YCg.*

Webcast Live: https://videocast.nih.gov/.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Glen Nuckolls, Ph.D., Program Director, National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Blvd., Rm. 2203, Bethesda, MD 20892, 301–496–5876, *MDCC@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

More information can be found on the Muscular Dystrophy Coordinating Committee home page: *https://mdcc.nih.gov/.*

Dated: November 15, 2021.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25209 Filed 11–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA and NIAAA Institutional Research Training Grant (T32) Review Panel.

Date: November 24, 2021.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Scientific Review Branch, 301 North Stonestreet Avenue, MSC 6021, National Institute on Drug Abuse, NIH, Bethesda, MD 20892, (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 16, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25270 Filed 11–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group Kidney, Urologic and Hematologic Diseases D Study Section Kidney, Urologic and Hematologic Diseases D Study Section (DDK–D)—NIDDK Initial Review Group.

Date: March 1–3, 2022.

Time: 5:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–496–9010, *hoffertj@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 15, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–25210 Filed 11–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX22EE000101100]

Public Meeting of the National Geospatial Advisory Committee

AGENCY: Department of Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the U.S. Geological Survey (USGS) is publishing this notice to announce that a Federal Advisory Committee meeting of the National Geospatial Advisory Committee (NGAC) will take place.

DATES: The meeting will be held as a webinar on Tuesday, December 7, 2021, from 1:00 p.m. to 5:00 p.m., and on Wednesday, December 8, 2021, from 1:00 p.m. to 5:00 p.m. (Eastern Daylight Time).

ADDRESSES: The meeting will be held on-line and via teleconference. Instructions for accessing the meeting will be posted at *www.fgdc.gov/ngac.* Comments can be sent to Ms. Dionne Duncan-Hughes, Group Federal Officer by email to *gs-faca@usgs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. John Mahoney, Federal Geographic Data Committee (FGDC), USGS, by mail at 909 First Avenue, Room 703, Seattle, WA 98104; by email at *jmahoney@usgs.gov;* or by telephone at (206) 220–4621.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., appendix 2), the Government in the

Sunshine Act of 1976 (5 U.S.C. 552B, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The NGAC provides advice and recommendations related to management of Federal and national geospatial programs, the development of the National Spatial Data Infrastructure (NSDI), and the implementation of the Geospatial Data Act of 2018 (GDA) and the Office of Management and Budget Circular A–16. The NGAC reviews and comments on geospatial policy and management issues and provides a forum to convey views representative of non-federal stakeholders in the geospatial community. The NGAC meeting is one of the primary ways that the FGDC collaborates with its broad network of partners. Additional information about the NGAC meeting is available at: *www.fgdc.gov/ngac.*

Agenda Topics:

—FGDC Update
—Geospatial Data Act Reporting
—Executive Order 14008/Climate Mapping Initiative
—Landsat Advisory Group
—Public-Private Partnerships
—Stakeholder Engagement
—Public Comment

Meeting Accessibility/Special Accommodations: The webinar meeting is open to the public and will take place from 1:00 p.m. to 5:00 p.m. on December 7, 2021, and from 1:00 p.m. to 5:00 p.m. on December 8, 2021. Members of the public wishing to attend the meeting should visit *www.fgdc.gov/ngac* or contact Mr. John Mahoney (see **FOR FURTHER INFORMATION CONTACT**). Webinar/conference line instructions will be provided to registered attendees prior to the meeting. Individuals requiring special accommodations to access the public meeting should contact Mr. John Mahoney (see **FOR FURTHER INFORMATION CONTACT**) at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Public Disclosure of Comments: There will be an opportunity for public comment during both days of the meeting. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited. Written comments may also be sent to the Committee for consideration. To allow for full consideration of information by the Committee members, written comments must be provided to John Mahoney (see **FOR FURTHER INFORMATION CONTACT**) at least three (3) business days prior to the meeting. Any written comments received will be provided to the committee members before the meeting.

Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you may ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. appendix 2.

Dated: November 16, 2021.

Kenneth Shaffer,

Deputy Executive Director, Federal Geographic Data Committee.

[FR Doc. 2021–25303 Filed 11–18–21; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–33010; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before November 6, 2021, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by December 6, 2021.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before November 5, 2021. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

CALIFORNIA

Marin County

Marin Art and Garden Center, 30 Sir Francis Drake Blvd., Ross, SG100007228

Merced County

Strand Theater, 655–661 West Main St., Merced, SG100007227

San Diego County

Inspiration Heights Historic District, Generally bounded by Sunset Blvd., Alameda Terr., St. James Pl., and Witherby St., San Diego, SG100007226

San Mateo County

Mathews, Arthur C. and Judith, House, 83 Wisteria Way, Atherton, SG100007224

ILLINOIS

Bureau County

Paddock, Colonel George H., House, 906 South Main St., Princeton, SG100007222

Cook County

Ramova Theater, 3508–3518 South Halsted St., Chicago, SG100007223

OHIO

Cuyahoga County

Garfield Terrace Apartments (Apartment Buildings in Ohio Urban Centers, 1870–1970 MPS), 13344 Euclid Ave., East Cleveland, MP100007225

Franklin County

Ohio Bell Southwestern Headquarters, 150 E Gay St., Columbus, SG100007231

OKLAHOMA

Garfield County

Liberty Federal Savings and Loan Association Building, 401 West Broadway Ave., Enid, SG100007233

Latimer County

Edwards-Hardaway Homestead and Cemetery, Norris Rd., 8 mi. NE of Red Oak, Red Oak vicinity, SG100007234

VERMONT

Franklin County

Perley Block, 366 Main St., Enosburg Falls, SG100007221

WISCONSIN

Grant County

Hinners, Carsten and Dora, House, 1195 West Main St., Platteville, SG100007229

Additional documentation has been received for the following resource:

NEVADA

Washoe County

First Church of Christ, Scientist (Additional Documentation), 501 Riverside Dr., Reno, AD99000939

(Authority: 36 CFR 60.13)

Dated: November 9, 2021.

Sherry A. Frear,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2021–25311 Filed 11–18–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–32902; PPWOCRAD10, PUC00RP14.R50000]

Cold War Advisory Committee Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: The National Park Service (NPS) is hereby giving notice that the Cold War Advisory Committee (Committee) will meet as indicated below.

DATES: The Committee will meet via GoToWebinar on Thursday, February 24, 2022, from 2:00 p.m. until approximately 4:00 p.m. (Eastern).

ADDRESSES: Teleconference participants may register for the meeting at the following url: *https://attendee.gotowebinar.com/register/5948428690832074256.*

After registering, participants will receive a confirmation email containing information about joining the teleconference. Participants may register at any time and will receive the login information immediately.

FOR FURTHER INFORMATION CONTACT: Lisa P. Davidson, Ph.D., Program Manager, National Historic Landmarks Program, National Park Service, telephone at (202) 354–2179, or email *lisa_davidson@nps.gov.*

SUPPLEMENTARY INFORMATION: The Committee was established by title VII, subtitle C, section 7210 of the Omnibus Public Land Management Act of 2009 (16 U.S.C. 1a–5 note).

The Committee meeting will be open to the public and will have time allocated for public comment. Depending on the number of persons wishing to speak, and the time available, the time for individual comments may be limited. Such requests should be made to the Designated Federal Officer at the beginning of the meeting.

Purpose of the Meeting: The Committee assists the Secretary of the Interior in the preparation of a national historic landmark theme study to identify sites and resources significant to the Cold War. The proposed meeting agenda includes the following:

1. Call to Order and Welcome
2. Welcome from the NPS
3. Introductions
4. Status Report—Mountain Home National Historic Landmarks Nomination and Cold War National Historic Landmarks Theme Study
5. Discussion of Cold War Interpretive Handbook
6. Public Comments
7. Adjourn Meeting

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Appendix 2)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2021–25299 Filed 11–18–21; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–667 and 731–TA–1559 (Final)]

Organic Soybean Meal From India; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–667 and 731–TA–1559 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of organic soybean meal from India, provided for in subheadings 1208.10.00 and 2304.00.00 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be subsidized and sold at less-than-fair-value.

DATES: November 2, 2021.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones ((202) 205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.—For purposes of these investigations, Commerce has defined the subject merchandise as ''certified organic soybean meal. Certified organic soybean meal results from the mechanical pressing of certified organic soybeans into ground products known as soybean cake, soybean chips, or soybean flakes, with or without oil residues. Soybean cake is the product after the extraction of part of the oil from soybeans. Soybean chips and soybean flakes are produced by cracking, heating, and flaking soybeans and reducing the oil content of the conditioned product. ''Certified organic soybean meal'' is certified by the U.S. Department of Agriculture (USDA) National Organic Program (NOP) or equivalently certified to NOP standards or NOP-equivalent standards under an existing organic equivalency or recognition agreement.

Certified organic soybean meal subject to this investigation has a protein content of 34 percent or higher.

Organic soybean meal that is otherwise subject to this investigation is included when incorporated in admixtures, including but not limited to prepared animal feeds. Only the organic soybean meal component of such admixture is covered by the scope of this investigation.''

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in India of organic soybean meal, and that such products are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on March 31, 2021, by the Organic Soybean Processors of America, Washington, DC, American Natural Processors, LLC, Dakota Dunes, South Dakota, Lester Feed & Grain Co., Lester, Iowa, Organic Production Services, LLC, Weldon, North Carolina, Professional Proteins Ltd., Washington, Iowa, Sheppard Grain Enterprises, LLC, Phelps, New York, Simmons Grain Co., Salem, Ohio, Super Soy, LLC, Brodhead, Wisconsin, and Tri-State Crush, Syracuse, Indiana.[1]

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on March 2, 2022, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Wednesday, March 16, 2022. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before Tuesday, March 8, 2022. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on Monday, March 14, 2022. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is March 9, 2022. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is March 23, 2022. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before March 23, 2022. On April 11, 2022, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before April 13, 2022, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

[1] On April 6, 2021, Lester Feed & Grain Co. voluntarily withdrew its status as a petitioner.

Issued: November 15, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–25234 Filed 11–18–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–670 and 731–TA–1570 (Preliminary)]

Freight Rail Coupler Systems and Components From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of freight rail coupler systems and components from China, provided for in subheading 8607.30.10 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of China.[2]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in § 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under §§ 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under §§ 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On September 29, 2021, the Coalition of Freight Coupler Producers consisting of McConway & Torley LLC (''M&T''), Pittsburgh, PA, and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO, CLC (''USW'') filed petitions with the Commission and Commerce,[3] alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of freight rail coupler systems and components from China and LTFV imports of freight rail coupler systems and components from China. Accordingly, effective September 29, 2021, the Commission instituted countervailing duty investigation No. 701–TA–670 and antidumping duty investigation No. 731–TA–1570 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 5, 2021 (86 FR 54997). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its conference through written testimony and video conference on October 20, 2021. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on November 15, 2021. The views of the Commission are contained in USITC Publication 5243 (November 2021), entitled *Freight Rail Coupler Systems and Components from China: Investigation Nos. 701–TA–670 and 731–TA–1570 (Preliminary).*

By order of the Commission.

Issued: November 15, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–25233 Filed 11–18–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1546–1549 (Final)]

Thermal Paper From Germany, Japan, Korea, and Spain

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of thermal paper from Germany, Japan, Korea, and Spain, provided for in subheadings 4811.90.80 and 4811.90.90 (statistical reporting numbers 4811.90.8030 and 4811.90.9030) of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').[2] [3]

Background

The Commission instituted these investigations effective October 7, 2020, following receipt of petitions filed with the Commission and Commerce by Appvion Operations, Inc. (Appleton, Wisconsin) and Domtar Corporation (Fort Mill, South Carolina). The Commission scheduled the final phase of the investigations following notification of preliminary determinations by Commerce that imports of thermal paper from Germany, Japan, Korea, and Spain were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 9,

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 86 FR 58864 (October 25, 2021) and 86 FR 58878 (October 25, 2021).

[3] Initially, Petitioner was M&T and another domestic producer. However, the other domestic producer withdrew, and USW was added to the petitions.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 86 FR 54152, 86 FR 54157, 86 FR 54154, and 86 FR 54162 (September 30, 2021).

[3] The Commission also finds that imports subject to Commerce's affirmative critical circumstances determinations are not likely to undermine seriously the remedial effect of the antidumping duty orders on Germany and Korea.

2021 (86 FR 30627) and June 24, 2021 (86 FR 33358). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its hearing through written testimony and video conference on September 21, 2021. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to § 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 15, 2021. The views of the Commission are contained in USITC Publication 5237 (November 2021), entitled *Thermal Paper from Germany, Japan, Korea, and Spain: Investigation Nos. 731–TA–1546–1549 (Final).*

By order of the Commission.

Issued: November 15, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–25216 Filed 11–18–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under Comprehensive Environmental Response, Compensation and Liability Act

On November 15, 2021, the Department of Justice lodged a proposed Consent Decree (''Consent Decree'') with the United States District Court for the Western District of New York in a lawsuit entitled *United States, the State of New York, and the Tuscarora Nation* v. *Honeywell International, Inc.,* Civil Action No. 21–1218. In the complaint, the plaintiffs, collectively the United States, the State of New York, and the Tuscarora Nation (also referred to as ''the Natural Resource Trustees''), seek natural resource damages under Section 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9607(a) from defendant Honeywell International, Inc. (''Honeywell''). The complaint alleges that Honeywell, as a successor to the Allied Chemical Corp./Buffalo Color Corp., is a liable party in connection with natural resource damages resulting from the release of hazardous substances into a portion of the Buffalo River, Buffalo, New York (''the Site''), from the early 1900s through at least the mid-1900s.

The proposed Consent Decree requires that Honeywell, as a Settling Defendant, pay $4,250,000 to the Natural Resource Trustees to compensate for natural resource damages. The payment will reimburse past assessment costs, and fund natural resource habitat restoration projects, cultural restoration projects, and oversight costs to oversee completion of the projects. Under the proposed settlement, conservation easements and restrictions will be recorded on approximately 70 undeveloped acres of land adjacent to the Buffalo River to preserve these properties in their undeveloped condition in perpetuity. These properties are currently owned by CSX Transportation or the City of Buffalo, who are settling parties under the Consent Decree. Additional settling parties include other parties that are potentially responsible for natural resource damages that have entered into separate settlements with Honeywell.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, the State of New York, and the Tuscarora Nation* v. *Honeywell International, Inc., Civil Action No. 21–1218,* D.J. Ref. No. 90–11–3–08780. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to:Consent Decree Library,U.S. DOJ—ENRD,P.O. Box 7611,Washington, DC 20044–7611.

Please enclose a check or money order for $9.75 (25 cents per page reproduction cost), payable to the United States Treasury.

Henry Friedman,

Assistant Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 2021–25309 Filed 11–18–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Standard Job Corps Contractor and Grantee Information Gathering

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Standard Job Corps Contractor and Grantee Information Gathering.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by January 18, 2022.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Lawrence Lyford by telephone at 202–693–3121 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *Lyford.Lawrence@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Job Corps, 200 Constitution Avenue NW, Room N4459 Washington, DC 20210; by email: *Lyford.Lawrence@dol.gov;* or by fax 202–693–3113.

FOR FURTHER INFORMATION CONTACT: Lawrence Lyford by telephone at 202–693–3121 (this is not a toll-free number) or by email at *Lyford.Lawrence@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized,

collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

Job Corps is the nation's largest residential, educational, and career technical training program for the economically disadvantaged youths. The Economic Opportunity Act established Job Corps in 1964, and it currently operates under the authority of the Workforce Innovation and Opportunity Act (WIOA) of 2014. For over 56 years, Job Corps has helped prepare over three million at-risk young people between the ages of 16 and 24 for success in our nation's workforce. With 121 centers in 50 states, Puerto Rico, and the District of Columbia, Job Corps assists students across the nation in attaining academic credentials, including High School Diplomas (HSD) and/or High School Equivalency (HSE), and career technical training credentials, including industry-recognized certifications, state licensures, and pre-apprenticeship credentials.

Job Corps is a national program administered by the U.S. Department of Labor (DOL) through the Office of Job Corps and six Regional Offices. DOL awards and administers contracts for the recruiting and screening of new students, center operations, and the placement and transitional support of graduates and former enrollees. Large and small corporations and nonprofit organizations manage and operate 95 Job Corps centers under contractual agreements with DOL. These contract Center Operators are selected through a competitive procurement process that evaluates potential operators' technical expertise, proposed costs, past performance, and other factors, in accordance with the Competition in Contracting Act and the Federal Acquisition Regulations. Many of the current contractors operate more than one center. The two centers operated under demonstration grants are run by the State of Idaho and the National Guard Job Challenge program respectively. Of the 121 current centers, 24 are managed and operated by the U.S. Department of Agriculture—Forest Service (USDA) through an interagency agreement. Additionally, there are 26 public colleges and universities operating Job Corps Scholars Program demonstration grants.

The Workforce Innovation Opportunity Act (WIOA), Section 116(b)(2)(A)(i), Section 159(c)(4) and Section 156(a) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless OMB approves the collection under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0219.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL.

Type of Review: Revision.

Title of Collection: Standard Job Corps Contractor and Grantee Information Gathering.

Form: Various. Center Financial Report—FMS 2110, Grantee Financial Report—FMS 2181, Center Vacancy/Separation Report—FMS 2110S, Center Operations Budget—FMS 2181, Environmental Health Inspections—OJC 6–36, Inspection of Residential & Educational Facilities—OJC 6–37, Inspection of Waste Treatment Facilities Costs—OJC 6–39, Inspection Water Supply Facilities—OJC 6–38, Disciplinary Discharge—ETA 6–131A, Review Board Hearings—ETA 6–131B, Rights to Appeal—ETA 6—131C, Student Profile—ETA 640, Student Separation—ETA 661, Grantee Data Collection Form: Application Data—ETA 9190C, Grantee Data Collection Form: Enrollee Data—ETA 9190B, Grantee Data Collection Form: Post Separation Data—ETA 9190A.

OMB Control Number: 1205–0219.

Affected Public: Individuals or Households and Private Sector businesses, grantees or other for-profits.

Estimated Number of Respondents: 2,570.

Frequency: Various.

Total Estimated Annual Responses: 277,570.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 84,096.

Total Estimated Annual Other Cost Burden: $ 0.

Angela Hanks,

Acting Assistant Secretary.

[FR Doc. 2021–25242 Filed 11–18–21; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Transmittal for Unemployment Insurance Materials

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Transmittal for Unemployment Insurance Materials.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by January 18, 2022.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting John

Schuettinger by telephone at 202–693–2680 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *Schuettinger.john@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Office of Unemployment Insurance, Room S–4520, 200 Constitution Avenue NW, Washington, DC 20210; by email: *Schuettinger.john@dol.gov;* or by fax (202) 693–3975.

FOR FURTHER INFORMATION CONTACT: John Schuettinger by telephone at 202–693–2680 (this is not a toll-free number) or by email at *schuettinger.john@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

ETA's administrative procedures regulation, found at 20 CFR 601, sets out the collection of information requirements. Section 601.2 requires states to submit copies of their unemployment compensation (UC) laws for approval by the Secretary of Labor (Secretary) so that the Secretary may determine the status of state laws and plans of operation. Section 601.3 requires states to ''submit all relevant state materials such as statutes, executive and administrative orders, legal opinions, rules, regulations, interpretations, court decisions, etc.''

These materials are used by the Secretary to determine whether the state law contains provisions required by Section 3304(a) of the Internal Revenue Code of 1986. DOL provides grants to states to fund the administration of their employment security laws if their UC laws and their plans of operation for public employment offices meet required conditions of Federal laws. The information transmitted by Form MA 8–7 is used by the Secretary to make findings (as specified in the above cited Federal laws) required for certification to the Secretary of the Treasury for payment to states or for certification of the state law for purposes of providing additional tax credits to employers in states with UC laws conforming to Federal law. If this information is not available, the Secretary cannot make such certifications. To facilitate transmittal of required material, DOL prescribes the use of Form MA 8–7, Transmittal for Unemployment Insurance Materials. This simple check-off form is used by the states to identify material being transmitted to the National Office and allows the material to be routed to appropriate staff for prompt action. 20 CFR 601.2 and 601.3 authorize this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0222.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Extension Without Change.

Title of Collection: Transmittal for Unemployment Insurance Materials.

Form: MA 8–7.

OMB Control Number: 1205–0222.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 53.

Frequency: Varies.

Total Estimated Annual Responses: 318.

Estimated Average Time per Response: 0.25 hour.

Estimated Total Annual Burden Hours: 79.5 hours.

Total Estimated Annual Other Cost Burden: $0.

Angela Hanks,

Acting Assistant Secretary, Employment and Training Administration.

[FR Doc. 2021–25244 Filed 11–18–21; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of the Federal Unemployment Tax Act (FUTA) Credit Reduction Applicable in 2021

Sections 3302(c)(2)(A) and 3302(d)(3) of the FUTA provide that employers in a state that has outstanding advances under Title XII of the Social Security Act on January 1 of two or more consecutive years are subject to a reduction in credits otherwise available against the FUTA tax for the calendar year in which the most recent such January 1 occurs, if advances remain on November 10 of that year. Further, Section 3302(c)(2)(C) of FUTA provides for an additional credit reduction for a year if a state has outstanding advances on five or more consecutive January 1 and has a balance on November 10 for such years. Section 3302(c)(2)(C) provides for waiver of this additional credit reduction and substitution of the credit reduction provided in Section 3302(c)(2)(B) if a state meets certain conditions.

Employers in the U.S. Virgin Islands (USVI) were potentially liable for the additional credit reduction under Section 3302(c)(2)(C) of FUTA. The jurisdiction applied for the waiver of this additional credit reduction. The Employment and Training

Administration determined that USVI met all of the criteria of the section necessary to qualify for the waiver of the additional credit reduction. Therefore employers in USVI will have no additional credit reduction applied for calendar year 2021. However, as a result of USVI having outstanding advances on each January 1 from 2010 through 2021, and an outstanding balance on November 10, 2021, employers in USVI are subject to a FUTA credit reduction of 3.3 percent in 2021.

Angela Hanks,

Acting Assistant Secretary for Employment and Training.

[FR Doc. 2021–25243 Filed 11–18–21; 8:45 am]

BILLING CODE P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (21–076)]

National Space-Based Positioning, Navigation, and Timing Advisory Board; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the National Space-Based Positioning, Navigation and Timing (PNT) Advisory Board. This will be the 25th meeting of the PNT Advisory Board.

DATES: Thursday, December 9, 2021, from 8:30 a.m.–6:00 p.m., Eastern Time; and Friday, December 10, 2021, from 8:30 a.m.–12:00 p.m., Eastern Time.

ADDRESSES: Sheraton Pentagon City Hotel, Galaxy Ballroom, 900 South Orme Street, Arlington, Virginia 22204.

FOR FURTHER INFORMATION CONTACT: Mr. James Joseph Miller, Designated Federal Officer, PNT Advisory Board, Space Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 262–0929 or *jj.miller@nasa.gov.*

SUPPLEMENTARY INFORMATION: This meeting will be open to the public up to the capacity of the meeting room. In-person attendees will be requested to sign a register prior to entrance to the proceedings. Webcast details to watch the meeting remotely will be available on the PNT Advisory Board website at: *www.gps.gov/governance/advisory/.*

The agenda for the meeting will include the following:

—Opening Remarks and Meeting Objectives by PNT Advisory Board Chair
—Reports and Updates from PNT Advisory Board Working Groups
—Preliminary Deliberations on any Findings and Recommendations
—Other PNT Advisory Board Business and Work Plan Schedule

For further information, visit the PNT Advisory Board website at: *https://www.gps.gov/governance/advisory/.*

It is imperative that the meeting be held on these dates to meet the scheduling availability of key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2021–25218 Filed 11–18–21; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board hereby gives notice of the scheduling of a teleconference of the Committee on Strategy (CS) for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, November 22, 2021, at 11:00 a.m.–12:00 p.m. EST.

PLACE: This meeting will be held by videoconference organized through the National Science Foundation.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Chair's remarks; Approval of July 30, 2021, meeting minutes; Discussion of NSF's 2022–2026 Strategic Plan, and review and action on NSB's Sense of the Board Statement.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, (703) 292–7000, *cblair@nsf.gov.* You may find meeting information and updates at *https://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–25337 Filed 11–17–21; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board hereby gives notice of the scheduling of a teleconference of the Committee on Strategy's Subcommittee on Technology, Innovation and Partnerships for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, November 22, 2021, from 6:00–7:00 p.m. EST.

PLACE: This meeting will be held by teleconference organized through the National Science Foundation.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Subcommittee Chair's Opening Remarks; Approval of Minutes from September 8, 2021, Meeting; and Discussion of Risk as it Relates to NSF's Technology, Innovation, and Partnerships Directorate.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–25338 Filed 11–17–21; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0276]

Information Collection: Physical Protection of Plants and Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Physical Protection of Plants and Materials.''

DATES: Submit comments by December 20, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this

particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0276 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2020–0276.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The supporting statement and the 10 CFR part 73 Annual Burden tables are available in ADAMS under Accession Nos. ML21244A281 and ML21101A001.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov/* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, part 73 of title 10 of the *Code of Federal Regulations* (10 CFR) ''Physical Protection of Plants and Materials.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on June 24, 2021, (86 FR 33382).

1. *The title of the information collection:* 10 CFR part 73 ''Physical Protection of Plants and Materials.''
2. *OMB approval number:* 3150–0002.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* N/A.
5. *How often the collection is required or requested:* Once for the initial submittal of Cyber Security Plans, Physical Security Plans, Safeguards Contingency Plans, and Security Training and Qualification Plans and then on occasion when changes are made. Required reports are submitted and evaluated as events occur.
6. *Who will be required or asked to respond:* Nuclear power reactor licensees licensed under 10 CFR parts 50 or 52 who possess, use, import, export, transport, or deliver to a carrier for transport, special nuclear material; actively decommissioning reactor licensees; Category I, Category II and Category III fuel facilities; nonpower reactors (research and test reactors); and other entities who mark and handle Safeguards Information.
7. *The estimated number of annual responses:* 130,968 (40,889 reporting responses + 89,869 third party disclosure responses + 210 record keepers).
8. *The estimated number of annual respondents:* 210 (56 power reactors + 20 decommissioning reactor facilities + 2 Category I fuel facilities + 5 Category II and III fuel facilities + 31 nonpower reactors + and 96 other entities who mark and handle Safeguards Information).
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 495,892 hours (22,631 reporting + 451,788 recordkeeping + 21,473 third party disclosure).
10. *Abstract:* The NRC regulations in 10 CFR part 73 prescribe requirements to establish and maintain a physical protection system and security organization with capabilities for protection of: (1) Special Nuclear Material (SNM) at fixed sites, (2) SNM in transit, and (3) plants in which SNM is used. 10 CFR part 73 contains reporting and recordkeeping requirements which are necessary to help ensure that an adequate level of protection is provided for nuclear facilities and nuclear material, such as: Development and maintenance of security documents including a physical security plan, a training and qualification plan, a safeguards contingency plan, a cyber security plan, and security implementing procedures; notifications to the NRC regarding safeguards and cyber security events; notifications to State governors and Tribes regarding shipments of irradiated reactor fuel; and requirements for conducting criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information. The objective is to ensure that activities involving SNM are consistent with interests of common defense and security and that these activities do not constitute an unreasonable risk to public health and safety. The information in the reports and records submitted by licensees is used by the NRC staff to ensure that the health and safety of the public and the environment are protected, and licensee

possession and use of SNM is in compliance with license and regulatory requirements.

Dated: November 15, 2021.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2021–25261 Filed 11–18–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 22, 29, December 6, 13, 20, 27, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of November 22, 2021

There are no meetings scheduled for the week of November 22, 2021.

Week of November 29, 2021—Tentative

There are no meetings scheduled for the week of November 29, 2021.

Week of December 6, 2021—Tentative

Tuesday, December 7, 2021

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting); (Contact: Larniece McKoy Moore: 301–415–1942)

Additional Information: The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/*. For those who would like to attend in person, note that all visitors are required to complete the NRC Self-Health Assessment and Certification of Vaccination forms. Visitors who certify that they are not fully vaccinated or decline to complete the certification must have proof of a negative Food and Drug Administration-approved polymerase chain reaction (PCR) or Antigen (including rapid tests) COVID–19 test specimen collection from no later than the previous 3 days prior to entry to an NRC facility. The forms and additional information can be found here *https://www.nrc.gov/about-nrc/covid-19/guidance-for-visitors-to-nrc-facilities.pdf.*

Thursday, December 9, 2021

9:00 a.m. Briefing on 10 CFR part 53 Licensing and Regulations of Advanced Nuclear Reactors (Public Meeting); (Contact: Donna Williams: 301–415–1322)

Additional Information: The public is invited to attend the Commission's meeting live by webcast at the web address—*https://video.nrc.gov/*. For those who would like to attend in person, note that all visitors are required to complete the NRC Self-Health Assessment and Certification of Vaccination forms. Visitors who certify that they are not fully vaccinated or decline to complete the certification must have proof of a negative Food and Drug Administration-approved PCR or Antigen (including rapid tests) COVID–19 test specimen collection from no later than the previous 3 days prior to entry to an NRC facility. The forms and additional information can be found here *https://www.nrc.gov/about-nrc/covid-19/guidance-for-visitors-to-nrc-facilities.pdf.*

Week of December 13, 2021—Tentative

There are no meetings scheduled for the week of December 13, 2021.

Week of December 20, 2021—Tentative

There are no meetings scheduled for the week of December 20, 2021.

Week of December 27, 2021—Tentative

There are no meetings scheduled for the week of December 27, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Tyesha.Bush@nrc.gov* or *Betty.Thweatt@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: November 17, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2021–25462 Filed 11–17–21; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0207]

Information Collection: Nuclear Material Events Database (NMED) for the Collection of Event Report, Response, Analyses, and Follow-Up Data on Events Involving the Use of Atomic Energy Act (AEA) Radioactive Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Nuclear Material Events Database (NMED) for the Collection of Event Report, Response, Analyses, and Follow-up Data on Events Involving the Use of Atomic Energy Act (AEA) Radioactive Byproduct Material.''

DATES: Submit comments by January 18, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0207. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–

0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0207 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2021–0207.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The supporting statement for Nuclear Material Events Database OMB Clearance (3150–0178) can be found in ADAMS under Accession No. ML21210A399.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0207 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov/* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Nuclear Material Events Database (NMED) for the Collection of Event Report, Response, Analyses, and Follow-up Data on Events Involving the Use of Atomic Energy Act (AEA) Radioactive Byproduct Material.

2. *OMB approval number:* 3150–0178.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* N/A.

5. *How often the collection is required or requested:* Agreement States are requested to provide copies of licensee nuclear material event reports electronically or by hard copy to the NRC within 30 days of receipt from their licensee. In addition, Agreement States are requested to report events that may pose a significant health and safety hazard to the NRC Headquarters Operations Officer within 24 hours of notification by an Agreement State licensee.

6. *Who will be required or asked to respond:* Current Agreement States and any State receiving Agreement State status in the future.

7. *The estimated number of annual responses:* 452.

8. *The estimated number of annual respondents:* 40.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 723 hours.

10. *Abstract:* NRC regulations require NRC licensees to report incidents and overexposures, leaking or contaminated sealed source(s), release of excessive contamination of radioactive material, lost or stolen radioactive material, equipment failures, abandoned well logging sources and medical events. Agreement State licensees are also required to report these events to their individual Agreement State regulatory authorities under compatible Agreement State regulations. The NRC is requesting that the Agreement States provide information to NRC on the initial notification, response actions, and follow-up investigations on events involving the use (including suspected theft or terrorist activities) of nuclear materials regulated pursuant to the Atomic Energy Act. The event information should be provided in a uniform electronic format, for assessment and identification of any facilities/site specific or generic safety concerns that could have the potential to impact public health and safety. The identification and review of safety concerns may result in lessons learned, and may also identify generic issues for further study which could result in proposals for changes or revisions to technical or regulatory designs, processes, standards, guidance or requirements.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: November 15, 2021.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2021–25264 Filed 11–18–21; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Privacy Act of 1974: New System of Records

AGENCY: Peace Corps.

ACTION: Notice of a new system of records.

SUMMARY: Peace Corps proposes to add a new system of records to its inventory of records systems subject to the Privacy Act of 1974. The purpose of this system is to allow the Peace Corps to collect and maintain records related to an individual's request and receipt of reasonable accommodations through the Office of Civil Rights and Diversity. Individuals include applicants, current, and former civilian personnel, interns, and Peace Corps Volunteers, and third-party individuals who either assist an individual in the application process, or professionals in a medical, health, or specialized field who provide information about the individual related to the reasonable accommodation request.

DATES: This new system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before December 20, 2021. The Routine Uses are effective at the close of the comment period.

ADDRESSES: Send written comments, identified by the docket number and title, to the Peace Corps, ATTN: Virginia Burke, FOIA/Privacy Act Officer, 1275 First Street NE, Washington, DC 20526, or by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke, FOIA/Privacy Act Officer, 1275 First Street NE, Washington, DC 20526; *pcfr@peacecorps.gov;* or 202–692–1887.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, the Peace Corps proposes to establish a new system of records titled, ''PC–27, Reasonable Accommodations Request Records.'' This system of records covers Peace Corps' collection and maintenance of records from applicants for employment, internships, Peace Corps Volunteer positions, current and former employees, interns, and Peace Corps Volunteers, third-party professionals, and any third-party participants engaged in Peace Corps activities who request and receive reasonable accommodations for a disability, or for medical or religious reasons. Records may include information on individuals' vaccination status and information to support a request for reasonable accommodation based on a disability, medical, or sincerely held religious belief.

Dated: November 15, 2021.

Virginia Burke,

FOIA/Privacy Act Officer.

PC–37—Peace Corps

SYSTEM NAME AND NUMBER:

Reasonable Accommodation Requests, PC–37.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Civil Rights and Diversity, Peace Corps, 1275 First Street NE, Washington, DC 20526. Some documents related to requests for reasonable accommodations may also be located in an electronic file in the Office of Human Resources at the same address.

SYSTEM MANAGER(S):

Director, Office of Civil Rights and Diversity, Peace Corps, 1275 First Street NE, Washington, DC 20526.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Peace Corps Act, as amended (22 U.S.C. 2503); the Rehabilitation Act of 1973, as amended (29 U.S.C. 791); Title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e); Civil Rights Act of 1991 42 U.S.C. 1981; Executive Order (E.O.) 13163, Increasing the Opportunities for Individuals with Disabilities to be Employed in the Federal Government; E.O. 13164, Requiring Federal Agencies To Establish Procedures To Facilitate the Provision of Reasonable Accommodation; E.O. 13548, Increasing Federal Employment of Individuals with Disabilities, and Executive Order 14043: Requiring Coronavirus Disease 2019 Vaccination for Federal Employees.

PURPOSE OF THE SYSTEM:

The purpose of this system is to document and manage the agency's receipt, review, approval or denial decision, and implementation of an individual's reasonable accommodation request under the Rehabilitation Act of 1973, as amended, Title VII of the Civil Rights Act, as amended, and the 1991 Civil Rights Act. The purpose is also to allow the agency to collect and maintain records on applicants for employment as well as employees with disability, medical condition or because of their religious beliefs, practice or observance who request or receive reasonable accommodations as required by the Rehabilitation Act of 1973, as amended, and Title VII of the Civil Rights Act, as amended, and the 1991 Civil Rights Act. This system will also track and report the processing of requests for reasonable accommodation to comply with applicable law and regulations and to preserve and maintain confidentiality of the records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals covered by the system are Peace Corps applicants, personnel, or public participants in a Peace Corps activity who request a reasonable accommodations on the bases of a disability, medical condition or for religious reasons. This includes federal job and internship applicants, current and former federal employees, political appointees, experts, and interns; Peace Corps Volunteer applicants, Peace Corps Volunteers, and Returned Peace Corps Volunteers; covered federal employees as defined in 5 U.S.C. 2105 to be fully vaccinated against COVID–19, and third parties who represent or advocate for or on the behalf of the requesting individual, or who participate in a Peace Corps activity or program.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in this system include the requesting individual's reasonable accommodation request form, the individual's supporting documentation for disability, or medical condition, medical records, medical notes or letters, the requested accommodation, information involving medical devices, impairments, disability type, and disability condition. Requests for accommodation for religious reasons may include documents related to support the request for religious accommodation including documents from third parties.

The categories of records also may include documents that describe the type of accommodation, documents that approve or deny the reasonable accommodation request; documents or information about the implementation of the accommodation request, emails, notes, letter and memoranda regarding the request for accommodation.

Identifying information includes the requesting individual's first and last name, office name and location; work email address and telephone numbers, employee position and grade; supervisor's full name, email address,

phone number, office name; a third-party advocate's first and last name and contact information; a health care provider's full name, work address, work phone number, fax number, work email address and signature; full name and office of personnel processing requests; the information related to the accommodation request such as medical or disability information, and religious affiliation, belief, practice, or observance for a religious accommodation request.

RECORD SOURCE CATEGORIES:

The information sources include individuals requesting reasonable accommodations, healthcare providers or supporting professionals, advocates for the individual; and Peace Corps personnel who participate in evaluation, review, determination, and implementation of a reasonable accommodation request.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, the Peace Corps may disclose all or a portion of the records or information contained in this system without the consent of the subject individual may be disclosed if the disclosure is compatible with the purpose for which the record was collected outside the Peace Corps as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. Disclosure for Law Enforcement Purposes. Information may be disclosed to the appropriate Federal, State, local, or foreign agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, if the information indicates a violation or potential violation of civil or criminal law or regulation within the jurisdiction of the receiving entity.

B. Disclosure Incident to Requesting Information. Information may be disclosed to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, or to identify the type of information requested); when necessary to obtain information relevant to a Peace Corps decision concerning retention of an employee or other personnel action (other than hiring), retention of a security clearance, the letting of a contract, or the issuance or retention of a grant or other benefit.

C. Disclosure to Requesting Agency. Information may be disclosed to a Federal, State, local, or other public authority of the fact that this system of records contains information relevant to the requesting agency's retention of an employee, the retention of a security clearance, the letting of a contract, or the issuance or retention of a license, grant, or other benefit. The other agency or licensing organization may then make a request supported by the written consent of the individual for part or all of the record if it so chooses. No disclosure will be made unless the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another Federal agency for criminal, civil, administrative, personnel, or regulatory action.

D. Disclosure to Office of Management and Budget. Information may be disclosed to the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB Circular No. A–19.

E. Disclosure to Congressional Offices. Information may be disclosed to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

F. Disclosure to Department of Justice. Information may be disclosed for purposes of litigation, provided that in each case the disclosure is compatible with the purpose for which the records were collected. Disclosure for these purposes may be made to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which the Peace Corps is authorized to appear. This disclosure may be made when: 1. The Peace Corps, or any component thereof; 2. Any employee of the Peace Corps in his or her official capacity; 3. Any employee of the Peace Corps in his or her individual capacity where the Department of Justice or the Peace Corps has agreed to represent the employee; or 4. The United States (when the Peace Corps determines that litigation is likely to affect the Peace Corps or any of its components) is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the Peace Corps is deemed by the Peace Corps to be relevant and necessary to the litigation.

G. Disclosure to the National Archives. Information may be disclosed to the National Archives and Records Administration in records management inspections.

H. Disclosure to Contractors, Grantees, and Others. Information may be disclosed to contractors, grantees, consultants, or Volunteers performing or working on a contract, service, grant, cooperative agreement, job, or other activity for the Peace Corps and who have a need to have access to the information in the performance of their duties or activities for the Peace Corps. When appropriate, recipients will be required to comply with the requirements of the Privacy Act of 1974 as provided in 5 U.S.C. 552a(m).

I. Disclosures for Administrative Claims, Complaints, and Appeals. Information may be disclosed to an authorized appeal grievance examiner, formal complaints examiner, equal employment opportunity investigator, arbitrator, or other person properly engaged in investigation or settlement of an administrative grievance, complaint, claim, or appeal filed by an employee, but only to the extent that the information is relevant and necessary to the proceeding, Agencies that may obtain information under this routine use include, but are not limited to: The Office of Personnel Management, Office of Special Counsel, Federal Labor Relations Authority, U.S. Equal Employment Commission, and Office of Government Ethics.

J. Disclosure to the Office of Personnel Management. Information may be disclosed to the Office of Personnel Management pursuant to that agency's responsibility for evaluation and oversight of Federal personnel management.

K. Disclosure in Connection with Litigation. Information may be disclosed in connection with litigation or settlement discussions regarding claims by or against the Peace Corps, including public filings with a court, to the extent that disclosure of the information is relevant and necessary to the litigation or discussions and except where court orders are otherwise required under Section (b)(11) of the Privacy Act of 1974, 5 U.S.C. 552a(b)(11).

L. Disclosure to U.S. Ambassadors. Information from this system of records may be disclosed to a U.S. Ambassador or his or her designee in a country where the Peace Corps serves when the information is needed to perform an official responsibility, to allow the Ambassador to knowledgeably respond to official inquiries and deal with in-country situations that are within the scope of the Ambassador's responsibility.

M. Disclosure to appropriate agencies, entities, and persons when (1) the Peace Corps suspects or has confirmed that there has been a breach of the system of records; (2) the Peace Corps has determined that as a result of the suspected or confirmed breach, there is a risk of harm to individuals, the Peace

Corps (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Peace Corps' efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

N. Disclosure another Federal agency or Federal entity, when the Peace Corps determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

O. Disclosures to Public Health Agencies and Authorities, individuals records' may be disclosed to federal, state, local, and Tribal health departments, other cooperating medical authorities, or other appropriate entities or organizations, in order for them to take measures to control, prevent, or treat communicable disease; and to deal more effectively with contagious diseases and conditions of public health.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records in this system of records are stored electronically on Peace Corps' database servers, hosted at the Peace Corps data center in Ashburn, VA. Access to these servers are restricted to authorized government personnel. Paper records are stored in a locked metal file cabinet.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Reasonable Accommodation Requests records and information may be retrieved by an individual's name, Employee ID number, assigned office, and date of request.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retired and destroyed in accordance with the Peace Corps' published record disposition schedules that are approved by the National Archives and Records Administration. Records in this system are subject to General Records Schedule (GRS) for ''Reasonable Accommodation Program Files,'' disposition authority: DAA–GRS–2018–0002–0001, GRS 2.3, item 010, and will be retained for three years unless a business use is identified that requires a longer retention.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The Peace Corps safeguards records in this system in accordance with applicable laws, rules and policies to protect personally identifiable information against unauthorized access or disclosure. The Peace Corps has imposed strict controls to minimize such risks. Administrative safeguards include but not limited to: Access to the records in this system is limited to authorized personnel who need to know the information to perform official duties, and whose roles have been authorized with such access permissions. All such individuals receive the appropriate privacy and cybersecurity training on an annual basis.

The physical controls in place include the servers storing electronic data are located offsite in a locked facility with access limited to authorized personnel. The servers are maintained in accordance with a government contract that requires adherence to applicable laws, rules, and policies on protecting individual privacy.

The technical controls in place include multiple firewalls, system access, encrypted data at rest, encrypted data in motion, periodic vulnerability scans to ensure security compliance, and security access logs. Security complies with applicable Federal Information Processing Standards (FIPS) issued by the National Institute of Standards and Technology (NIST). Access is restricted to specific authorized Peace Corps individuals who have internet access through work computers using a Personally Identity Verification (PIV) or an assigned RSA token for general login access. Individual users can only access records with the proper pre-approved accreditation.

RECORD ACCESS PROCEDURES:

Individuals seeking access to their records should follow the procedures in 22 CFR part 308. Individuals should address written inquiries to the Privacy Officer at *FOIA@peacecorps.gov*. Provide a signed written request containing the name and number of this system of records notice along with the individual's full name, current address, and email address. The requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the appropriate format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

Individuals may request that records about them be amended or appeal an adverse decision by writing to the Peace Corps, Privacy Act Officer, Privacy Act Office at 1275 First Street NE, Washington, DC 20526 or submitting an electronic request to *FOIA@peacecorps.gov* and furnish the same information as required in the ''Record Access Procedures'' (full name, identify the system of records, provide the relevant signed declaration). In addition, clearly and concisely state what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought.

NOTIFICATION PROCEDURES:

See ''Record Access Procedures.''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2021–25327 Filed 11–18–21; 8:45 am]

BILLING CODE 6051–01–P

RAILROAD RETIREMENT BOARD

Privacy Act of 1974; New System of Records

AGENCY: U.S. Railroad Retirement Board (RRB).

ACTION: Notice of a new system of records.

SUMMARY: The Railroad Retirement Board (RRB) proposes to add a new system of records to its existing inventory of systems of records subject to the Privacy Act of 1974. This new system of records is titled: RRB–60, Religious and Reasonable Accommodation Records. We hereby publish this notice for public comments.

DATES: These changes become effective as proposed without further notice on December 20, 2021. We will file a report of these Systems of Records Notices with the Committee on Homeland Security and Governmental Affairs of the Senate; the Committee on Oversight and Government Reform of the House of

Representatives; and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

ADDRESSES: Send comments to Stephanie Hillyard, Secretary to the Board, U.S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

FOR FURTHER INFORMATION CONTACT: Chad Peek, Chief Privacy Officer, U.S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092; telephone: 312–751–3389, email: *chad.peek@rrb.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, as amended, the RRB has determined that it needs to introduce a new system of records. The RRB proposes a new system of records, RRB–60, Religious and Reasonable Accommodation Records. The purpose of this system of records is to cover all records pertaining to requests for an accomodation for a disability or a sincerely held religious belief, practice, or observance under federal law. The records are maintained depending on the how the request is initiated. Records may be with the immediate supervisor or within the Bureau of Human Resources.

By Authority of the Board.

Stephanie Hillyard,

Secretary to the Board.

RRB–60

SYSTEM NAME AND NUMBER:

RRB–60, Religious and Reasonable Accommodation Records.

SECURITY CLASSIFICATION:

Controlled Unclassified Information (CUI).

SYSTEM LOCATION:

U.S. Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

SYSTEM MANAGER(S):

Director of Human Resources, Office of Administration, U.S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

a. 45 U.S.C. 231f(b)(9), Railroad Retirement Board Powers and Duties,

b. 29 U.S.C. 791, The Rehabilitation Act of 1973,

c. 42 U.S.C. 2000e *et seq.,* Title VII of the Civil Rights Act of 1964,

d. 29 CFR 1605, Guidelines on Discrimination Because of Religion,

e. 29 CFR 1614, Federal Sector Equal Employment Opportunity,

f. Executive Order 13164, Requiring Federal Agencies to Establish Procedures to Facilitate the Provision of Reasonable Accommodation,

g. Executive Order 13548, Increasing Federal Employment of Individuals with Disabilities.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to: (1) Allow RRB to collect and maintain records on prospective and active (as of the date of the request) employees who request or receive a reasonable accommodation by RRB based on a disabling medical condition; (2) allow RRB to collect and maintain records on prospective, and active (as of the date of the request) employees who request or receive an accommodation by RRB based on sincerely held religious beliefs, practices, or observances; (3) track and report the processing of requests for RRB in accordance with and to comply with applicable laws and regulations; and (4) preserve and maintain the confidentiality of medical and religious information submitted by or on behalf of applicants or employees requesting a reasonable accommodation.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prospective, and active (at time of request), Railroad Retirement Board (RRB) employees who request, receive and/or are denied a reasonable accommodation for a disabling medical condition or a sincerely held religious belief, practice, or observance.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name and relevant employment information of prospective or active (at time of request) employees needing an accommodation; requestor's name and contact information (if different than the employee who requested the accommodation); date request was initiated; information concerning the nature of the disability and the need for accommodation, including administratively acceptable documentation; information concerning the nature of the sincerely held religious belief, practice, or observance; why the accommodation is needed/justification for the requested accommodation, including any appropriate documentation; details of the accommodation request, such as: Type of accommodation requested; requested accommodation; how the requested accommodation would ensure the essential functions of the position would be performed; any additional information provided by the requestor related to the processing of the request; any documentation created as a result of the interactive process; any alternative accommodations; whether the request was approved (in whole or in part), modified or denied; whether the accommodation was approved for a set period of time; notification(s) to the employee and his/her supervisor(s) regarding the status and result of the requested accommodation; and, any other information collected or developed in connection with the request for a reasonable accomodation.

RECORD SOURCE CATEGORIES:

RRB employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or, information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside the RRB as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Standard Disclosure 1.—Congressional. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual if that individual would not be denied access to the information.

Standard Disclosure 2.—Presidential. Disclosure of relevant information from the record of an individual may be made to the Office of the President in response to an inquiry from that office made at the request of that individual or a third party on the individual's behalf if that individual would not be denied access to the information.

Standard Disclosure 3.—Contractors working for Federal Government. Disclosure may be made to contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal government, to the extent necessary to accomplish an RRB function related to this system of records.

Standard Disclosure 4.—Law Enforcement. Disclosure may be made to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating, enforcing, or prosecuting a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant

thereto, if the disclosure would be to an agency engaged in functions related to the Railroad Retirement Act or the Railroad Unemployment Insurance Act, or if disclosure would be clearly in the furtherance of the interest of the subject individual.

Standard Disclosure 5.—Breach Notification. Disclosure may be made, to appropriate agencies, entities, and persons when (1) the Railroad Retirement Board suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Railroad Retirement Board has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Railroad Retirement Board or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Railroad Retirement Board's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

To another Federal agency or Federal entity, when the RRB determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency, or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

Standard Disclosure 6.—National Archives. Disclosure may be made to the National Archives and Records Administration or other Federal government agencies for records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

Standard Disclosure 7.—Attorney Representative. Disclosure of non-medical information in this system of records may be made to the attorney representing such individual upon receipt of a written letter or declaration stating the fact of representation, if that individual would not be denied access to the information. Medical information may be released to an attorney when such records are requested for the purpose of contesting a determination either administratively or judicially.

In addition to the conditions of disclosure listed in 5 U.S.C. 552a(b) of the Privacy Act and the RRB's Standard Disclosures (above), the RRB may release these records:

a. Records may be disclosed to the Department of Justice, including Offices of the U.S. Attorneys; another Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body; another party in litigation before a court, adjudicative, or administrative body; or to a court, adjudicative, or administrative body. Such disclosure is permitted only when it is relevant or necessary to the litigation or proceeding, and one of the following is a party to the litigation or has an interest in such litigation:

(1) RRB, or any component thereof;

(2) Any employee or former employee of RRB in his or her official capacity;

(3) Any employee or former employee of RRB in his or her capacity where the Department of Justice or RRB has agreed to represent the employee.

b. Records may be disclosed in response to a request for discovery or for the appearance or a witness, to the extent that what is disclosed is relevant to the subject matter involved in a pending judicial or administrative proceeding.

c. Relevant records from this system of records may be disclosed to an agency, organization, or individual for the purpose of performing an audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to RRB officers and employees.

d. Relevant records from this system of records may be disclosed to physicians or other medical professionals to provide them with or obtain from them the necessary medical documentation and/or certification for reasonable accommodations.

e. Relevant records from this system of records may be disclosed to another federal agency or commission with responsibility for labor or employment relations or other issues, including equal employment opportunity and reasonable accommodation issues, when that agency or commission has jurisdiction over reasonable accommodation issues.

f. Relevant records from this system of records may be disclosed to the Department of Labor (DOL), Office of Personnel Management (OPM), Equal Employment Opportunity Commission (EEOC), or Office of Special Counsel (OSC) to obtain advice regarding statutory, regulatory, policy, and other requirements related to reasonable accommodation.

g. Relevant records from this system of records may be disclosed to appropriate third-parties contracted by the Agency to facilitate mediation or other alternative dispute resolution procedures or programs.

h. Relevant records from this system of records may be disclosed to a Federal agency or entity authorized to procure assistive technologies and services in response to a request for reasonable accommodation.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and electronic media.

RETRIEVAL:

Records can typically be retrieved by any of the data elements below:

a. Name or other unique personal identifiers

SAFEGUARDS:

Paper: Maintained in areas not accessible to the public in locking filing cabinets. Access is limited to authorized RRB employees. The Bureau of Human Resources is controlled by key card locked doors. Building has 24 hour on-site security officers, closed circuit television monitoring and intrusion detection systems.

Electronic media: Computer, computer storage rooms and Cloud storage are restricted to authorized personnel; on-line query safeguards include a lock/unlock password system, a terminal oriented transaction matrix, role based access controls and audit trail. For computerized records electronically transmitted between headquarters and field office locations, system securities are established in accordance with National Institute of Standards and Technology (NIST) guidelines, including network monitoring, defenses in-depth, incident response and forensics. In addition to the on-line query safeguards, they include encryption of all data at rest and when transmitted and exclusive use of leased telephone lines.

RETENTION AND DISPOSAL:

Retained and disposal in accordance with National Archives and Records Administration (NARA), General Record Schedules, or RRB Records Disposition Schedules:

a. *Paper:* These records will be maintained permanently at RRB until their official retention period is established by the National Archives and Records Administration (NARA).

b. *Electronic media:* Storage drives and Cloud storage: Continually updated and permanently retained. When storage drives and Cloud storage or other electronic media are no longer serviceable, they are sanitized in accordance with NIST guidelines.

RECORD ACCESS PROCEDURES:

See Notification section below.

CONTESTING RECORD PROCEDURES:

See Notification section below.

NOTIFICATION PROCEDURES:

Requests for information regarding an individual's record should be in writing addressed to the Systems Manager identified above, including the full name and social security number of the individual. Before information about any record will be released, the System Manager may require the individual to provide proof of identity or require the requester to furnish an authorization from the individual to permit release of information.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2021–25380 Filed 11–18–21; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93576; File No. SR–NYSENAT–2021–21]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Rebates

November 15, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 1, 2021, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees and Rebates (''Fee Schedule'') to (1) modify the fee for non-tiered orders adding liquidity in securities priced at or above $1.00; (2) modify the requirements to qualify for Removing Tier 4; and (3) add new Removing Tier 5. The Exchange proposes to implement the rule change on November 1, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to (1) modify the fee for non-tiered orders adding liquidity in securities priced at or above $1.00; (2) modify the requirements to qualify for Removing Tier 4; and (3) add new Removing Tier 5.

The proposed changes respond to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing and liquidity-removing orders by offering further incentives for ETP Holders to send additional adding and removing liquidity to the Exchange.

The Exchange proposes to implement the rule change on November 1, 2021.

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [4]

As the Commission itself has recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [5] Indeed, equity trading is currently dispersed across 16 exchanges,[6] 31 alternative trading systems,[7] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 18% of the market.[8] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's share of executed volume of equity trades in Tapes A, B and C securities is less than 2%.[9]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain products, in response to fee changes. While it is not possible to know a firm's reason for moving order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange trading venues to which a firm routes order flow. These fees can vary from month to month, and not all are publicly available. With respect to non-marketable order flow that would provide liquidity on an exchange, ETP Holders can choose from any one of the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[5] *See* Securities Exchange Act Release No. 51808, 84FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[6] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[7] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[8] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[9] *See id.*

16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange utilizes a ''taker-maker'' or inverted fee model to attract orders that provide liquidity at the most competitive prices. Under the taker-maker model, offering rebates for taking (or removing) liquidity increases the likelihood that market participants will send orders to the Exchange to trade with liquidity providers' orders. This increased taker order flow provides an incentive for market participants to send orders that provide liquidity. The Exchange generally charges fees for order flow that provides liquidity. These fees are reasonable due to the additional marketable interest (in part attracted by the Exchange's rebate to remove liquidity) with which those order flow providers can trade.

Proposed Rule Change

To respond to this competitive environment, the Exchange proposes the following changes to its Fee Schedule designed to provide order flow providers with additional incentives to route order flow to the Exchange. As described above, ETP Holders have a choice of where to send their order flow.

Change of Fee for Non-Tiered Orders Adding Liquidity

The Exchange proposes to increase the fee for non-tiered orders adding liquidity in securities priced at or above $1.00, currently set at $0.0028 per share, to $0.0029 per share. The proposed fee is competitive and would still be less than the fees charged by other markets for non-tiered orders adding liquidity.[10]

Proposed Change To Removing Tier 4 and Addition of New Removing Tier 5

Under current Removing Tier 4, the Exchange provides a rebate of $0.0015 per share to ETP Holders that remove liquidity from the Exchange in securities with a per share price of $1.00 or more and that have at least 50,000 Adding ADV.

The Exchange proposes to revise Removing Tier 4 by adding an additional requirement. As proposed, ETP Holders would qualify for the current rebate by if they have at least 50,000 Adding ADV *and* Adding ADV and Removing ADV combined of at least 0.04% of US CADV. The Exchange does not propose any changes to the removing rate for orders that remove liquidity that qualify for Removing Tier 4.

In addition, the Exchange proposes to add new Removing Tier 5, which would provide a rebate of $0.0007 per share to ETP Holders that remove liquidity from the Exchange in securities with a per share price of $1.00 or more and that have at least 50,000 Adding ADV.

The Exchange believes that together, these proposed changes will incentivize more ETP Holders to route liquidity-removing and liquidity-adding order flow to the Exchange to meet the tier requirements for Removing Tier 4 by adding the proposed requirement to Removing Tier 4 of a combination of Adding and Removing ADV.[11] For ETP Holders who cannot meet the proposed additional requirement to qualify for proposed Removing Tier 4, the Exchange believes that the addition of proposed new Removing Tier 5 would encourage additional removing order flow to the Exchange by providing a $0.0007 per share rebate for ETP Holders that meet the 50,000 Adding ADV requirement, which would still be less than the fees charged by other markets for non-tiered orders adding liquidity.[12]

The Exchange believes that the increased order flow that may result from these proposed changes would in turn support the quality of price discovery on the Exchange and provide additional price improvement opportunities for incoming orders.

As noted, the Exchange operates in a competitive environment. The Exchange does not know how much order flow ETP Holders choose to route to other exchanges or to off-exchange venues. Based on the profile of firms generally, the Exchange believes that additional ETP Holders could qualify for Removing Tier 4 with the additional qualification criteria if they choose to direct order flow to the Exchange. Without having a view of ETP Holders' activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any additional ETP Holders directing orders to the Exchange in order to qualify for the Removing Tier 4 or Removing Tier 5 rate.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[14] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15] While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [16]

Given the current competitive environment, the Exchange believes that the proposal represents a reasonable attempt to attract additional order flow to the Exchange while aligning the Exchange's fees with those charged by other markets. Specifically, the

[10] *See, e.g.,* Nasdaq BX Pricing Schedule, available at *https://www.nasdaqtrader.com/Trader.aspx?id=bx_pricing* (providing $0.0030 standard rate for adding displayed liquidity); Cboe EDGA Exchange Fee Schedule, available at *https://www.cboe.com/us/equities/membership/fee_schedule/edga/* (providing $0.0030 standard rate for adding displayed liquidity).

[11] The Exchange currently uses a similarly-structured requirement for Removing Tier 1. *See* Securities Exchange Act Release No. 89640 (August 12, 2020), 85 FR 53041 (August 27, 2020) (SR–NYSENAT–2020–27).

[12] *See* Nasdaq BX Pricing Schedule, available at *https://www.nasdaqtrader.com/Trader.aspx?id=bx_pricing* (providing rebates of $0.0005 for Tapes A and B and $0.0004 for Tape C for firms adding at least 50,000 ADV).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) & (5).

[15] *See* Regulation NMS, *supra* note 4, at 37499.

[16] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

proposed fee increase for non-tiered orders adding liquidity in securities priced at or above $1.00 is reasonable because it is competitive and the proposed fee would remain advantageous when compared to the fees charged by other markets for non-tiered orders adding liquidity.[17] In addition, the Exchange believes that the proposed changes to the Removing Tiers are reasonable because they would encourage greater liquidity for ETP Holders routing order flow to the Exchange.

The Exchange believes that the proposal as a whole represents a reasonable effort to promote price discovery and enhanced order execution opportunities for ETP Holders. All ETP Holders would benefit from the greater amounts of liquidity on the Exchange, which would represent a wider range of execution opportunities.

The Proposal Is an Equitable Allocation of Fees and Rebates

The Exchange believes the proposed rule change equitably allocates its fees among its market participants. The proposed change would continue to encourage ETP Holders to both submit additional liquidity to the Exchange and execute orders on the Exchange, thereby contributing to robust levels of liquidity, to the benefit of all market participants.

The Exchange believes that increasing the fee currently charged for non-tiered orders adding liquidity in securities priced at or above $1.00 is an equitable allocation of fees. Even though the proposed change would increase the fee for non-tiered orders, the Exchange does not believe that it will discourage executions on the Exchange because the proposed fee would remain advantageous when compared with comparable fees charged by other markets.[18] To the extent that the proposed change continues to attract order flow to the Exchange, this order flow would make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would continue to improve market quality for all market participants on the Exchange and, as a consequence, continue to attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

Similarly, the Exchange believes that the proposed changes to the Removing Tiers would encourage the submission of additional liquidity to the Exchange, thus enhancing order execution opportunities for ETP Holders from the additional amounts of liquidity present on the Exchange. All ETP Holders would benefit from the greater amounts of liquidity that would be present on the Exchange, which would provide greater execution opportunities and improve market quality.

The Exchange further believes that the proposal constitutes an equitable allocation of fees and credits because all similarly situated ETP Holders and other market participants would be eligible for the same general and tiered rates and would be eligible for the same fees and credits. Moreover, the proposed change is equitable because the revised fees would apply equally to all similarly situated ETP Holders. The proposal neither targets nor will it have a disparate impact on any particular category of market participant.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, ETP Holders are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

Moreover, the proposal neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal does not permit unfair discrimination because the proposal would be applied to all similarly situated ETP Holders and all ETP Holders would be subject to the same modified fee for non-tiered orders adding liquidity in securities priced at or above $1.00, and to the same qualification requirements for modified Removing Tier 4 and new Removing Tier 5. Accordingly, no ETP Holder already operating on the Exchange would be disadvantaged by the proposed allocation of fees and credits.

The Exchange further believes that the proposed changes would not permit unfair discrimination among ETP Holders because the non-tiered and tiered rates are available equally to all ETP Holders. As described above, in today's competitive marketplace, order flow providers have a choice of where to direct order flow, and the Exchange believes there are additional ETP Holders that could qualify if they chose to direct their order flow to the Exchange.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[19] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity and order flow to a public exchange, thereby enhancing order execution opportunities for ETP Holders. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [20]

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange. As described above, the Exchange believes that the proposed change would provide additional incentives for market participants to route liquidity-providing and liquidity-removing orders to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages ETP Holders to send orders, thereby contributing to robust levels of liquidity. The proposed revised requirements for the tiered rebates and fees would be available to all similarly-situated market participants, and thus, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and off-exchange venues. Because competitors are free to modify their own fees and rebates in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

[17] *See supra* note 10.

[18] *See id.*

[19] 15 U.S.C. 78f(b)(8).

[20] Regulation NMS, 70 FR at 37498–99.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [21] of the Act and subparagraph (f)(2) of Rule 19b–4 [22] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [23] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2021–21 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2021–21. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2021–21 and should be submitted on or before December 10, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–25228 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(2).

[23] 15 U.S.C. 78s(b)(2)(B).

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34418; 812–15268]

SEI Asset Allocation Trust, et al.

November 15, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under Section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from Section 15(c) of the Act.

SUMMARY: The requested exemption would permit a Trust's board of trustees (the ''Board'') to approve new sub-advisory agreements and material amendments to existing sub-advisory agreements without complying with the in-person meeting requirement of Section 15(c) of the Act.

APPLICANTS: SEI Asset Allocation Trust, SEI Daily Income Trust, SEI Institutional International Trust, SEI Institutional Investments Trust, SEI Institutional Managed Trust, SEI Tax Exempt Trust, Adviser Managed Trust, New Covenant Funds, SEI Catholic Values Trust (each a ''Trust'') and SEI Investments Management Corporation.

FILING DATES: The application was filed on September 27, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below.

Hearing requests should be received by the Commission by 5:30 p.m. on December 10, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: John J. O'Brien, Esq., *johnobrien@morganlewis.com.*

FOR FURTHER INFORMATION CONTACT: Lisa Reid Ragen, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and condition, please refer to Applicants' application, dated September 27, 2021, which may be obtained via the Commission's website by searching for the file number, using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–25231 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93570; File No. SR–NYSEArca-2021–37]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the First Trust SkyBridge Bitcoin ETF Trust Under NYSE Arca Rule 8.201–E

November 15, 2021.

On May 6, 2021, NYSE Arca, Inc. (''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the First Trust SkyBridge Bitcoin ETF Trust under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on May 27, 2021.[3]

On July 7, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On August 20, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7]

Section 19(b)(2) of the Act [8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on May 27, 2021.[9] The 180th day after publication of the proposed rule change is November 23, 2021. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised in the comment letters that have been submitted in connection therewith. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates January 22, 2022, as the date by which the Commission shall either approve or disapprove the proposed rule change (File Number SR–NYSEArca-2021–37).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–25224 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93574; File No. SR–NYSEArca–2021–29]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of ConvexityShares 1x SPIKES Futures ETF Under NYSE Arca Rule 8.200–E (Trust Issued Receipts)

November 15, 2021.

On May 13, 2021, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the ConvexityShares 1x SPIKES Futures ETF, a series of the ConvexityShares Trust, under NYSE Arca Rule 8.200–E, Commentary .02 (''Trust Issued Receipts''). The proposed rule change was published for comment in the **Federal Register** on May 26, 2021.[3] On July 2, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[5] On July 26, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.[6] On August 12, 2021, the Commission noticed filing of Amendment No. 1 and instituted proceedings pursuant to Section 19(b)(2)(B) of the Act [7] to determine whether to approve or disapprove the proposed rule change.[8]

Section 19(b)(2) of the Act [9] provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on May 26, 2021. November 22, 2021 is 180 days from that date, and January 21, 2022 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and comment

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91962 (May 21, 2021), 86 FR 28646. Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-nysearca-2021-37/srnysearca202137.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92333, 86 FR 36826 (July 13, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92714, 86 FR 47662 (Aug. 26, 2021).

[8] 15 U.S.C. 78s(b)(2).

[9] *See supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91952 (May 20, 2021), 86 FR 28410.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92321, 86 FR 36173 (July 8, 2021).

[6] Amendment No. 1 is available at: *https://www.sec.gov/comments/sr-nysearca-2021-29/srnysearca202129.htm.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 92650, 86 FR 46287 (August 18, 2021). The comment letter received is available on the Commission's website at: *https://www.sec.gov/comments/sr-nysearca-2021-29/srnysearca202129.htm.*

[9] 15 U.S.C. 78s(b)(2).

letter received. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates January 21, 2022 as the date by which the Commission shall either approve or disapprove the proposed rule change, as modified by Amendment No. 1 (File No. SR–NYSEArca–2021–29).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–25226 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93577; File No. SR–Phlx–2021–68]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend FINRA Fees

November 15, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 5, 2021, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Phlx's Pricing Schedule at Equity 7, Section 4, Membership Fees, and Options 7, Section 9, Other Member Fees, to reflect adjustments to FINRA Registration Fees and Fingerprinting Fees.

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on January 2, 2022.[4]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

This proposal amends Phlx's Schedule at Equity 7, Section 4, Membership Fees, and Options 7, Section 9, Other Member Fees, to reflect adjustments to FINRA Registration Fees and Fingerprinting Fees.[5] The FINRA fees are collected and retained by FINRA via Web CRD for the registration of employees of Phlx members that are not FINRA members (''Non-FINRA members''). The Exchange is merely listing these fees on its Pricing Schedule. The Exchange does not collect or retain these fees.

Options 7

Today, Phlx Options 7, Section 9C, provides a list of FINRA Fees. The Exchange proposes to amend Options 7, Section 9C to: (1) Add the title ''General Registration Fees:''; (2) indicate ''CRD'' is the ''Central Registration Depository'' or ''CRD''; and (3) remove the numbering from (1) to (3).

With respect to the General Registration Fees, the Exchange proposes to increase the $100 fee to $125 for each initial Form U4 filed for the registration of a representative or principal. This amendment is made in accordance with a recent FINRA rule change to adjust to its fees.[6] The Exchange also proposes to amend the description of the $45 registration fee from ''annually for each of the member's registered representatives and principals for system processing'' to ''FINRA Annual System Processing Fee Assessed only during Renewals.'' The proposed new title is more precise.

With respect to the fingerprint processing fees, the Exchange notes that the current fees do not reflect the fees assessed by FINRA today. The Exchange proposes to amend the current fees to reflect the current fees that are assessed by FINRA. The proposed new rule text, with the title, ''Fingerprint Processing Fees:'' added, would provide,

Fingerprint Processing Fees:
$29.50—Initial Submission (Electronic)
$44.50—Initial Submission (Paper)
$15.00—Second Submission (Electronic)
$30.00—Second Submission (Paper)
$29.50—Third Submission (Electronic)
$44.50—Third Submission (Paper)
$30.00—FINRA Processing Fee for Fingerprint Results Submitted by Self-Regulatory Organizations other than FINRA.

In 2012, FINRA only offered one set of fees ($27.50 for the initial submission, $13.00 for the second submission, and $27.50 for the third submission). In 2013, FINRA amended its fingerprint fees and offered two sets of fees. For fingerprints submitted on paper card, the fees are $44.50 per initial submission, $30.00 per second submission, and $44.50 per third submission. For fingerprints submitted electronically, the fees are $29.50 per initial submission, $15.00 per second submission, and $29.50 per third submission.[7] By updating the

[10] *Id.*

[11] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR–FINRA–2020–032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adjust FINRA Fees To Provide Sustainable Funding for FINRA's Regulatory Mission).

[5] FINRA operates Web CRD, the central licensing and registration system for the U.S. securities industry. FINRA uses Web CRD to maintain the qualification, employment and disciplinary histories of registered associated persons of broker-dealers.

[6] *Id.* FINRA noted in its rule change that it was adjusting its fees to provide sustainable funding for FINRA's regulatory mission.

[7] *See* Securities Exchange Act Release No. 67247 (June 25, 2012) 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–030) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Sections 4 and 6 of Schedule A to the FINRA By-Laws Regarding Fees Relating to the Central Registration Depository). FINRA notes in this rule change that it is proposing a two-tiered fingerprint processing fee structure in part to reflect that the costs associated with processing fingerprints submitted via a hard copy fingerprint card are much higher than those that are submitted electronically. Specifically, fingerprints submitted by a hard copy card require additional processing by FINRA, including adding a barcode, if necessary, to the card for tracking purposes; scanning the fingerprints and converting them to a digital image for submission to the FBI; and, for first-time registrants, entering the individual's personal and demographic information into the CRD system. FINRA noted that members will be able to choose how they submit their associated persons' fingerprints and therefore will have some control over the fees they incur for fingerprint processing. FINRA also noted an FBI Fee of $11.25 is assessed as well.

fingerprinting fees, the Exchange would properly reflect the fees assessed today by FINRA.[8]

The Exchange is deleting the fees noted within current Options 7, Section 9C at (4)–(7).[9] These fingerprint fees, which are proposed to be deleted, were superseded by the FINRA fingerprinting fees which were adopted in 2013.

The FINRA Web CRD Fees are user-based and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a Non-FINRA member. Accordingly, the proposed fees mirror those currently assessed by FINRA.

The Exchange also proposes to update a rule citation within the Continuing Education Fees from ''General 4, Section 1.1240'' to ''General 4, Section 1240.''

Equity 7

The Exchange also proposes to amend Equity 7, Section 4, Membership Fees, to add a new section ''B'' titled ''Regulatory, Registration, and Processing Fees.'' This new section ''B'' would inform PSX members that applicable FINRA fees are located within Options 7, Section 9C. Members of Phlx may elect to become PSX only members, therefore this new rule text would provide information to those members regarding FINRA Fees. The Exchange proposes to state, ''A list of fees that will be collected and retained by FINRA via the Web CRD registration system for the registration of associated persons of Exchange members that are not also FINRA members is available within Options 7, Section 9C.''

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Options 7

The Exchange believes it is reasonable to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 in accordance with an adjustment to FINRA's fees.[12] The Exchange's rule text will reflect the current registration rate that will be assessed by FINRA as of January 2, 2022. Amending the title of the $45 fee to be more precise will provide greater transparency to this fee. Updating FINRA's fingerprint processing fees to reflect the current charges will bring greater transparency to these charges that are currently assessed and collected by FINRA. The proposed fees are identical to those adopted by FINRA for use of Web CRD for disclosure and the registration of FINRA members and their associated persons. These costs are borne by FINRA when a Non-FINRA member uses Web CRD.

The Exchange believes that its proposal to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 is equitable and not unfairly discriminatory as the amendment will reflect the current fee that will be assessed by FINRA to all members who require Form U4 filings as of January 2, 2022. Amending the title of the $45 fee to be more precise will provide greater transparency to this fee. Updating the fingerprint processing fees to reflect the current fees is equitable and not unfairly discriminatory as FINRA currently assesses these rates to all members. Further, the proposal is also equitable and not unfairly discriminatory because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

Equity 7

The Exchange's proposal to amend Equity 7, Section 4, Membership Fees, to add a new section ''B'' titled ''Regulatory, Registration, and Processing Fees'' that informs members of applicable FINRA Fees is reasonable. This new section ''B'' would inform PSX members that applicable FINRA fees are located within Options 7, Section 9C. Members of Phlx may elect to become PSX only members. The proposed rule text would provide information to those members regarding FINRA Fees.

The Exchange's proposal to amend Equity 7, Section 4, Membership Fees, to add a new section ''B'' titled ''Regulatory, Registration, and Processing Fees'' that informs members of applicable FINRA Fees is equitable and not unfairly discriminatory because the Exchange will not be collecting or retaining these fees, therefore will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Options 7

The Exchange believes that its proposal to increase the $100 fee for each initial Form U4 filed for the registration of a representative or principal to $125 does not impose an undue burden on competition as the amendment will reflect the current fee that will be assessed by FINRA to all members who require Form U4 filings as of January 2, 2022. Amending the title of the $45 fee to be more precise will provide greater transparency to this fee. Updating the fingerprint processing fees to reflect the current fees does not impose an undue burden on competition as FINRA currently assesses these rates to all members. Further, the proposal does not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

Equity 7

The Exchange's proposal to amend Equity 7, Section 4, Membership Fees, to add a new section ''B'' titled ''Regulatory, Registration, and Processing Fees'' that informs members of applicable FINRA Fees does not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees, therefore will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

[8] *See https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees.*

[9] The Exchange proposes to delete the following rule text:

(4) $15 for processing and posting to the CRD system each set of fingerprints submitted electronically by the member, plus a pass-through of any other charge imposed by the United States Department of Justice for processing each set of fingerprints;

(5) $30 for processing and posting to the CRD system each set of fingerprint cards submitted in non-electronic format by the member to FINRA, plus any other charge that may be imposed by the United States Department of Justice for processing each set of fingerprints;

(6) $30 for processing and posting to the CRD system each set of fingerprint results and identifying information that has been processed through a self-regulatory organization other than FINRA; and

(7) $110 for the additional processing of each initial or amended Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See* note 3 above.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2021–68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2021–68. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2021–68, and should be submitted on or before December 10, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–25229 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93575; File No. SR–NYSEArca–2021–28]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of ConvexityShares Daily 1.5x SPIKES Futures ETF Under NYSE Arca Rule 8.200–E (Trust Issued Receipts)

November 15, 2021.

On May 13, 2021, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the ConvexityShares Daily 1.5x SPIKES Futures ETF, a series of the ConvexityShares Trust, under NYSE Arca Rule 8.200–E, Commentary .02 (''Trust Issued Receipts''). The proposed rule change was published for comment in the **Federal Register** on May 26, 2021.[3] On July 2, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[5] On July 26, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.[6] On August 12, 2021, the Commission noticed filing of Amendment No. 1 and instituted proceedings pursuant to Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change.[8] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[9] provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on May 26, 2021. November 22, 2021 is 180 days from that date, and January 21, 2022 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates January 21, 2022 as the date by which the Commission shall either approve or disapprove the proposed rule change, as modified by Amendment No. 1 (File No. SR–NYSEArca–2021–28).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91949 (May 20, 2021), 86 FR 28420.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92320, 86 FR 36309 (July 9, 2021).

[6] Amendment No. 1 is available at: *https://www.sec.gov/comments/sr-nysearca-2021-28/srnysearca202128-9090695-246773.pdf.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 92651, 86 FR 46292 (August 18, 2021).

[9] 15 U.S.C. 78s(b)(2).

[10] *Id.*

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–25227 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93571; File No. SR–CboeBZX–2021–039]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the Wise Origin Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

November 15, 2021.

On May 10, 2021, Cboe BZX Exchange, Inc. (''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Wise Origin Bitcoin Trust under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on June 1, 2021.[3]

On July 13, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On August 23, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7]

Section 19(b)(2) of the Act[8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on June 1, 2021.[9] The 180th day after publication of the proposed rule change is November 28, 2021. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised in the comment letters that have been submitted in connection therewith. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates January 27, 2022, as the date by which the Commission shall either approve or disapprove the proposed rule change (File Number SR–CboeBZX–2021–039).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–25225 Filed 11–18–21; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17167 and #17168; California Disaster Number CA–00345]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of California

AGENCY: Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of California (FEMA–4619–DR), dated 09/12/2021.

Incident: Caldor Fire.

Incident Period: 08/14/2021 through 10/21/2021.

DATES: Issued on 11/10/2021.

Physical Loan Application Deadline Date: 11/12/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/13/2022.

ADDRESSES: Submit completed loan applications to:U.S. Small Business Administration,Processing and Disbursement Center,14925 Kingsport Road,Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of California, dated 09/12/2021, is hereby amended to establish the incident period for this disaster as beginning 08/14/2021 through 10/21/2021.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–25273 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

Privacy Act of 1974; System of Records Notice

AGENCY: Small Business Administration.

ACTION: Notice of a modified system of records.

SUMMARY: The U.S. Small Business Administration (SBA) proposes to modify its system ofrecords titled, Disaster Loan Case File, (SBA 20), to its inventory of records systems subject to thePrivacy Act of 1974, as amended. Publication of this notice complies with the Privacy Act and the Office of Management and Budget (OMB) Circular A–108 and Circular A–130. System of Records Notice (SORN) Disaster Loans Case Files, (SBA 20), includes modifying the name from ''Disaster Loan Case File'' to ''Disaster Loans Case Files'', modifying system location, contact information, authority, purpose, categories of individuals, categories of records, record source categories, routine use, storage, retention, retrieval, safeguards, record access, contesting, notification procedures, and supplemental information. SBA 20 has also expanded the scope of its system of records with additional applications and processes, serving a unique purpose for carrying out the mission of the SBA Office of Disaster Assistance.

[11] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91994 (May 25, 2021), 86 FR 29321. Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-cboebzx-2021-039/srcboebzx2021039.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92388, 86 FR 38163 (July 19, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92721, 86 FR 48272 (Aug. 27, 2021).

[8] 15 U.S.C. 78s(b)(2).

[9] *See supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

DATES: Submit comments on or before December 20, 2021. This revised system will be effective upon publication.

ADDRESSES: You may submit comments on this notice by any of the following methods:

Federal e-Rulemaking Portal: *http://www.regulations.gov:* Follow the instructions forsubmitting comments. Mail/Hand Delivery/Courier: Submit written comments to:Barbara Carson, Deputy Associate Administrator, Office of Disaster Assistance, U.S. SmallBusiness Administration, 409 3rd Street SW, Suite 6032, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: General questions, please contact Michael Yeager, Information Technology (IT) Director, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6032, Washington, DC 20416 or via email *Michael.Yeager@sba.gov,* telephone 202–205–6536. For Privacy related matters, please contact Keith A. Bluestein, Chief Information Officer/ Senior Agency Official for Privacy, Office of the Chief Information Officer, U.S. Small Business Administration, 409 3rd Street SW, Suite 4000, Washington, DC 20416 or via email to *Privacyofficer@sba.gov.*

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974 (5 U.S.C. 552a), as amended, embodies fair information practice principles in a statutory framework governing how Federal agencies collect, maintain, use, and disseminate individuals' personal information. The Privacy Act applies to records about individuals that are maintained in a ''system of records.'' A system of records is a group of any records under the control of a federal agency from which information is retrieved by the name of an individual or by a number, symbol or another identifier assigned to the individual. The Privacy Act requires each Federal agency to publish in the **Federal Register** a System of Records Notice (SORN) identifying and describing each system of records the agency maintains, the purposes for which the Agency uses the Personally Identifiable Information (PII) in the system, the routine uses for which the Agency discloses such information outside the Agency, and how individuals can exercise their rights related to their PII information.

The modified Privacy Act system of records titled Disaster Loan Case File, (SBA 20) will be used to provide notice to applicants and recipients of disaster assistance through its Office of Disaster Assistance (ODA), which coordinates low-interest, long-term loans for damages caused by a declared disaster for individuals, businesses of all sizes, private non-profit organizations, homeowners, and renters. SBA 20 also includes loan advances and grants administered by ODA, which are available to small businesses, including sole proprietors, and private non-profit organizations.

SBA 20 collects information relating to pre-application registrants, disaster home andbusiness loan applicants, recipients of a disaster home and business loans from the time of pre-application registration, loan advance applicants and recipients, and grant applicants and recipients. Non-exhaustive list includes loan applications, loan advance applications, grant applications, supporting documentation, personal history, financial statements, tax information, credit information, investigative reports, appraisal reports, waivers, loan record transfers, correspondence, recommendations, authorizations, award amount, disbursement amount, loan term and rate, payment history, collateral, UCC filings and re-filings, collection and liquidation activities, settlements and compromises, bank information, field visit reports, borrower's insurance information and loan accounting information.

Major application/system components to this system of records comprise of Disaster CreditManagement System(s), Shuttered Venue Operators Grant System (SVOG), Rapid Finance (RF) Portal, Ayaya Automated Interactive Voice Response (IVR), cloud services, legacyand multiple portals. The modification of SBA 20 will not have any undue impact on the privacy ofindividuals and its use is compatible with collection.

SYSTEM NAME AND NUMBER:

Disaster Loans Case Files, (SBA 20).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

SBA DCMS Operations Center, Herndon, VA, Washington, DC, Chicago, IL, other Salesforce, and Microsoft Offsite locations within the United States; Rapid Financein Bethesda, MD;

SYSTEM MANAGER(S):

Michael Yeager, IT Director, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6032, Washington, DC 20416 or via email *Michael.Yeager@sba.gov,* telephone 202–205–6536.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 634(b)(6), 44 U.S.C. 3101The Economic Aid to Hard-Hit Small Businesses, Nonprofits and Venues Act, Public Law 116–260

PURPOSE(S) OF THE SYSTEM:

SBA 20 collects information relating to pre-applicationregistrants, disaster home and business loan applicants, recipients of a disaster home andbusiness loans from the time of pre-application registration, loan advance applicants and recipients, and grant applicants and recipients.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals, businesses, principals, including sole proprietors, homeowners, renters, and non-profits.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information relating to pre-application registrants, disaster home and business loan applicants, loan advance, grant applicants and recipients of loan advances, grants, disaster home and business loans. Included are name, business name, address, tax identification number, date of birth, telephone number, identification, loan information, loan advance, grant applications, supporting documents, personal history, financial statements, credit information, investigative reports, appraisers' reports, waivers, loan record transfers, correspondence, recommendations,authorizations, disbursement amount, term and rate, payment history, collateral, Uniform Commercial Code (UCC) filings and re-filings, collection and liquidation activities, financial statements, settlements and compromises, bank information, field visit reports, borrower's insurance information and loan accounting information.

RECORD SOURCE CATEGORIES:

Subject, individuals, SBA employees, SBA contractors, financial institutions, credit reporting agencies, law enforcement agencies, Treasury Department and Federal Emergency Management Agency (FEMA).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDINGCATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act,all or a portion of the information contained in this system may be disclosed to authorizedentities, as is determined to be relevant and necessary, outside SBA as a routine use pursuant to 5U.S.C. 552a(b)(3) as follows:

A. To the public on approved loans. This information includes recipient name and address, term and rate of the loan and the amount paid in full or charged off.

B. To the public on approved loan advances and grants. This information includes recipient name, address, period of performance and amount of the loan advance or grant.

C. To provide information to potential investors who are interested in bidding on loans made available by the Agency in a sale of assets. Investors will be required to execute a confidentiality agreement prior to reviewing any record or information.

D. To the Federal, State, local or foreign agency or professional organization which has responsibility for investigating, prosecuting, or enforcing violations, statutes, rules, regulations or orders issued when the Agency identifies a record, either alone or in conjunction with other information, which indicates a violation or potential violation of law.

E. To request information from a Federal, State, or local agency or a private credit agency maintaining civil, criminal, or other information relevant to determining an applicant's suitability for a loan, loan advance, or grant; this may be requested individually or part of a computer match.

F. In response to a request from a State or Federal agency in connection with the issuance of a grant, loan or other benefit by that agency which is relevant to their decision on the matter; this may be requested individually or part of a computer match.

G. To other Federal agencies to conduct computer matching programs to locate and identify delinquent SBA borrowers who are receiving Federal salaries or benefit payments. Disclosure will be made if the records indicate the loan is in default, at least 30 days past due or to update a previous disclosure. SBA will make disclosures to obtain repayments of debts under the provisions of the Debt Collection Act of 1982 by voluntary repayment, or administrative or salary offset procedures.

H. To a consumer reporting agency to also include information from the new ID Theft Form 3515.

I. To provide the Internal Revenue Service (IRS) with access to an individual's records for an official audit to the extent the information is relevant to the IRS's function.

J. To a court, magistrate, grand jury, or administrative tribunal, opposing counsel during such proceedings or in settlement negotiations when presenting evidence.

K. To a Congressional office from an individual's record when that office is inquiring onthe individual's behalf; the Member's access rights are no greater than the individuals.

L. In a proceeding before a court, or adjudicative body, or a dispute resolution body before which SBA is authorized to appear or before which any of the following is a party to litigation or has an interest in litigation, provided, however, that SBA determines that the use of such records is relevant and necessary to the litigation, and that, in each case, SBA determines that disclosure of the records to a court or other adjudicative body is a use of the information contained in the records that is a compatible purpose for which the records were collected: SBA, or any SBA component; any SBA employee in their official capacity; any SBA employee in their individual capacity where DOJ has agreed to represent the employee; or The United States Government, where SBA determines that litigation is likely to affect SBA or any of its components.

M. To transmit data to U.S. Department of the Treasury to effect issuance of loan, loan advance, or grant funds to borrowers or recipients.

N. To the Federal Emergency Management Agency (FEMA) to coordinate the issuance offederal disaster assistance to disaster victims and monitor for duplication.

O. To the Department of Justice (DOJ), including offices of the U.S Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is deemed by the SBA to be relevant or necessary to the litigation or the SBA has an interest in such litigation when any of the following are a party to the litigation or have an interest in the litigation: (1) Any employee or former employee of the SBA in his or her official capacity; (2) Any employee or former employee of the SBA in his or her individual capacity when DOJ or SBA has agreed to represent the employee or a party to the litigation or have an interest in the litigation; or (3)The United States or any agency thereof.

P. To the National Archives and Records Administration (NARA) or General Services Administration (GSA) pursuant to records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

Q. To an agency or organization, including the SBA's Office of Inspector General, for the purpose of performing audit or oversight operations as authorized by law. but only such information as is necessary and relevant to such audit or oversight function.

R. To appropriate agencies, entities, and persons when (1) SBA suspects or has confirmed that there has been a breach of the system of records, (2) SBA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, SBA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with SBA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

S. To another Federal agency or Federal entity, when SBA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

T. To another agency or agent of a Government jurisdiction within or under the control of the U.S., lawfully engaged in national security or homeland defense when disclosure is undertaken for intelligence, counterintelligence activities (as defined by 50 U.S.C. 3003(3)), counterterrorism, homeland security, or related law enforcement purposes, as authorized by U.S. law or Executive Order.

U. To SBA contractors, grantees, volunteers, interns, regulators, and experts who have been engaged by SBA to assist in the performance and performance improvement of a service related to this system of records and who need access to the records to perform this activity which may also include for regulatory purposes. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper and electronic files.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name of individual, business name, application number, grant number, Data Universal Numbering System, cross-referenced loan number or borrower's Social

Security Number or Employer Identification Number or FEMA registration number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained in accordance with latest edition SBA Standard Operating Procedure (SOP) series 00 41, schedules Records Management Records and Agency Accountability Records. Records maintained as part of the General Records Schedules (GRS) are disposed of in accordance with applicable SBA policies.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access and use are limited to persons with official need to know. Users are evaluated on a recurring basis to ensure need-to-know still exists. Safeguards are implemented in accordance with the Federal Information Security Modernization Act of 2014 (FISMA) and are evaluated on a recurring basis to ensure desired operation.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to records about them should submit a Privacy Act request to the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.* Individuals must provide their full name, mailing address, personal email address, telephone number, and a detailed description of the records requested. Individuals requesting access must also follow SBA's Privacy Act regulations regarding verification of identity and access to records (13 CFR part 102 subpart B).

CONTESTING RECORD PROCEDURES:

Individuals wishing to contest information contained in records about them should submit a Privacy Act request to the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.* Individuals must provide their full name, mailing address, personal email address, telephone number, and a detailed description of the records requested. Requesting individuals must follow SBA's Privacy Act regulations regarding verification of identity and access to records (13 CFR part 102 subpart B).

NOTIFICATION PROCEDURES:

Individuals may make record inquiries in person at the address listed below or in writing to the Systems Manager through the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.*

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

74 FR 14889 (April 1, 2009); 72 FR 48312 (August 23, 2007); 69 FR 76964 (December 23, 2004); and 69 FR 58597 (September 30, 2004).

James Rivera,

Associate Administrator for Disaster Assistance, Office of Disaster Assistance.

[FR Doc. 2021–25276 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17119 and #17120; CALIFORNIA Disaster Number CA–00340]

Presidential Declaration Amendment of a Major Disaster for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of California (FEMA–4610–DR), dated 08/24/2021.

Incident: Wildfires.

Incident Period: 07/14/2021 through 10/25/2021.

DATES: Issued on 11/10/2021.

Physical Loan Application Deadline Date: 11/08/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 05/24/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of California, dated 08/24/2021, is hereby amended to establish the incident period for this disaster as beginning 07/14/2021 through 10/25/2021.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–25284 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17196 and #17197; CALIFORNIA Disaster Number CA–00347]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of California (FEMA–4610–DR), dated 09/24/2021.

Incident: Wildfires.

Incident Period: 07/14/2021 through 10/25/2021.

DATES: Issued on 11/10/2021.

Physical Loan Application Deadline Date: 11/23/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/24/2022.

ADDRESSES: Submit completed loan applications to:U.S. Small Business Administration,Processing and Disbursement Center,14925 Kingsport Road,Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of California, dated 09/24/2021, is hereby amended to establish the incident period for this disaster as beginning 07/14/2021 through 10/25/2021.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administratorfor Disaster Assistance.

[FR Doc. 2021–25282 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17165 and #17166; Pennsylvania Disaster Number PA–00113]

Presidential Declaration Amendment of a Major Disaster for the Commonwealth of Pennsylvania

AGENCY: Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the Commonwealth of Pennsylvania (FEMA–4618–DR), dated 09/10/2021.

Incident: Remnants of Hurricane Ida.

Incident Period: 08/31/2021 through 09/05/2021.

DATES: Issued on 11/05/2021.

Physical Loan Application Deadline Date: 12/10/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/10/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the Commonwealth of Pennsylvania, dated 09/10/2021, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 12/10/2021.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–25239 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17268 and #17269; Michigan Disaster Number MI–00104]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Michigan

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Michigan (FEMA–4607–DR), dated 11/10/2021.

Incident: Severe Storms, Flooding, and Tornadoes.

Incident Period: 06/25/2021 through 06/26/2021.

DATES: Issued on 11/10/2021.

Physical Loan Application Deadline Date: 01/10/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 08/10/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/10/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Ionia, Wayne

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17268 6 and for economic injury is 17269 0.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–25236 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

Privacy Act of 1974; System of Records Notice

AGENCY: Small Business Administration.

ACTION: Notice of a new system of records.

SUMMARY: The U.S. Small Business Administration (SBA) proposes a new system of records titled Reasonable Accommodations, Personal Assistance Services, and Medical/Religious Exceptions (SBA 42), to its inventory of records systems subject to the Privacy Act of 1974, as amended. Publication of this notice complies with the Privacy Act and the Office of Management and Budget (OMB) Circular A–108 and Circular A–130. System of Records Notice (SORN) titled Reasonable Accommodations, Personal Assistance Services, and Medical/Religious Exceptions (SBA 42), includes current and former SBA employees, applicants for employment, and members of the public that request reasonable accommodations, personal assistance services or medical/religious exceptions. Reasonable accommodations and personal services for former and current federal employees may be requested to perform work-related duties. SBA is fully committed to providing reasonable accommodation and personal assistance services to employees and SBA applicants for employment as part of the larger effort to foster an inclusive organizational culture that empowers all employees to realize their full potential. Members of the public may request reasonable accommodations to attend SBA sponsored events or meetings and to seek information or services from SBA's programs or products. Medical/religious exceptions may be requested by employees and SBA applicants based on a medical condition or circumstance or a sincerely held religious belief, practice, or observance. All requests are processed through the Office of Diversity, Inclusion and Civil Rights (ODI&CR).

DATES: Submit comments on or before December 20, 2021. This new system will be effective upon publication.

ADDRESSES: You may submit comments on this notice by any of the following methods: Federal e-Rulemaking Portal: *http://www.regulations.gov:* Follow the instructions for submitting comments. Mail/Hand Delivery/Courier: Submit written comments to: Gaye Walker, Deputy Assistant Administrator, Office of Diversity, Inclusion and Civil Rights, U.S. Small Business Administration, 409 3rd Street SW, Suite 6400, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: General questions, please contact Dr. Zina Sutch, Assistant Administrator Office of Diversity, Inclusion, and Civil Rights, U.S. Small Business Administration, 409 3rd Street SW, Suite 6400, Washington, DC, 20416 or

via email, *Zina.Sutch@sba.gov,* telephone 202–836–0036. For Privacy related matters, please contact Keith A. Bluestein, Chief Information Officer/ Senior Agency Official for Privacy, Office of the Chief Information Officer, U.S. Small Business Administration, 409 3rd Street SW, Suite 4000, Washington, DC, 20416 or via email to *Privacyofficer@sba.gov.*

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974 (5 U.S.C. 552a), as amended, embodies fair information practice principles in a statutory framework governing how Federal agencies collect, maintain, use, and disseminate individuals' personal information. The Privacy Act applies to records about individuals that are maintained in a ''system of records.'' A system of records is any group of records under the control of a federal agency from which information is retrieved by the name of an individual or by a number, symbol or any other identifier assigned to the individual. The Privacy Act requires each federal agency to publish in the **Federal Register** a System of Records Notice (SORN) identifying and describing each system of records the agency maintains, the purpose for which the agency uses the Personally Identifiable Information (PII) in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals can exercise their rights related to their PII information.

The new Privacy Act system of records titled Reasonable Accommodations, Personal Assistance Services, and Medical/Religious Exceptions (SBA 42) will be used to provide notice to requesters for, and recipients of, reasonable accommodations, personal assistance services, and medical/religious exceptions through the ODI&CR. The mission of the ODI&CR is to champion a diverse workforce and inclusive culture by ensuring equal access and equitable treatment regarding employment and entrepreneurial endeavors.

Requests for reasonable accommodations and personal assistance services may be made orally; however, such request must eventually be transferred to the applicable template.

This system of records is comprised of electronic and hardcopy records managed by ODI&CR. SBA 42 will not have any undue impact on the privacy of individuals and its use is compatible with collection.

SYSTEM NAME AND NUMBER:

Reasonable Accommodations, Personal Assistance Services, and Medical/Religious Exceptions (SBA 42).

SECURITY CLASSIFICATION:

Controlled Unclassified Information.

SYSTEM LOCATION:

Office of Diversity, Inclusion and Civil Rights, 409 Third Street SW, Suite 6400 Washington, DC 20416.

SYSTEM MANAGER(S):

Gaye Walker, Deputy Assistant Administrator, Office of Diversity, Inclusion and Civil Rights, U.S. Small Business Administration, 409 3rd Street SW, Suite 6400, Washington, DC 20416 or via email *Gaye.Walker@sba.gov,* telephone: 202–205–6753.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Rehabilitation Act of 1973, as amended (29 U.S.C. 791 *et seq.*); the Americans with Disabilities Act of 1990, as amended (42 U.S.C. 12102, 12114); the Americans with Disabilities Act (ADA) Amendments Act of 2008); Federal regulations (29 U.S.C. 791 *et seq.*); and 29 CFR 1614 and 1630. 29 CFR part 1630 implements the Americans with Disabilities Act; Title VII of the Civil Rights Act of 1964 (Title VII), as amended—codified at 42 U.S.C. 2000e *et seq.,* Religious Freedom Restoration Act of 1993, Executive Order (E.O.)14043, ''Requiring Coronavirus Disease 2019 Vaccination for Federal Employees''.

PURPOSE(S) OF THE SYSTEM:

The purpose of the System is to allow SBA to collect and maintain records on applicants for employment, employees (including former employees) and members of the public who request a reasonable accommodation under sections 501, 504, and 701 of the Rehabilitation Act of 1973 and under the ADA Amendments of 2008; employees who request or receive personal assistance services under Section 501, as amended, under the Rehabilitation Act; and employees requesting medical/religious exceptions in compliance with E.O. 14043, ''Requiring Coronavirus Disease 2019 Vaccination for Federal Employees'', and any other applicable laws or regulations. In addition, the purpose of the system is to track and report to appropriate entities the processing of requests for reasonable accommodations, personal assistance services and medical/religious exception requests to ensure compliance with applicable laws and regulations, and to preserve and maintain the confidentiality of medical and religious affiliation information. Information in this system will be used to evaluate, approve, deny, and/or implement a request for reasonable accommodations personal assistance services, or medical/ religious exceptions.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for employment, employees (current and former), and any other individuals who request(ed) or receive(d) a reasonable accommodation under Sections 501, 504, and 701 of the Rehabilitation Act of 1973 and under the ADA Amendments of 2008; employees who request(ed) or receive(d) personal assistance services under Section 501, as amended, of the Rehabilitation Act; and employees requesting medical/ religious exceptions per E.O. 14043. This also includes authorized individuals or representatives who file requests for reasonable accommodation on behalf of an application for employment, or who file requests for reasonable accommodations, personal assistance services or medical/religious exceptions on behalf of an employee, or other individual, as well as former employees who requested or received reasonable accommodations, personal assistance services or medical/religious exceptions during their employment with SBA.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include, but are not limited to:

- Requester's name, contact information (*i.e.,* address, telephone number, email address and any other information provided), or other unique identifier.
- Requester's authorized representative's name and contact information (*i.e.,* address, telephone number, email address and any other information provided).
- Requester's status (*i.e.,* applicant, employee, or other).
- Request date.
- Meeting or other event for which the request was made (date and time of meeting/event, location).
- Job(s) (occupational series, grade level, and agency component) for which a reasonable accommodation or personal assistance service was requested.
- Information concerning the nature of any disability and the need for accommodation or assistance.
- Appropriate medical or other documentation provided in support of the request.
- Appropriate religious affiliation documents provided in support of the request.

• Details of a reasonable accommodation or personal assistance service request to include: Type(s) of accommodation or assistance requested; whether the accommodation requested was pre-employment or during employment, or for some other reason; whether the assistance requested was during employment; how the requested accommodation would assist the individual in applying for a job, how the requested accommodation or assistance would assist the individual in performing current job functions, or meeting some other need/requirement; the amount of time taken to process the request; whether the request was granted or denied and, if denied, the reason for the denial; and the sources of any assistance consulted in trying to identify possible reasonable accommodations or providing personal assistance services.

RECORD SOURCE CATEGORIES:

Current and former SBA employees, applicants for employment, and members of the public.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside SBA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To disclose information to medical personnel to meet a bona fide medical emergency.

B. To the federal, state, local or foreign agency or professional organization which has responsibility for investigating, prosecuting, or enforcing violations, statutes, rules, regulations or orders issued when the Agency identifies a record, either alone or in conjunction with other information, which indicates a violation or potential violation of law.

C. To disclose to an authorized appeal grievance examiner formal complaints examiner, administrative judge, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement, or a grievance, complaint, or appeal filed by an employee or applicant.

D. To a court, magistrate, grand jury, or administrative tribunal, opposing counsel during such proceedings or in settlement negotiations when presenting evidence.

E. To a Congressional office from an individual's record when that office is inquiring on the individual's behalf; the Member's access rights are no greater than the individuals.

F. In a proceeding before a court, or adjudicative body, or a dispute resolution body before which SBA is authorized to appear or before which any of the following is a party to litigation or has an interest in litigation, provided, however, that SBA determines that the use of such records is relevant and necessary to the litigation, and that, in each case, SBA determines that disclosure of the records to a court or other adjudicative body is a use of the information contained in the records that is a compatible purpose for which the records were collected: SBA, or any SBA component; any SBA employee in their official capacity; any SBA employee in their individual capacity where DOJ has agreed to represent the employee; or The United States Government, where SBA determines that litigation is likely to affect SBA or any of its components.

G. To another federal agency or commission with responsibility for labor or employment relations or other issues, including equal employment opportunity and reasonable accommodation or personal assistance service issues, when that agency or commission has jurisdiction over reasonable accommodation or personal assistance service.

H. To the Office of Management and Budget, Department of Justice (DOJ), Department of Labor, Office of Personnel Management, Equal Employment Opportunity Commission, or Office of Special Counsel to obtain advice regarding statutory, regulatory, policy, and other requirements related to reasonable accommodation or personal assistance service.

I. To the Department of Justice (DOJ), including offices of the U.S Attorneys, or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is deemed by the SBA to be relevant or necessary to the litigation or the SBA has an interest in such litigation when any of the following are a party to the litigation or have an interest in the litigation: (1) Any employee or former employee of SBA in their official capacity; (2) Any employee or former employee of SBA in their individual capacity when DOJ or SBA has agreed to represent the employee or a party to the litigation or have an interest in the litigation; or (3) The United States or any agency thereof.

J. To the National Archives and Records Administration (NARA) or General Services Administration (GSA) pursuant to records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

K. To an agency or organization, including the SBA's Office of Inspector General, for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

L. To appropriate agencies, entities, and persons when (1) SBA suspects or has confirmed that there has been a breach of the system of records, (2) SBA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, SBA (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with SBA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

M. To another federal agency or federal entity, when SBA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

N. To SBA contractors, grantees, volunteers, interns, regulators, and experts who have been engaged by SBA to assist in the performance and performance improvement of a service related to this system of records and who need access to the records to perform this activity which may also include for regulatory purpose. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

O. To consultants, contractor personnel, entities, vendors or suppliers, employees of other government agencies, whether federal, state or local, as necessary to consider a request for accommodation or to implement the decision.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper and electronic files. Maintained in locked file cabinets and cloud platform.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name of individual, program/staff office, or request date.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained in accordance with latest edition SBA Standard Operating Procedure (SOP) series 00 41, schedules Records Management Records and Agency Accountability Records. Records maintained as part of the General Records Schedules (GRS) are disposed of in accordance with applicable SBA policies.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access and use are limited to persons with official need to know. Users are evaluated on a recurring basis to ensure need-to-know still exists. Safeguards are implemented in accordance with the Federal Information Security Modernization Act of 2014 (FISMA) and are evaluated on a recurring basis to ensure desired operation.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to records about them should submit a Privacy Act request to the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.* Individuals must provide their full name, mailing address, personal email address, telephone number, and a detailed description of the records requested. Individuals requesting access must also follow SBA's Privacy Act regulations regarding verification of identity and access to records (13 CFR part 102 subpart B).

CONTESTING RECORD PROCEDURES:

Individuals wishing to contest information contained in records about them should submit a Privacy Act request to the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.* Individuals must provide their full name, mailing address, personal email address, telephone number, and a detailed description of the records contested. Requesting individuals must follow SBA's Privacy Act regulations regarding verification of identity and access to records (13 CFR part 102 subpart B).

NOTIFICATION PROCEDURES:

Individuals may make record inquiries in person at the address listed below or in writing to the Systems Manager through the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.*

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Zina Sutch,

Assistant Administrator, Office of Diversity, Inclusion and Civil Rights.

[FR Doc. 2021–25232 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17179 and #17180; Texas Disaster Number TX–00610]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Texas

AGENCY: Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Texas (FEMA–4586–DR), dated 09/13/2021.

Incident: Severe Winter Storms.

Incident Period: 02/11/2021 through 02/21/2021.

DATES: Issued on 11/12/2021.

Physical Loan Application Deadline Date: 11/12/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 06/13/2022.

ADDRESSES: Submit completed loan applications to:U.S. Small Business Administration,Processing and Disbursement Center,14925 Kingsport Road,Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Texas, dated 09/13/2021, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties:

Archer, Bexar, Brazos, Caldwell, Coleman, Comal, Fayette, Galveston, Jones, Kendall.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administratorfor Disaster Assistance.

[FR Doc. 2021–25271 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 18, 2022.

ADDRESSES: Send all comments to Mark Williams, *mark.williams@sba.gov* Program Manager, Office of Veteran Business Development, Small Business Administration.

FOR FURTHER INFORMATION CONTACT: Mark Williams, Program Manager, Office of Veterans Business Development, *mark.williams@sba.gov,* 202–205–6157, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Boots to Business is an entrepreneurial education initiative offered by the U.S. Small Business Administration (SBA) as a career track within the Department of Defense's revised Training Assistance Program. The curriculum provides valuable assistance to transitioning service members exploring self-employment opportunities by leading them an overview of the key steps for evaluating business concepts and the foundational knowledge required for developing a business plan. Participants are also introduced to SBA resources available to help access startup capital and additional technical assistance.

The Boots to Business Post Course surveys will be online, voluntary surveys that enable the Boots to Business program office to capture data related but not limited to the effectiveness of all Boots to Business courses and the quality of the

instructors and materials, and number of small businesses created as a result of participating in Boots to Business. In an effort to improve response rates and better capture participant feedback, the Boots to Business survey will be administered to participants, using an online form, immediately prior to the final course module.

Every 12 months following course completion, a follow up survey will be emailed to all participants, to measure participant outcomes as the SBA seeks to gauge the impact of course completion on the creation of veteran owned small businesses or the motivation and confidence of veterans to pursue business ownership. Participants will be surveyed once a year for 5 years following course completion to allow for business incubation.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

OMB Control Number: 3245–0390.

Title: Boots to Business Post Course Surveys.

Description of Respondents: Service members, veterans and spouses.

Form Number: N/A.

Total Estimated Annual Responses: 18,000.

Total Estimated Annual Hour Burden: 4,000.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2021–25240 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17270 and #17271; Florida Disaster Number FL–00170]

Administrative Declaration of a Disaster for the State of Florida

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Florida dated 11/15/2021.

Incident: Severe Storms and Flooding.

Incident Period: 09/15/2021 through 09/19/2021.

DATES: Issued on 11/15/2021.

Physical Loan Application Deadline Date: 01/14/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 08/15/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Citrus.

Contiguous Counties:

Florida Hernando, Levy, Marion, Sumter.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	3.125
Homeowners without Credit Available Elsewhere	1.563
Businesses with Credit Available Elsewhere	5.710
Businesses without Credit Available Elsewhere	2.855
Non-Profit Organizations with Credit Available Elsewhere	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.855
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17270 6 and for economic injury is 17271 0.

The State which received an EIDL Declaration # is Florida.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2021–25238 Filed 11–18–21; 8:45 am]

BILLING CODE 8026–03–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36545]

Dallas, Garland & Northeastern Railroad, Inc.—Lease and Operation Exemption Including Interchange Commitment—Union Pacific Railroad Company

Dallas, Garland & Northeastern Railroad, Inc. (DGNO), a Class III railroad, has filed a verified notice of exemption under 49 CFR 1150.41 to amend its lease and continue to operate approximately 30.7 miles of rail line in Texas owned by Union Pacific Railroad Company (UP) (the Lines). The Lines consist of: (1) A portion of the Garland Subdivision (also known as the Greenville Subdivision) from milepost 741.3 near Lake Ray Hubbard to milepost 713.6 at Greenville, Tex.; and (2) the Sprecher Lead (also known as the Safeway Lead) at Garland, Tex. DGNO states that the Sprecher Lead has no official mileposts, but DGNO informally designates the mileposts as extending from milepost 0 to milepost 3 beginning at the switch at milepost 753.4.

According to the verified notice, DGNO has leased and operated the Lines since at least 2001. DGNO states that, pursuant to an amended lease agreement (Amended Lease) with UP, DGNO's operations over the Lines will be extended for an additional 10 years.[1]

Further, DGNO certifies that its projected revenues as a result of the transaction will not exceed those that would qualify it as a Class III carrier, but that its current annual revenues exceed $5 million. Pursuant to 49 CFR 150.42(e), if a carrier's projected annual revenues will exceed $5 million, it must, at least 60 days before this exemption is to become effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. However, DGNO has petitioned for

[1] According to DGNO, in preparing the verified notice, it determined that DGNO's acquisition of Board authority for lease and operation of the Lines under the current lease appears to be incomplete because the authority only applies to a portion of the Garland Subdivision and none of the Sprecher Lead. *See Dall., Garland & Ne. R.R.—Lease Exemption—Union Pac. R.R.,* FD 33686 (STB served Feb. 5, 1999) (granting authority to operate on milepost 741.3 to milepost 729.5 of the Garland Subdivision, among others). DGNO states that, in addition to seeking authority to operate under the Amended Lease, it also is seeking to correct the Board's records of the lines operated by DGNO and to confirm its authority to operate on the Lines. This request will be addressed in a subsequent decision.

waiver of the 60-day advance labor notice requirements. DGNO's waiver request will be addressed in a subsequent decision, and the effectiveness of the exemption will be postponed pending that decision.

As required under 49 CFR 1150.43(h)(1), DGNO has disclosed in its verified notice that its lease agreement with UP contains an interchange commitment pertaining to interchange with carriers other than UP. DGNO has provided additional information regarding the interchange commitment as required by 49 CFR 1150.43(h).[2]

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than November 26, 2021.

All pleadings, referring to Docket No. FD 36545, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading must be served on DGNO's representative, Eric M. Hocky, Clark Hill PLC, Two Commerce Square, 2001 Market Street, Suite 2620, Philadelphia, PA 19103.

According to DGNO, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: November 16, 2021.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Aretha Laws-Byrum,

Clearance Clerk.

[FR Doc. 2021–25298 Filed 11–18–21; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0155]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Verizon Connect, Inc.

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

ACTION: Notice of application for exemption; request for comments.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) requests public comment on an application for exemption from Verizon Connect, Inc. (Verizon) to allow its Integrated Video Dashcam to be mounted lower in the windshield on commercial motor vehicles than is currently permitted.

DATES: Comments must be received on or before December 20, 2021.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2021–0155 using any of the following methods:

- *Website: http://www.regulations.gov.* Follow the instructions for submitting comments on the Federal electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Dockets Operations, Ground Floor, Room W12–140, DOT Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m. E.T., Monday–Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

Instructions: All submissions must include the Agency name and docket number for this notice. For detailed instructions on submitting comments and additional information on the exemption process, see the ''Public Participation'' heading below. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the ''Privacy Act'' heading for further information.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to Room W12–140, DOT Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Public participation: The *http://www.regulations.gov* website is generally available 24 hours each day, 365 days each year. You may find electronic submission and retrieval help and guidelines under the ''help'' section of the *http://www.regulations.gov* website as well as the DOT's *http://docketsinfo.dot.gov* website. If you would like notification that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgment page that appears after submitting comments online.

FOR FURTHER INFORMATION CONTACT: Mr. José R. Cestero, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–5541, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2021–0155), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comments online, go to *www.regulations.gov* and put the docket number, ''FMCSA–2021–0155'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all

[2] A copy of the lease with the interchange commitment was submitted under seal. *See* 49 CFR 1150.43(h)(1).

comments and material received during the comment period and may grant or not grant this application based on your comments.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31315(b) to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Verizon's Application for Exemption

The Federal Motor Carrier Safety Regulations require devices meeting the definition of ''vehicle safety technology,'' including Verizon's Integrated Video Dashcam, such as Collision Mitigation Systems, Adaptive Cruise Control, Lane Departure Warning, Lane Keeping Assist, Collision Mitigation, High Beam Assist, and Traffic Sign Recognition, to be mounted (1) not more than 4 inches below the upper edge of the area swept by the windshield wipers, or (2) not more than 7 inches above the lower edge of the area swept by the windshield wipers, and outside the driver's sight lines to the road and highway signs and signals. Verizon has applied for an exemption from 49 CFR 393.60(e)(1) to allow its Integrated Video Dashcam to be mounted lower in the windshield than is currently permitted. A copy of the application is included in the docket referenced at the beginning of this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b)(6), FMCSA requests public comment from all interested persons on Verizon's application for an exemption from 49 CFR 393.60(e)(1). All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–25249 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2021–0033]

Agency Information Collection Activities; Notice and Request for Comment; Government 5-Star Safety Ratings Label Consumer Research

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for public comments on approval of a new collection of information.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a new collection of information. Before a federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes one collection of information for consumer research purposes regarding the Government 5-Star Safety Ratings section of the Monroney label for which NHTSA intends to seek OMB approval. On April 28, 2020, NHTSA published a notice in the **Federal Register** soliciting public comments with a 60-day comment period. NHTSA received 4 public comments submitted to the docket during this period. Given the extended time period since the initial publication of that notice, NHTSA is publishing this new 60-day notice. This notice also responds to the comments received on the original notice.

DATES: Written comments should be submitted on or before January 18, 2022.

ADDRESSES: You may submit comments, identified by the docket number NHTSA–2021–0033 by any of the following methods:

- *Electronic submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- M*ail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.
- *Fax:* 202–493–2251.

Instructions: All submissions must include the agency name and docket number for this notice. For detailed instructions on submitting comments and additional information on the information-collection process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to

background documents, contact Mike Joyce, Marketing Specialist, Office of Communications and Consumer Information (NCO–0200), National Highway Traffic Safety Administration, 1200 New Jersey Ave, SE, W52–238, Washington, DC, 20590. Mike Joyce's phone number is 202–366–5600 and his email address is *Mike.Joyce@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) how to enhance the quality, utility and clarity of the information to be collected; and (iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB:

Title: Government 5-Star Safety Ratings Label Consumer Research.

OMB Control Number: 2127–New.

Form Number(s):

Type of Request: Request for approval of a new information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: Three years from approval date.

Abstract: The National Highway Traffic Safety Administration (NHTSA) was established by the Highway Safety Act of 1970 (Pub. L. 91–605, 202(a), 84 Stat. 1713, 1739–40). NHTSA'S mission is to save lives, prevent injuries and reduce economic costs due to crashes on the nation's highways. Part C of the Motor Vehicle and Driver Programs, at 49 U.S.C. 32302, requires the Secretary of Transportation (NHTSA by delegation) to provide to the public information about the safety of new passenger motor vehicles. Under its New Car Assessment Program (NCAP) and 5-Star Safety Ratings Program, NHTSA conducts frontal crash, side crash and rollover resistance tests of new vehicles and, based on the results, assigns safety ratings to the tested vehicles. The ratings enable consumers to consider and assess the relative safety of vehicles before deciding which new vehicle they want to purchase.

In 2005, Congress enacted the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (Pub. L. 109–59), which required the safety ratings assigned by NHTSA under NCAP or a statement that the vehicle was not assigned safety ratings under NCAP to be included on the window label for new vehicles, known as the Monroney label.[1] Per 15 U.S.C. 1232(g), the window label must contain the safety ratings published or released by NHTSA's New Car Assessment Program, including the graphical depiction of those ratings, reference to the safety rating categories (*e.g.,* frontal impact crashes tests, side impact crash tests, and rollover restistance tests), and information describing the nature and meaning of the crash test data presented and a reference to *http://www.safercar.gov.* This information must be presented in a legible, visible, and prominent fashion that covers at least 8 percent of the total area of the label, or an area with a minimum length of four and a half inches and a minimum height of three and a half inches. If a vehicle has not been rated by NHTSA's New Car Assessment Program, then the label much state that.[2] On December 4, 2015, Congress enacted the Fixing America's Surface Transportation (FAST) Act, which requires the Secretary of Transportation (NHTSA by delegation) to issue a rule to ensure crash-avoidance information is provided next to crashworthiness information on vehicle window stickers.[3]

In continuing support of its mission and to assist the agency in meeting its FAST Act requirement, NHTSA proposes to conduct qualitative research using focus groups in four geographic markets located across the country to evaluate design and consumer information improvements to the Government 5-Star Safety Ratings section of the Monroney label.[4] This information collection will involve a one-time, voluntary phone screening survey involving members of the public to identify research participants and a one-time, in-person focus group. Participants in the research program will be asked to evaluate design and consumer information improvements to the Government 5-Star Safety Ratings section of the vehicle window sticker. NHTSA will use the findings from this research to support planned changes to the current label requirements and future designs for communicating vehicle safety ratings and advanced driver assistance systems performance assessments to consumers.

Summary of the Collection of Information: In this collection of information, NHTSA is seeking approval to conduct qualitative focus groups with 66 consumer participants. The focus groups aim to achieve the following objectives:

(1) Evaluate the overall appeal of each label concept and identify specific likes and dislikes associated with specific components of the label;

(2) Measure the ease of comprehension for each label concept and understand which visual and text features are most effective at conveying vehicle safety information;

(3) Assess the distinctiveness of how the information is displayed and understand how best to make the vehicle safety information stand out on the Monroney label; and,

(4) Identify additional areas of improvement related to the three main label sections relating to safety protection, safety technology, and overall vehicle safety performance.

Description of the Need for the Information and the Proposed Use of the Information: This collection of information will allow NHTSA to obtain critical information to assist the agency in fulfilling the 2015 FAST Act's requirement that NHTSA issue a rule to ensure that crash-avoidance information is provided next to crashworthiness information on vehicle windows stickers.[5] Specifically, the data from this

[1] The Automobile Information Disclosure Act of 1958, 15 U.S.C. 1231–1233, requires that new vehicles carry a sticker on a window containing specified information about the vehicle.

[2] 12 U.S.C. 1232(h).

[3] Section 24322 of Part II—Safety Through Informed Consumers Act of 2015. Public Law 114–94.

[4] 15 U.S.C. 1232.

[5] Section 24322 of Part II—Safety Through Informed Consumers Act of 2015 requires the Secretary of Transportation (NHTSA by delegation) to issue a rule to ensure that crash-avoidance information is indicated next to crashworthiness information on stickers placed on motor vehicles by their manufacturers. Public Law 114–94, December 4, 2015.

collection will be used to not only enhance consumer understanding of NHTSA's vehicle safety ratings and advanced driver assistance systems performance assessments, but also guide the development of communications that will help consumers as they consider this information in their vehicle purchase decisions.

Affected Public: Members of the public 18 years of age or older with a driver's license, who are a decision-maker for vehicle purchases for their household, has either purchased or leased a vehicle in the last six months or is planning to do so in the next 12 months and lives in one of the four recommended markets to conduct the research (Arlington, VA; Dallas, TX; Columbus, OH; or San Jose, CA).

Frequency: One time.

Number of Respondents: 500.

For this information collection, NHTSA plans to conduct a total of eight focus group sessions (two groups in each of the following recommended markets: Arlington, VA; Dallas, TX; Columbus, OH; and San Jose, CA), each lasting approximately 90 minutes. NHTSA intends for each focus group to consist of approximately nine participants (six participants in Arlington, due to social distancing restrictions) for a total of 66 participants in the focus group sessions. Based on experience, NHTSA will need to recruit up to 14 people per focus group in order to ensure that the desired number will appear at the focus group facility at the appointed time. If more than the desired number of participants show up at the facility for a given session, the research team will select nine participants (six in Arlington) based on their profile information provided in the recruitment grid to seat. The remaining participants will be paid their honorarium, thanked for their willingness to participate, and informed that they are free to go. Therefore, in order to ensure that there are approximately nine participants (six in Arlington) per focus group session, a total of 100 potential participants (eight per focus group in Arlington and 14 per focus group in other markets) will be recruited via telephone screening calls, which are estimated to take five minutes per call. In order to recruit 100 potential participants, NHTSA estimates that it will be necessary to initially reach out to and screen 500 people. This is based on experience that demonstrates that, of the people who are contacted, 20% will qualify for the study, be available and be interested in participating in the focus group.

Estimated Total Annual Burden Hours: 141 hours.

NHTSA estimates the total burden per person actually participating in this focus group research is estimated to be 95 minutes (five minutes for the screening/recruiting telephone call plus 90 minutes in the focus group discussion session). Additionally, the total burden per person recruited (but not participating in the discussions) is five minutes. Therefore, the total annual estimated burden imposed by this collection is approximately 141 hours.

Category of respondent	Number of respondents	Participation time (minutes)	Burden (hours)
Recruit/screening call (assumes 20% qualify, are available and interested in participating in the focus group)	500	5	*41.7
Participation in 90-minute group	66	90	99.0
Total Burden	.....	.....	141

*Hours or 42 hours (rounded).

Estimated Burden Costs to All Respondents: $3,360.00.

The only cost burdens respondents will incur are costs related to travel to and from the research location. The costs are minimal and are expected to be offset by the honorarium that will be provided to all research participants. NHTSA estimates that each of the focus group participants will travel less than 30 miles one-way to the focus group location (60 miles round trip). Using the IRS standard mileage rate of $0.56 per mile,[6] each respondent is expected to incur no more than $33.60 in transportation costs. Therefore, NHTSA estimates that the total costs to all respondents will be $3,360.00.

Public Comments Received During the First 60-Day Notice Period:

On April 28, 2020, NHTSA published a notice in the **Federal Register** soliciting public comments with a 60-day comment period. The comment period closed on June 29, 2020. NHTSA received 4 public comments submitted to the docket during this period including those from a disabled veteran, DEVCO Design & Development, The Center for Automotive Safety, and the National Transportation Safety Board. Comments from the public were invited on any aspects of the information collection, including (1) whether the proposed collection of information was necessary for the proper performance of the functions of the Department, including whether the information would have practical utility; (2) the accuracy of the Department's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

NHTSA received comments on the following topics:

(1) Manufacturing vehicles with appropriate standards of safety to relieve the burden for people with disabilities;

(2) Including a title and summary for the consumer research that is not restricted to the number of stars and is inclusive of the test results of conditions at speed;

(3) Concerns about the proposed collection of information lacking specificity about crash avoidance and other technology to be included in the evaluated labels and consideration for performance ratings for vulnerable road user protection systems; and

(4) Defining NCAP testing regimen before designing new safety labels.

The public comments and NHTSA's responses are summarized below:

(1) *Disabled Veteran:* ''*It would help relieve the burden for people with disabilities to have a vehicle that is appropriate for standards of safety.*''

Response: The National Highway Traffic Safety Administration's mission is to save lives, prevent injuries, and reduce economic costs due to road traffic crashes, through education, research, safety standards, and enforcement. NHTSA's 5-Star Safety Program provides comparative

[6] From Internal Revenue Services' 2021 Standard Mileage Rate for business miles driven. *https://www.irs.gov/tax-professionals/standard-mileage-rates,* last accessed May 7, 2021.

information on the safety performance of new vehicles to assist consumers with vehicle purchasing decisions and to encourage safety improvements. This proposed collection of information specifically seeks to evaluate design and consumer information improvements to the Government 5-Star Safety Ratings section of the Monroney label. NHTSA's website is accessible and 508-compliant so that vehicle safety information is available and may benefit the purchasing decisions of everyone, including those with disabilities.

(2) David DeVeau, DEVCO Design & Development: Consideration for a title and summary for the consumer research that is not restricted to the number of stars and is inclusive of the test results of conditions at speed.

Response: The title of the proposed consumer research is based on the New Car Assessment Program's (NCAP) current consumer program, the Government 5-Star Safety Ratings. NHTSA began using the 5-Star Safety Ratings system in 1993 to help consumers make informed safety choices when buying new or used vehicles. The proposed research seeks to evaluate a variety of label concepts to explore both graphical and text-based communications as potential modifications to the Government 5-Star Safety Ratings section of the Monroney label with the intent of finding the most effective way to display information related to vehicle safety. The research will also explore whether consumers prefer ratings using a 5-Star system (1–5 stars), a numerical value or numerical scale. If research findings determine that consumers prefer the presentation of ratings in an alternative way, NHTSA will explore further research which may have implications for changes to the title of the consumer program.

(3) NTSB: Concerns about the proposed collection of information lacking specificity about crash avoidance and other technology to be included in the evaluated labels and consideration for performance ratings for vulnerable road user protection systems.

Response: As NHTSA has done in the past, there are two separate tracks for NHTSA efforts to upgrade NCAP. One track is the development of NHTSA's planned changes to NCAP—which is still ongoing, and the Agency intends to seek public comment on its proposal later in 2021. This track includes specific information about the crash avoidance and other technologies that NHTSA is considering including in NCAP such as performance thresholds, testing crash avoidance features, and developing a rating system that would compare all of those features. The other track is the rulemaking proceeding to update the safety ratings section on the Monroney label, which is the visualization of the safety performance information that would be available to consumers. NHTSA conducts comprehensive consumer research to inform its rulemakings to update the visualization of NCAP's rating information that would be included on the Monroney label. This consumer research does not focus on the details of the underlying rating system or any substantive changes to NCAP. Instead, NHTSA plans to use this consumer research to determine how to best convey vehicle safety rating information, including crash avoidance technologies, to the public. This 60-day notice initiates the multi-phase consumer research that NHTSA intends to use to inform its future update to the Monroney label. NHTSA is mindful in its development of a new rating system and accompanying visualization of the rating system through the Monroney label of the flexibility necessary to allow the agency to regularly update NCAP while also minimizing the number of rulemaking actions needed each time the agency incorporates a new technology or program in NCAP.

(4) Center for Auto Safety: Defining NCAP testing regimen before designing new safety labels.

Response: Similar to the explanation provided to NTSB's comment, there are two separate tracks for upgrading NCAP and upgrading the visualization of NCAP rating information on the Monroney label. Defining the NCAP testing regimen will be part of the first track, which will be detailed in upcoming requests for comments to upgrade NCAP. The consumer research efforts focus more on the consumer understanding of the safety information on the Monroney label and what NHTSA disseminates to the public. Also, due to the limited area on the Monroney label, the consumer research will help guide NHTSA on which visualization would best convey complex safety information to the public in a more consumer-friendly and flexible approach that is intended to minimize the number of rulemaking actions to update the Monroney label after future NCAP upgrades.

Public Comments Invited: The results of this research will be used to inform labeling requirement proposals and communications for the New Car Assessment Program, also known as the Government 5-Star Safety Ratings Program. You are asked to comment on any aspects of this information collection, including (1) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the Department's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Issued on: November 16, 2021.

Juliette Marie Vallese,

Associate Administrator, Office of Communications and Consumer Information.

[FR Doc. 2021–25241 Filed 11–18–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of the Tier 2 Tax Rates

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the tier 2 tax rates for calendar year 2022 as required by the Internal Revenue Code. Tier 2 taxes on railroad employees, employers, and employee representatives are one source of funding for benefits under the Railroad Retirement Act.

DATES: The tier 2 tax rates for calendar year 2022 apply to compensation paid in calendar year 2022.

FOR FURTHER INFORMATION CONTACT: Kathleen Edmondson, CC:EEE:EOET:ET1, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, Telephone Number (202) 317–6798 (not a toll-free number).

Tier 2 Tax Rates: The tier 2 tax rate for 2022 under section 3201(b) on employees is 4.9 percent of compensation. The tier 2 tax rate for 2022 under section 3221(b) on employers is 13.1 percent of compensation. The tier 2 tax rate for 2022 under section 3211(b) on employee representatives is 13.1 percent of compensation.

Dated: November 9, 2021.

Rachel D. Levy,

Associate Chief Counsel (Employee Benefits, Exempt Organizations and Employment Taxes).

[FR Doc. 2021–25296 Filed 11–18–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0618]

Agency Information Collection Activity: Application by Insured Terminally Ill Person for Accelerated Benefit; Withdrawn

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice; withdrawal.

SUMMARY: On November 5, 2021 the Veterans Benefits Administration (VA), published a notice in the **Federal Register** announcing an opportunity for public comment on the proposed collection Application by Insured Terminally Ill Person for Accelerated Benefit Form SGLI 8284. This notice was published in error; therefore, this document corrects that error by withdrawing this FR notice, document number 2021–24223.

DATES: As of November 15, 2021, the FR notice published at 86 FR 61400 on Friday, November 5, 2021, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.*

SUPPLEMENTARY INFORMATION: FR Doc. 2021–24223, published on November 5, 2021 (86 FR 61400), is withdrawn by this notice.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer,Office of Enterprise and Integration/Data Governance Analytics,Department of Veterans Affairs.

[FR Doc. 2021–25258 Filed 11–18–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0353]

Agency Information Collection Activity: Certification of Lessons Completed

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before January 18, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0353'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0353'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3032(d), 3034, 3241, 3323, 3474, 3481, 3484, 3534(b), 3680(b), 3684, 3686(a), and 10 U.S.C 16131(e), and chapter 31 section 510., and 38 CFR 21.4203(e), 21.4206, 21.5200(d) & (g), 21.7140(c)(3), 21.7159, 21.7640(a)(4), 21.7659, and 21.9720.

Title: Certification of Lessons Completed.

OMB Control Number: 2900–0353.

Type of Review: Revision of a currently approved collection.

Abstract: VA uses information from the current collection to determine the number of lessons completed by the student and serviced by the correspondence school, and to determine the date of completion or termination of correspondence training. VA pays education benefits based on the information furnished on the form. Without this information, VA would be unable to determine the proper payment or the student's training status.

Affected Public: Individuals and Households.

Estimated Annual Burden: 103 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Quarterly.

Estimated Number of Respondents: 616.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–25265 Filed 11–18–21; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

Vol. 86 Friday,
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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, et al.
Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, 411, 414, 415, 423, 424, and 425

[CMS–1751–F]

RIN 0938–AU42

Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

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

ACTION: Final rule.

SUMMARY: This major final rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; requirements for prepayment and post-payment medical review activities; requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan, or a Medicare Advantage Prescription Drug (MA–PD) plan; updates to the Medicare Ground Ambulance Data Collection System; changes to the Medicare Diabetes Prevention Program (MDPP) expanded model; and amendments to the physician self-referral law regulations.

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

FOR FURTHER INFORMATION CONTACT: *DivisionofPractitionerServices@cms.hhs.gov,* for any issues not identified below.

Michael Soracoe, (410) 786–6312, or *DivisionofPractitionerServices@cms.hhs.gov,* for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to telehealth services and other services involving communications technology.

Julie Adams, (410) 786–8932, for issues related to payment for anesthesia services.

Sarah Leipnik, (410) 786–3933, or *DivisionofPractitionerServices@cms.hhs.gov,* for issues related to split (or shared) services.

Michelle Cruse, (410) 786–7540, and Michael Konieczny, (410) 786–0825, for issues related to payment for vaccine administration services.

Regina Walker-Wren, (410) 786–9160, for issues related to billing for services of physician assistants and PFS payment for teaching physician services.

Pamela West, (410) 786–2302, for issues related to PFS payment for therapy services, medical nutrition therapy services, and services of registered dietitians and nutrition professionals.

Liane Grayson, (410) 786–6583, for issues related to coinsurance for certain colorectal cancer screening services and PFS payment for critical care services.

Lisa Parker, (410) 786–4949, and Michele Franklin, (410) 786–9226, for issues related to RHCs and FQHCs.

Laura Kennedy, (410) 786–3377, for issues related to drugs payable under Part B.

Heather Hostetler, (410) 786–4515, and Elizabeth Truong, 410–786–6005, for issues related to removal of selected national coverage determinations.

Sarah Fulton, (410) 786–2749, for issues related to Appropriate Use Criteria for Advanced Diagnostic Imaging (AUC); and Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation.

Rachel Katonak, (410) 786–8564, for issues related to Medical Nutrition Therapy.

Sabrina Ahmed, (410) 786–7499, for issues related to the Medicare Shared Savings Program (Shared Savings Program) quality reporting requirements and quality performance standard.

Janae James, (410) 786–0801, Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment, repayment mechanism requirements, and benchmarking methodology.

Naseem Tarmohamed, (410) 786–0814, or *SharedSavingsProgram@cms.hhs.gov,* for inquiries related to Shared Savings Program application, compliance and beneficiary notification requirements.

Amy Gruber, *AmbulanceDataCollection@cms.hhs.gov,* for issues related to the Medicare Ground Ambulance Data Collection System.

Juliana Tiongson, (410) 786–0342, for issues related to the Medicare Diabetes Prevention Program (MDPP).

Laura Ashbaugh, (410) 786–1113, for issues related to Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance and Use of Electronic Travel Logs.

Frank Whelan, (410) 786–1302, for issues related to Medicare provider enrollment regulation updates.

Katie Mucklow, (410) 786–0537, for issues related to provider and supplier prepayment and post-payment medical review requirements.

Lindsey Baldwin, (410) 786–1694, and Michele Franklin, (410) 786–9226, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Lisa O. Wilson, (410) 786–8852, or Meredith Larson, (410) 786–7923, for inquiries related to the physician self-referral law.

Joella Roland, (410) 786–7638, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan.

Kathleen Ott, (410) 786–4246, for issues related to open payments.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Brittany LaCouture, (410) 786–0481, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/index.html.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2022 PFS final rule, refer to item CMS–1751–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact *DivisionofPractitionerServices@cms.hhs.gov.*

CPT (Current Procedural Terminology) Copyright Notice:

Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major final rule includes revisions to other Medicare payment policies described in sections III. and IV.

B. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that we establish each year by regulation the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are establishing RVUs for CY 2022 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies.

Specifically, this final rule addresses:

- Practice Expense RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Telehealth and Other Services Involving Communications Technology (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management Visits (section II.F.)
- Billing for Physician Assistant Services (section II.G.)
- Therapy Services (section II.H.)
- Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests (section II.I.)
- Vaccine Administration Services (section II.J.)
- Payment for Medical Nutrition Therapy Services and Related Services (section II.K.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (sections III.A., III.B., and III.C.)
- Requiring Certain Manufacturers to Report Drug Pricing Information for Part B and Determination of ASP for Certain Self-administered Drug Products (sections III.D.1. and 2.)
- Medicare Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act (section III.E.)
- Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.F.)
- Removal of Selected National Coverage Determinations (section III.G.)
- Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (section III.H.)
- Medical Nutrition Therapy (section III.I.)
- Medicare Shared Savings Program (section III.J.)
- Medicare Ground Ambulance Data Collection System (section III.K.)
- Medicare Diabetes Prevention Program (MDPP) (section III.L.)
- Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs (section III.M.)
- Medicare Provider and Supplier Enrollment Changes (section III.N.1.)
- Provider/Supplier Medical Review Requirements: Addition of Provider/Supplier Requirements related to Prepayment and Post-payment Reviews (section III.N.2.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.O.)
- Updates to the Physician Self-Referral Regulations (section III.P.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.Q.)
- Open Payments (section III.R.)
- Updates to the Quality Payment Program (section IV.)
- Collection of Information Requirements (section V.)
- Regulatory Impact Analysis (section VI.)

3. Summary of Costs and Benefits

We have determined that this final rule is economically significant. For a detailed discussion of the economic impacts, see section VI., Regulatory Impact Analysis, of this final rule.

II. Summary of the Proposed Provisions, Analysis of and Response to Public Comments, and the Provisions of the Final Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the RVUs into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the RVUs

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in

determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the Federal Government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the Federal Government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, October 31, 1994), amended by section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (BBA '97) (Pub. L. 105–33, August 5, 1997) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA '97 provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some resource costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those specific facility resource costs is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, November 29, 1999) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA '97 amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the States, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently from one another. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for

potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of BN to Adjustments of RVUs

As described in section VI. of this final rule, the Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. Please refer to the CY 2020 PFS final rule for a discussion of the last GPCI update (84 FR 62615 through 62623).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS' Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2022 PFS final rule PE/HR'' on the CMS website under downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2022, we have incorporated the available utilization data for two new specialties, each of which became a recognized Medicare specialty during 2020. These specialties are Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD). We proposed to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Micrographic Dermatologic Surgery (MDS) from Dermatology; and
- Adult Congenital Heart Disease (ACHD) from Cardiology

These updates are reflected in the ''CY 2022 PFS final rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.*

We received public comments on our proposal to use proxy PE/HR values for MDS and ACHD. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that they appreciated and supported the proposal incorporating the available utilization data for MDS to establish an indirect PE/HR for their newly designated specialty. The commenter stated that they also agreed with the proposal to use a proxy PE/HR value by crosswalking to the PE/HR for Dermatology and urged CMS to finalize this policy.

Response: We appreciate the support from the commenter for our proposed PE/HR crosswalk.

Comment: Several commenters questioned the assigned specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services. Commenters stated that they appreciated that CMS acknowledged their concerns last year and agreed to update the indirect factors for home PT/INR monitoring by crosswalking to the General Practice specialty which helped address the on-going substantial reductions in payment for home PT/INR monitoring. However, the commenters stated that the predominant code for PT/INR monitoring (HCPCS code G0249) will again be significantly and negatively impacted by the proposed changes in the clinical labor rates which will completely negate any benefit from the crosswalk to General Practice. The commenters requested CMS change the crosswalk for home PT/INR monitoring services to All Physicians which would partially offset the proposed reduction that HCPCS code G0249 is facing due to changes in the clinical labor rates.

Response: We finalized a crosswalk to the General Practice specialty for home PT/INR monitoring services (HCPCS codes G0248, G0249, and G0250) in the CY 2021 PFS final rule (85 FR 84477–84478). The data submitted by the commenters indicated that the direct-to-indirect cost percentages to furnish home PT/INR monitoring are in the range of 31:69, similar to the ratio associated with the General Practice specialty. We disagree that these home PT/INR monitoring services should now be reassigned to a different specialty that is less reflective of the cost structure for these services to offset reductions in payment for the services that result from an unrelated policy proposal (the clinical labor pricing update). Additionally, we did not propose to change the assigned specialty for PT/INR services. As such, this comment is outside the scope of the proposed rule. Therefore, we are not finalizing any changes to the assigned specialty for PT/INR services. We note however that, recognizing the changing practice of medicine and increasing use of innovative technologies and supplies to furnish certain services, we are reviewing our underlying data as part of a comprehensive review of our PE inputs and overall methodology. We continue to engage with stakeholders on this crucial topic of updating the PE data, for example, at our recent PE town hall this year.

After consideration of the comments, we are finalizing our proposed PE/HR crosswalks for the new MDS and ACHD specialties.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00

(2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

• Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

• Then, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We did not make any proposals associated with the list of expected specialty assignments for low volume services, however we received public comments on this topic from stakeholders. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for CY 2022. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the major adverse impact on MP RVUs that result from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a lengthy list of low volume HCPCS codes with recommended expected specialty assignments. One commenter requested changing the override specialty for a series of codes from thoracic surgery to cardiac surgery based on whether the procedures in question are performed on the heart and surrounding structures versus performed on the lungs, esophagus, chest wall and mediastinum.

Response: We appreciate the submission of expected specialty assignments for additional low volume HCPCS codes. After reviewing the information provided by the commenters to determine that the submitted specialty assignments were appropriate for the service in question, we are finalizing the additions in Table 1 to the list of expected specialty assignments for low volume services.

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TABLE 1: New Additions to Expected Specialty Assignment List

HCPCS	Short Descriptor	Expected Specialty Assignment
10008	Fna bx w/fluor gdn ea addl	Interventional Radiology
10010	Fna bx w/ct gdn ea addl	Interventional Radiology
15774	Gfrg autol fat lipo ea addl	Plastic and Reconstructive Surgery
15824	Removal of forehead wrinkles	Plastic and Reconstructive Surgery
15825	Removal of neck wrinkles	Plastic and Reconstructive Surgery
15826	Removal of brow wrinkles	Plastic and Reconstructive Surgery
15828	Removal of face wrinkles	Plastic and Reconstructive Surgery
15829	Removal of skin wrinkles	Plastic and Reconstructive Surgery
15845	Skin and muscle repair face	Plastic and Reconstructive Surgery
15876	Suction lipectomy head&neck	Plastic and Reconstructive Surgery
15877	Suction lipectomy trunk	Plastic and Reconstructive Surgery
15878	Suction lipectomy upr extrem	Plastic and Reconstructive Surgery
15879	Suction lipectomy lwr extrem	Plastic and Reconstructive Surgery
15944	Remove hip pressure sore	Plastic and Reconstructive Surgery
15950	Remove thigh pressure sore	Plastic and Reconstructive Surgery
17380	Hair removal by electrolysis	Dermatology
19272	Extensive chest wall surgery	Thoracic Surgery
19298	Place breast rad tube/caths	Radiation Oncology
19367	Brst rcnstj 1 pdcl tram flap	Plastic and Reconstructive Surgery
20555	Place ndl musc/tis for rt	Radiation Oncology
20703	Rmvl imed rx delivery device	Orthopedic Surgery
20932	Osteoart algrft w/surf & bl	Orthopedic Surgery
20933	Hemicrt intrclry algrft prtl	Orthopedic Surgery
20934	Intercalary algrft compl	Orthopedic Surgery
20955	Fibula bone graft microvasc	Plastic and Reconstructive Surgery
21196	Reconst lwr jaw w/fixation	Maxillofacial Surgery
21356	Opn tx dprsd zygomatic arch	Plastic and Reconstructive Surgery
21603	Exc ch wal tum w/lymphadec	Thoracic Surgery
24164	Remove radius head implant	Orthopedic Surgery
26665	Treat thumb fracture	Hand Surgery
27161	Incision of neck of femur	Orthopedic Surgery
27330	Biopsy knee joint lining	Orthopedic Surgery
28052	Biopsy of foot joint lining	Podiatry
30920	Ligation upper jaw artery	Otolaryngology
31577	Largsc w/rmvl foreign bdy(s)	Otolaryngology
31578	Largsc w/removal lesion	Otolaryngology
31725	Clearance of airways	Pulmonary Disease
32501	Repair bronchus add-on	Thoracic Surgery
32540	Removal of lung lesion	Thoracic Surgery
33018	Prcrd drg 0-5yr or w/anomly	Cardiology*
33275	Tcat rmvl perm ldls pm w/img	Cardiology*
33417	Repair of aortic valve	Cardiac Surgery
33440	Rplcmt a-valve tlcj autol pv	Cardiac Surgery
33741	Tas congenital car anomal	Cardiology*
33745	Tis cgen car anomal 1st shnt	Cardiology*
33746	Tis cgen car anomal ea addl	Cardiology*
33910	Remove lung artery emboli	Cardiac Surgery
33983	Replace vad intra w/bp	Cardiac Surgery
34421	Removal of vein clot	Vascular Surgery
34820	Opn iliac art expos	Vascular Surgery
35092	Repair artery rupture aorta	Vascular Surgery
36468	Njx sclrsnt spider veins	Vascular Surgery
36572	Insj picc rs&i <5 yr	Interventional Radiology
37718	Ligate/strip short leg vein	Vascular Surgery

HCPCS	Short Descriptor	Expected Specialty Assignment
37760	Ligate leg veins radical	Vascular Surgery
41820	Excision gum each quadrant	Oral Surgery
41821	Excision of gum flap	Oral Surgery
41850	Treatment of gum lesion	Maxillofacial Surgery
41870	Gum graft	Oral Surgery
42550	Injection for salivary x-ray	Diagnostic Radiology
43263	Ercp sphincter pressure meas	Gastroenterology
43640	Vagotomy & pylorus repair	General Surgery
44132	Enterectomy cadaver donor	General Surgery
44133	Enterectomy live donor	General Surgery
44135	Intestine transplnt cadaver	General Surgery
44136	Intestine transplant live	General Surgery
45005	Drainage of rectal abscess	General Surgery
45112	Removal of rectum	Colorectal Surgery
45307	Proctosigmoidoscopy fb	General Surgery
46257	Remove in/ex hem grp & fiss	Colorectal Surgery
46262	Remove in/ex hem grps w/fist	General Surgery
47800	Reconstruction of bile ducts	General Surgery
48120	Removal of pancreas lesion	General Surgery
49013	Prpertl pel pack hemrrg trma	General Surgery
49014	Reexploration pelvic wound	General Surgery
49425	Insert abdomen-venous drain	General Surgery
49555	Rerepair fem hernia reduce	General Surgery
50040	Drainage of kidney	Urology
50280	Removal of kidney lesion	Urology
50606	Endoluminal bx urtr rnl plvs	Interventional Radiology
51065	Remove ureter calculus	Urology
51100	Drain bladder by needle	Urology
51101	Drain bladder by trocar/cath	Urology
52305	Cystoscopy and treatment	Urology
54164	Frenulotomy of penis	Urology
54401	Insert self-contd prosthesis	Urology
54416	Remv/repl penis contain pros	Urology
55810	Extensive prostate surgery	Urology
57320	Repair bladder-vagina lesion	Obstetrics/Gynecology
57465	Cam cervix uteri drg colp	Obstetrics/Gynecology
58572	Tlh uterus over 250 g	Obstetrics/Gynecology
58943	Removal of ovary(s)	Gynecologist/Oncologist
58960	Exploration of abdomen	Gynecologist/Oncologist
59000	Amniocentesis diagnostic	Obstetrics/Gynecology
60545	Explore adrenal gland	General Surgery
61050	Remove brain canal fluid	Diagnostic Radiology
62192	Establish brain cavity shunt	Neurosurgery
62280	Treat spinal cord lesion	Interventional Pain Management
63077	Spine disk surgery thorax	Orthopedic Surgery
63086	Remove vertebral body add-on	Orthopedic Surgery
66225	Repair/graft eye lesion	Ophthalmology
66740	Destruction ciliary body	Ophthalmology
67227	Dstrj extensive retinopathy	Ophthalmology
67922	Repair eyelid defect	Ophthalmology
68850	Injection for tear sac x-ray	Diagnostic Radiology
70240	X-ray exam pituitary saddle	Diagnostic Radiology
70390	X-ray exam of salivary duct	Diagnostic Radiology
76946	Echo guide for amniocentesis	Obstetrics/Gynecology
76979	Us trgt dyn mbubb ea addl	Diagnostic Radiology
78015	Thyroid met imaging	Diagnostic Radiology

HCPCS	Short Descriptor	Expected Specialty Assignment
78103	Bone marrow imaging mult	Nuclear Medicine
78262	Gastroesophageal reflux exam	Diagnostic Radiology
78291	Leveen/shunt patency exam	Diagnostic Radiology
79403	Hematopoietic nuclear tx	Nuclear Medicine
92517	Vemp test i&r cervical	Otolaryngology
92518	Vemp test i&r ocular	Otolaryngology
92519	Vemp tst i&r cervical&ocular	Otolaryngology
92975	Dissolve clot heart vessel	Cardiology*
93316	Echo transesophageal	Anesthesiology
93565	Inject l ventr/atrial angio	Cardiology*
94014	Patient recorded spirometry	Pulmonary Disease
94015	Patient recorded spirometry	Pulmonary Disease
95857	Cholinesterase challenge	Neurology
96935	Rcm celulr subcelulr img skn	Dermatology
97545	Work hardening	Physical Therapist
97546	Work hardening add-on	Physical Therapist
99151	Mod sed same phys/qhp <5 yrs	Pediatric Medicine
99455	Work related disability exam	Family Practice
99456	Disability examination	Family Practice
G0076	Care manag h vst new pt 20 m	Internal Medicine
G0077	Care manag h vst new pt 30 m	Internal Medicine
G0078	Care manag h vst new pt 45 m	Internal Medicine
G0079	Care manag h vst new pt 60 m	Internal Medicine
G0080	Care manag h vst new pt 75 m	Internal Medicine
G0081	Care man h v ext pt 20 mi	Internal Medicine
G0082	Care man h v ext pt 30 m	Internal Medicine
G0083	Care man h v ext pt 45 m	Internal Medicine
G0084	Care man h v ext pt 60 m	Internal Medicine
G0085	Care man h v ext pt 75 m	Internal Medicine
G0086	Care man home care plan 30 m	Internal Medicine
G0087	Care man home care plan 60 m	Internal Medicine
G0106	Colon ca screen;barium enema	Diagnostic Radiology
G0117	Glaucoma scrn hgh risk direc	Ophthalmology
G0118	Glaucoma scrn hgh risk direc	Optometry
G0120	Colon ca scrn; barium enema	Diagnostic Radiology
G0128	Corf skilled nursing service	Internal Medicine
G0276	Pild/placebo control clin tr	Interventional Pain Management
G0329	Electromagntic tx for ulcers	Physical Therapist
G0341	Percutaneous islet celltrans	Interventional Radiology
G0342	Laparoscopy islet cell trans	General Surgery
G0343	Laparotomy islet cell transp	General Surgery
G0409	Corf related serv 15 mins ea	Clinical Social Worker
G0412	Open tx iliac spine uni/bil	Orthopedic Surgery
G0516	Insert drug del implant, >=4	Obstetrics/Gynecology
G0517	Remove drug implant	Obstetrics/Gynecology
G0518	Remove w insert drug implant	Obstetrics/Gynecology
G2000	Blinded conv. tx mdd clin tr	Psychiatry
G2001	Post d/c h vst new pt 20 m	Internal Medicine
G2002	Post-d/c h vst new pt 30 m	Internal Medicine
G2003	Post-d/c h vst new pt 45 m	Internal Medicine
G2004	Post-d/c h vst new pt 60 m	Internal Medicine
G2005	Post-d/c h vst new pt 75 m	Internal Medicine
G2006	Post-d/c h vst ext pt 20 m	Internal Medicine
G2014	Post-d/c care plan overs 30m	Internal Medicine
G2015	Post-d/c care plan overs 60m	Internal Medicine
G2250	Remot img sub by pt, non e/m	Internal Medicine

HCPCS	Short Descriptor	Expected Specialty Assignment
G2251	Brief chkin, 5-10, non-e/m	Physical Therapist
G2252	Brief chkin by md/qhp, 11-20	Internal Medicine
G6010	Radiation treatment delivery	Radiation Oncology
G9156	Evaluation for wheelchair	Internal Medicine
G9481	Remote e/m new pt 10mins	Internal Medicine
G9482	Remote e/m new pt 20mins	Internal Medicine
G9483	Remote e/m new pt 30mins	Internal Medicine
G9484	Remote e/m new pt 45mins	Internal Medicine
G9485	Remote e/m new pt 60mins	Internal Medicine
G9486	Remote e/m est. pt 10mins	Internal Medicine
G9487	Remote e/m est. pt 15mins	Internal Medicine
G9489	Remote e/m est. pt 40mins	Internal Medicine
G9490	Cmmi mod home visit	Internal Medicine
G9868	CMMI asyntelehealth <10min	Dermatology
G9869	CMMI asyntelehealth 10-20min	Dermatology
G9870	CMMI asyntelehealth >20min	Dermatology
G9978	Remote e/m new pt 10mins	Internal Medicine
G9979	Remote e/m new pt 20mins	Internal Medicine
G9980	Remote e/m new pt 30 mins	Internal Medicine
G9981	Remote e/m new pt 45mins	Internal Medicine
G9982	Remote e/m new pt 60mins	Internal Medicine
G9983	Remote e/m est. pt 10mins	Internal Medicine
G9984	Remote e/m est. pt 15mins	Internal Medicine
G9985	Remote e/m est. pt 25mins	Internal Medicine
G9986	Remote e/m est. pt 40mins	Internal Medicine
G9987	Bpci advanced in home visit	Internal Medicine
Q0035	Cardiokymography	Cardiology

* Recommended specialty assignment crosswalked; see below.

Commenters recommended an expected specialty assignment of interventional cardiology for CPT codes 33018, 33741, 33745, 33746, 92975, and 93565 and an expected specialty assignment of cardiac electrophysiology for CPT code 33275. However, we do not have PE/HR data for the interventional cardiology and cardiac electrophysiology specialties as they were not part of the PPIS when it was conducted in 2007. These specialties both use the cardiology specialty for their PE/HR data, and therefore, we have also crosswalked the CPT codes in question to the cardiology specialty on the list of expected specialty assignments for low volume services.

Based on the information provided by the commenters, we are finalizing the changes in expected specialty assignment for the five CPT codes in Table 2 which were already included on the list.

TABLE 2: Revisions to Expected Specialty Assignment List

HCPCS	Short Descriptor	Previous Specialty	Updated Specialty
31781	Reconstruct windpipe	Thoracic Surgery	Otolaryngology
35180	Repair blood vessel lesion	Thoracic Surgery	Vascular Surgery
43313	Esophagoplasty congenital	Thoracic Surgery	General Surgery
43314	Tracheo-esophagoplasty cong	Thoracic Surgery	General Surgery
96440	Chemotherapy intracavitary	Thoracic Surgery	Hematology/Oncology

We are not finalizing the recommended changes in expected specialty assignment for the CPT codes in Table 3 associated with the thoracic surgery specialty.

TABLE 3: Rejected Revisions to Expected Specialty Assignment List

HCPCS	Short Descriptor	Previous Specialty	Recommended Specialty
33203	Insert epicard eltrd endo	Thoracic Surgery	Cardiac Surgery
33251	Ablate heart dysrhythm focus	Thoracic Surgery	Cardiac Surgery
33320	Repair major blood vessel(s)	Thoracic Surgery	Cardiac Surgery
33414	Repair of aortic valve	Thoracic Surgery	Cardiac Surgery
33468	Revision of tricuspid valve	Thoracic Surgery	Cardiac Surgery
33470	Revision of pulmonary valve	Thoracic Surgery	Cardiac Surgery
33471	Valvotomy pulmonary valve	Thoracic Surgery	Cardiac Surgery
33476	Revision of heart chamber	Thoracic Surgery	Cardiac Surgery
33478	Revision of heart chamber	Thoracic Surgery	Cardiac Surgery
33502	Coronary artery correction	Thoracic Surgery	Cardiac Surgery
33503	Coronary artery graft	Thoracic Surgery	Cardiac Surgery
33504	Coronary artery graft	Thoracic Surgery	Cardiac Surgery
33505	Repair artery w/tunnel	Thoracic Surgery	Cardiac Surgery
33506	Repair artery translocation	Thoracic Surgery	Cardiac Surgery
33507	Repair art intramural	Thoracic Surgery	Cardiac Surgery
33600	Closure of valve	Thoracic Surgery	Cardiac Surgery
33602	Closure of valve	Thoracic Surgery	Cardiac Surgery
33606	Anastomosis/artery-aorta	Thoracic Surgery	Cardiac Surgery
33608	Repair anomaly w/conduit	Thoracic Surgery	Cardiac Surgery
33610	Repair by enlargement	Thoracic Surgery	Cardiac Surgery
33611	Repair double ventricle	Thoracic Surgery	Cardiac Surgery
33612	Repair double ventricle	Thoracic Surgery	Cardiac Surgery
33615	Repair modified fontan	Thoracic Surgery	Cardiac Surgery
33617	Repair single ventricle	Thoracic Surgery	Cardiac Surgery
33619	Repair single ventricle	Thoracic Surgery	Cardiac Surgery
33620	Apply r&l pulm art bands	Thoracic Surgery	Cardiac Surgery
33621	Transthor cath for stent	Thoracic Surgery	Cardiac Surgery
33622	Redo compl cardiac anomaly	Thoracic Surgery	Cardiac Surgery
33645	Revision of heart veins	Thoracic Surgery	Cardiac Surgery
33647	Repair heart septum defects	Thoracic Surgery	Cardiac Surgery
33660	Repair of heart defects	Thoracic Surgery	Cardiac Surgery
33665	Repair of heart defects	Thoracic Surgery	Cardiac Surgery
33670	Repair of heart chambers	Thoracic Surgery	Cardiac Surgery
33675	Close mult vsd	Thoracic Surgery	Cardiac Surgery
33676	Close mult vsd w/resection	Thoracic Surgery	Cardiac Surgery
33677	Cl mult vsd w/rem pul band	Thoracic Surgery	Cardiac Surgery
33684	Repair heart septum defect	Thoracic Surgery	Cardiac Surgery
33688	Repair heart septum defect	Thoracic Surgery	Cardiac Surgery
33690	Reinforce pulmonary artery	Thoracic Surgery	Cardiac Surgery
33692	Repair of heart defects	Thoracic Surgery	Cardiac Surgery
33694	Repair of heart defects	Thoracic Surgery	Cardiac Surgery
33697	Repair of heart defects	Thoracic Surgery	Cardiac Surgery
33702	Repair of heart defects	Thoracic Surgery	Cardiac Surgery
33710	Repair of heart defects	Thoracic Surgery	Cardiac Surgery
33720	Repair of heart defect	Thoracic Surgery	Cardiac Surgery
33722	Repair of heart defect	Thoracic Surgery	Cardiac Surgery
33724	Repair venous anomaly	Thoracic Surgery	Cardiac Surgery
33726	Repair pul venous stenosis	Thoracic Surgery	Cardiac Surgery
33730	Repair heart-vein defect(s)	Thoracic Surgery	Cardiac Surgery
33732	Repair heart-vein defect	Thoracic Surgery	Cardiac Surgery
33735	Revision of heart chamber	Thoracic Surgery	Cardiac Surgery
33736	Revision of heart chamber	Thoracic Surgery	Cardiac Surgery
33737	Revision of heart chamber	Thoracic Surgery	Cardiac Surgery
33750	Major vessel shunt	Thoracic Surgery	Cardiac Surgery
33755	Major vessel shunt	Thoracic Surgery	Cardiac Surgery
33762	Major vessel shunt	Thoracic Surgery	Cardiac Surgery

HCPCS	Short Descriptor	Previous Specialty	Recommended Specialty
33764	Major vessel shunt & graft	Thoracic Surgery	Cardiac Surgery
33766	Major vessel shunt	Thoracic Surgery	Cardiac Surgery
33767	Major vessel shunt	Thoracic Surgery	Cardiac Surgery
33768	Cavopulmonary shunting	Thoracic Surgery	Cardiac Surgery
33770	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33771	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33774	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33775	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33776	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33777	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33778	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33779	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33780	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33781	Repair great vessels defect	Thoracic Surgery	Cardiac Surgery
33782	Nikaidoh proc	Thoracic Surgery	Cardiac Surgery
33783	Nikaidoh proc w/ostia implt	Thoracic Surgery	Cardiac Surgery
33786	Repair arterial trunk	Thoracic Surgery	Cardiac Surgery
33788	Revision of pulmonary artery	Thoracic Surgery	Cardiac Surgery
33800	Aortic suspension	Thoracic Surgery	Cardiac Surgery
33802	Repair vessel defect	Thoracic Surgery	Cardiac Surgery
33803	Repair vessel defect	Thoracic Surgery	Cardiac Surgery
33813	Repair septal defect	Thoracic Surgery	Cardiac Surgery
33814	Repair septal defect	Thoracic Surgery	Cardiac Surgery
33820	Revise major vessel	Thoracic Surgery	Cardiac Surgery
33822	Revise major vessel	Thoracic Surgery	Cardiac Surgery
33824	Revise major vessel	Thoracic Surgery	Cardiac Surgery
33840	Remove aorta constriction	Thoracic Surgery	Cardiac Surgery
33845	Remove aorta constriction	Thoracic Surgery	Cardiac Surgery
33851	Remove aorta constriction	Thoracic Surgery	Cardiac Surgery
33852	Repair septal defect	Thoracic Surgery	Cardiac Surgery
33853	Repair septal defect	Thoracic Surgery	Cardiac Surgery
33917	Repair pulmonary artery	Thoracic Surgery	Cardiac Surgery
33920	Repair pulmonary atresia	Thoracic Surgery	Cardiac Surgery
33922	Transect pulmonary artery	Thoracic Surgery	Cardiac Surgery
33924	Remove pulmonary shunt	Thoracic Surgery	Cardiac Surgery
33925	Rpr pul art unifocal w/o cpb	Thoracic Surgery	Cardiac Surgery
33926	Repr pul art unifocal w/cpb	Thoracic Surgery	Cardiac Surgery
33927	Impltj tot rplcmt hrt sys	Thoracic Surgery	Cardiac Surgery
35182	Repair blood vessel lesion	Thoracic Surgery	Cardiac Surgery
36835	Artery to vein shunt	Thoracic Surgery	Cardiac Surgery
38382	Thoracic duct procedure	Thoracic Surgery	Cardiac Surgery

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Commenters requested that the expected specialty assignment for the CPT codes in this group be changed from the thoracic surgery specialty to the cardiac surgery specialty. We did not finalize this same request in previous rulemaking cycles in both CY 2020 (84 FR 62576) and CY 2021 (85 FR 84479) for the same group of CPT codes. We finalized a proposal in CY 2020 to update the expected specialty list to accurately reflect a previously finalized crosswalk to thoracic surgery for the services in question. As we stated at the time, we did not finalize a proposal to assign the codes in question to the cardiac surgery specialty. Instead, we finalized a proposal to update the incorrect documentation in our expected specialty list to accurately reflect a previously finalized crosswalk to thoracic surgery for these services. The previously finalized assignment of the cardiac surgery specialty to these services has been in place since the CY 2012 rule cycle, and we believe that the expected specialty list should be updated to reflect the correct specialty assignment. We have previously considered and declined to make the changes suggested by commenters, and we are not finalizing such changes in this CY 2022 PFS final rule. We direct readers to the discussion of this topic in the CY 2020 PFS final rule (84 FR 62574 through 62578) and we reiterate that we do not anticipate this finalized proposal from CY 2020 having a discernible effect on the valuation of the affected codes due to the similarity between the cardiac surgery and thoracic surgery specialties.

We also note for commenters that each HCPCS code that appears on the list of expected specialty assignments for low volume services remains on the list from year to year, even if the volume

for the code in question rises to over 100 services for an individual calendar year. The HCPCS codes and expected specialty assignment remain on the list, and will be applied should the volume fall below 100 services in any calendar year; there is no need to ''reactivate'' individual codes as some commenters indicated in their submissions.

Comment: Several commenters stated that in previous years, CMS has applied the expected specialty override to services with fewer than 100 allowed services in a 3-year average of Medicare claims data without adjusting the utilization to interpret any CPT modifiers. Although commenters agreed with the use of a 3-year average to identify low volume services for expected specialty assignment, commenters stated that not adjusting for certain modifiers will result in undercounting or overcounting of certain services. For example, commenters stated that if a single procedure is performed by both a primary surgeon and an assistant at surgery, this service should only be counted once even though each of the practitioners would report the service on a separate claim. Commenters recommended that CMS should set the frequency to zero for post-operative only (modifier '55') and assistant at surgery (modifier '80') records, multiply the frequency by 2 for bilateral surgery records (modifier '50'), and divide the frequency by 2 for co-surgery records (modifier '62').

Response: We do not agree that it would be more appropriate to make the adjustments to utilization as described by the commenters to determine low volume status. As we stated in the CY 2020 PFS final rule (84 FR 62576), we finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use claims data to determine which codes are low volume for the coming year, defining ''low volume'' as those that had fewer than 100 allowed services in the Medicare claims data. We did not finalize a policy to discount this utilization based on modifiers that identify certain circumstances, and we do not believe that it would be more appropriate to do so, as a service is still furnished and billed in each case, even if payment is discounted. Additionally, we did not make any proposals concerning the methodology used to identify low volume services in the proposed rule, and therefore, we are not finalizing any changes to this methodology.

After consideration of the public comments, we are finalizing the updates to the list of expected specialty assignments for low volume services as detailed above.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its

associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 4.

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TABLE 4: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

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- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only*), is associated with the global service, CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 5 details the manner in which the modifiers are applied.

TABLE 5: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act requires that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We will apply the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a

time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate) ∧ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally, 150,000 minutes
usage = variable, *see* discussion below in this final rule
price = price of the particular piece of equipment
life of equipment = useful life of the particular piece of equipment
maintenance = factor for maintenance; 0.05.
interest rate = variable, *see* discussion below in this final rule

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 6.

TABLE 6: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose any changes to the equipment interest rates for CY 2022.

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2022 direct PE input public use files, which are available on the CMS website under downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of

clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases, the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in

developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2022, we are continuing to display two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. Technical Corrections to Direct PE Input Database and Supporting Files

For CY 2022, we proposed to address the following:

• Following the publication of the CY 2021 PFS proposed rule, several commenters questioned the proposed RVUs associated with several occupational therapy evaluation procedures (CPT codes 97165 through 97167). Commenters stated that the PE valuation for these codes appeared to be illogical as it was counterintuitive for the PE RVU to go down as the level of complexity increased. Commenters stated that the distribution of code usage has not changed in any manner to justify a reduction in the code values and that all three evaluation codes should reimburse at the same rate. In response to the commenters, we noted that although the three codes in question shared the same work RVU and the same direct PE inputs, they did not share the same specialty distribution in the claims data, and therefore, would not necessarily receive the same allocation of indirect PE. In the CY 2021 PFS final rule (85 FR 84490), we finalized the implementation of a technical change intended to ensure that these three services received the same allocation of indirect PE. We agreed with commenters that it was important to avoid a potential rank order anomaly in which the simple case for a service was valued higher than the complex case.

After the publication of the CY 2021 PFS final rule, stakeholders stated their appreciation for the technical change made in the final rule to ensure that the indirect PE allocation was the same for all three levels of occupational therapy evaluation codes. However, stakeholders expressed concern that the PE RVUs we finalized for CPT codes 97165–97167 decreased as compared to the PE RVUs we proposed for CY 2021. Stakeholders stated that nothing had occurred in the past year that would account for a reduction to the proposed PE for these codes, especially in a year where the proposed PE increased for the corresponding physical therapy evaluation procedures (CPT codes 97161–97163), and stakeholders questioned whether there had been an error in applying the indirect PE methodology.

We reviewed the indirect PE allocation for CPT codes 97165–97167 in response to the stakeholder inquiry and we do not agree that there was an error in applying the indirect PE methodology. We finalized a technical change in the CY 2021 PFS final rule intended to ensure that these three services received the same allocation of indirect PE, which achieved its desired goal of assigning equivalent indirect PE to these three services. However, by forcing CPT codes 97165–97167 to have the same indirect PE allocation, the indirect PE values for these codes no longer relied on the claims data, which ended up affecting the indirect practice cost index for the wider occupational therapy specialty. Because CPT codes 97165–97167 are high volume services, this resulted in a lower indirect practice cost index for the occupational therapy specialty and a smaller allocation of indirect PE for CY 2021 than initially proposed.

We proposed to address this issue for CY 2022 by assigning all claims data associated with CPT codes 97165–97167 to the occupational therapy specialty. This should ensure that CPT codes 97165–97167 will always receive the same indirect PE allocation, as well as prevent any fluctuations to the indirect practice cost index for the wider occupational therapy specialty. This is intended to avoid a potential rank order anomaly in which the simple case for a service is valued higher than the complex case. As the utilization for CPT codes 97165–97167 is overwhelmingly identified as performed by occupational therapists, we do not anticipate that assigning all of the claims data for these codes to the occupational therapy specialty will have a noticeable effect on their valuation. We solicited public comments regarding this proposal, and specifically on what commenters suggest as the most appropriate method of assigning indirect PE allocation for these services.

The following is a summary of the comments we received on our proposal and our responses.

Comment: Several commenters stated that they appreciated CMS taking steps to review the PE calculations and make the correction to maintain the PE values equally for CPT codes 97165, 97166 and 97167. The commenters stated that they appreciated and agreed with the correction in calculation. The commenters also urged CMS to review this policy again if and when the evaluation codes are stratified because the current rank order anomaly caused by indirect PE when the codes are paid the same will not exist in the future when the code values are stratified based on complexity level.

Response: We appreciate the support for our proposal from the commenters.

After consideration of the public comments, we are finalizing our proposal to assign all claims data associated with CPT codes 97165–97167 to the occupational therapy specialty.

In the CY 2020 PFS final rule (84 FR 63102 through 63104), we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis for the provision of self-administered esketamine. In the CY 2021 PFS final rule, we finalized a proposal to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that summed the values associated with several codes (85 FR 84641 through 84642). Following the publication of the CY 2021 PFS final rule, stakeholders expressed concerns that the finalized PE RVU had decreased for HCPCS codes G2082 and G2083 as compared to the proposed valuation and as compared to the previous CY 2020 interim final valuation. Stakeholders questioned whether there had been an error in the PE allocation since CMS had finalized increases in the direct PE inputs for the services.

We reviewed the indirect PE allocation for HCPCS codes G2082 and G2083 in response to the stakeholder inquiry and discovered a technical change that was applied in error. Specifically, we inadvertently assigned a different physician specialty than we intended (''All Physicians'') to HCPCS codes G2082 and G2083 for indirect PE allocation in our ratesetting process during valuation of these codes in the CY 2020 PFS final rule, and continued that assignment into the CY 2021 PFS proposed rule. This specialty assignment caused the PE value for these services to be higher than anticipated for CY 2020. We intended to revise the assigned physician specialty for these codes to ''General Practice'' in the CY 2021 PFS final rule; however, we neglected to discuss this change in the course of PFS rulemaking for CY 2021. Since we initially applied this technical change in the CY 2021 PFS final rule without providing an explanation, we

issued a correction notice (86 FR 14690) to remove this change from the CY 2021 PFS final rule, and to instead maintain the All Physicians specialty assignment through CY 2021. We apologize for any confusion this may have caused.

For CY 2022, we proposed to maintain the currently assigned physician specialty for indirect PE allocation for HCPCS codes G2082 and G2083. We proposed to assign these two services to the All Physicians specialty for indirect PE allocation which will maintain payment consistency with the rates published in the CY 2020 PFS final rule and the CY 2021 PFS proposed rule. Although we had previously intended to assign the General Practice specialty to these codes, stakeholders have provided additional information about these services suggesting that maintaining the All Physicians specialty assignment for these codes will help maintain payment stability and preserve access to this care for beneficiaries. We solicited public comments to help us discern which specialty would be the most appropriate to use for indirect PE allocation for HCPCS codes G2082 and G2083. We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, should appropriately reflect the typical costs for the specialty the commenters suggest. For example, we do not believe it would be appropriate to assign the Psychiatry specialty for these services given that HCPCS codes G2082 and G2083 include the high direct costs associated with esketamine supplies. The Psychiatry specialty is an outlier compared to most other specialties, allocating indirect costs at a 15:1 ratio based on direct costs because psychiatry services typically have very low direct costs. Assignment of most other specialties would result in allocation of direct costs at roughly a 3:1 ratio. We requested that commenters explain in their comments how the indirect PE allocation would affect the payment for these services. Specifically, to ensure appropriate payment for HCPCS codes G2082 and G2083, we would like to get a better understanding of the indirect costs associated with these services, relative to other services furnished by the suggested specialty.

The following is a summary of the comments we received on our proposal and our responses.

Comment: Several commenters supported the proposal to maintain the currently assigned physician specialty (All Physicians) for indirect PE allocation for HCPCS codes G2082 and G2083. Commenters thanked CMS for making technical corrections to restore the payment levels for services related to self-administered esketamine to their CY 2020 amounts. One commenter encouraged CMS to maintain the current rates to ensure payment stability and beneficiary access to this evidence-based treatment option. Another commenter urged CMS either to maintain its current approach by allowing continued use of the all-physician specialty designation or to provide a blend of the Psychiatry (⅔) and All Physicians (⅓) designations.

Response: We appreciate the support for our proposed policies from the commenters.

Comment: Several commenters stated that esketamine services were best identified as procedures assigned to the specialty of Psychiatry. Commenters stated that approximately 95 percent of the providers administering esketamine are psychiatric professionals and that utilization data from CMS demonstrated that nearly 75 percent of providers in the non-facility setting fall within the Psychiatry specialty for both codes. Commenters stressed the high costs to the provider of administering esketamine which result in more risk due to up-front supply costs, and several commenters requested assigning HCPCS codes G2082 and G2083 to the Psychiatry specialty to offset potential decreases in valuation resulting from the proposed clinical labor pricing update. One commenter requested a specialty blend of three-fourths Psychiatry and one-fourth ''All Physicians'' which the commenter stated was clinically coherent, consistent with the data available, and would result in the total non-facility national average reimbursement amount that most closely approximates CY 2021 levels.

Response: We appreciate the feedback from the commenters regarding the costs associated with administering esketamine. However, we continue to believe that the All Physicians specialty most accurately captures the indirect PE allocation associated with these services. We do not assign a blended combination of specialties for any other services and the commenters did not provide new data to support a change in specialty assignment aside from noting that many providers in the non-facility setting fall within the Psychiatry specialty for both codes. We continue to believe that it would not be accurate to assign the Psychiatry specialty for HCPCS codes G2082 and G2083 due to its outlier status amongst specialties, whereby Psychiatry allocates indirect costs at a 15:1 ratio based on direct costs as compared to most other specialties having approximately a 3:1 ratio. We do not believe that this would be an accurate specialty designation for HCPCS codes G2082 and G2083 given the high direct costs associated with esketamine (which would translate into disproportionately high indirect PE allocation at said 15:1 ratio).

As we noted in the CY 2021 PFS final rule (85 FR 84498 through 84499) and again in this rule, the RAND Corporation is currently studying potential improvements to our PE allocation methodology and the data that underlie it. We are interested in exploring ways that the PE methodology can be updated, which could include improvements to the indirect PE methodology to address unusual codes like G2082 and G2083 which have a direct to indirect ratio that does not match their most commonly billed specialties. Under the current PE methodology, however, we agree with the commenters who supported the proposal to maintain the currently assigned physician specialty (All Physicians) for indirect PE allocation.

After consideration of the public comments, we are finalizing our proposal to maintain the All Physicians specialty for indirect PE allocation for HCPCS codes G2082 and G2083.

A stakeholder contacted us regarding a potential error involving the intraservice work time for CPT code 35860 (Exploration for postoperative hemorrhage, thrombosis or infection; extremity). The stakeholder stated that the RUC recommended an intraservice work time of 90 minutes for this code when it was last reviewed in the CY 2012 PFS final rule and we finalized the work time without refinement at 60 minutes (76 FR 73131). The stakeholder requested that the intraservice work time for CPT code 35860 should be updated to 90 minutes.

We reviewed the intraservice work time for CPT code 35860 and found that the RUC inadvertently recommended a time of 60 minutes for the code, which we proposed and finalized without comment in rulemaking for the CY 2012 PFS. As a result, we do not believe that this is a technical error on our part. However, since the stakeholder has clarified that the RUC intended to recommend 90 minutes of intraservice work time for CPT code 35860 based on the surveyed median time, we proposed to update the intraservice work time to 90 minutes to match the survey results.

We did not receive public comments on our proposal to update the intraservice work time for CPT code 35860, and we are finalizing as proposed.

We did not make any proposals specifically associated with the utilization crosswalk file or public use

file as described below, however we received a public comment on these topics from one stakeholder. The following is a summary of the comments we received and our responses.

Comment: One stakeholder contacted CMS identifying what appeared to be duplicate data in the utilization crosswalk file. The stakeholder stated that the first 15,875 rows of the file appeared to almost exclusively contain duplicate lines in sets of two, and requested clarification on whether the utilization file was in error.

Response: Due to a technical error, the utilization for anesthesia services was unintentionally duplicated in the files associated with the proposed rule. We have corrected this error for the final rule and we apologize for any confusion which may have resulted from this inadvertent mistake in the utilization crosswalk file.

Comment: One commenter stated that they believed the public use files contain an error in the clinical labor portion of the PE RVU calculation. The commenter stated that the CY 2022 PE RVU summary file provided the pre-, intra-, and post-service costs for CPT codes 65778 and 65779. The commenter stated that this file showed no cost for pre-service activities or post-service activities, however the accompanying Clinical Labor New Activity Detail public use file showed a series of staff activities associated with CPT codes 65778 and 65779. The commenter requested that CMS review the pre-service and post-service costs and correct or update the clinical labor values for these codes accordingly. The commenter also stated that the patient contact time reflected in the public use file is understated by approximately 50 percent for CPT codes 65778 and 65779 and encouraged CMS to evaluate whether the public use file values should be updated prior to implementation of the PFS for CY 2022.

Response: We reviewed the public use files described by the commenter and we can confirm that there was no error in the calculation of the rates for these services. The clinical labor tasks described by the commenter for CPT codes 65778 and 65779 all take place during the intra-service period, not the pre-service or post-service period, and the Clinical Labor New Activity Detail public use file correctly lists the clinical labor for these services. If the commenter has reason to believe that the clinical labor is undervalued for these services, we encourage them to nominate CPT codes 65778 and 65779 as potentially misvalued for additional review.

c. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2022, we proposed to update the price of six supplies and two equipment items in response to the public submission of invoices. Since this is the final year of the supply and equipment pricing update, the new pricing for each of these supply and equipment items will take effect for CY 2022 as there are no remaining years of the transition. The six supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 23, CY 2022 Invoices Received for Existing Direct PE Inputs.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, April 1, 2014) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.*

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- The **Federal Register**, current DPEI data, historical proposed and final rules prior to CY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

(1) If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

(2) If no data were available for commercial products, the current CMS prices were used as the RP.

GSA prices were not used to calculate the StrategyGen recommended prices, due to our concern that the GSA system curtails the number and type of suppliers whose products may be accessed on the GSA Advantage website, and that the GSA prices may often be lower than prices that are

available to non-governmental purchasers. After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicated that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties would experience increases or decreases in their Medicare payments if we were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, in the CY 2019 PFS proposed rule we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 7.

TABLE 7: Example of Direct PE Pricing Transition

Current Price	$100	
Final Price	$200	
Year 1 (CY 2019) Price	$125	1/4 difference between $100 and $200
Year 2 (CY 2020) Price	$150	1/3 difference between $125 and $200
Year 3 (CY 2021) Price	$175	1/2 difference between $150 and $200
Final (CY 2022) Price	$200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make

use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer timeframe will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

We received many comments regarding the market-based supply and equipment pricing proposal following the publication of the CY 2019 PFS proposed rule. For a full discussion of these comments, we direct readers to the CY 2019 PFS final rule (83 FR 59475 through 59480). In each instance in which one commenter raised questions about the accuracy of a supply or equipment code's recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to ensuring that the recommended price was based on the correct item in question and the clarified unit of measure. Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. After consideration of the comments and this additional price research, we updated the recommended prices for approximately 70 supply and equipment codes identified by the commenters. Table 9 in the CY 2019 PFS final rule lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing (83 FR 59479 through 59480).

After consideration of the public comments, we finalized our proposals associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2022, we received invoice submissions from stakeholders for approximately half a dozen supply and equipment codes as part of the fourth year of the market-based supply and equipment pricing update. We used these submitted invoices in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. We reviewed the invoices, as well as our own data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. Based on this review, we proposed to update the prices of six supply items listed in the valuation of specific codes section of the preamble under Table 23: CY 2022 Invoices Received for Existing Direct PE Inputs. Since this is the final year of the supply and equipment pricing update, the new pricing for each of these supply and equipment items would take effect immediately for CY 2022.

The proposed prices for the supply and equipment items listed in Table 23 of CY 2022 were generally calculated following our standard methodology of averaging together the prices on the submitted invoices. In the case of the Liquid coverslip (Ventana 650–010) (SL479) supply, we proposed a price of $0.051 based on the median invoice due to the presence of an outlier invoice that substantially increased the pricing when using an average. We believe that the price of $0.051 will be more typical for the SL479 supply based on the pricing information contained on the other submitted invoices. We also received several invoices for the 3C patch system (SD343) supply; however, since we established a price of $625.00 for this supply in last year's CY 2021 PFS final rule and the submitted invoices had an average price of $612.50, we did not propose to update the price. We believe that the submitted invoices confirm that the current pricing of $625.00 is typical for the SD343 supply.

We received public comments on the fourth and final year of the market-based supply and equipment pricing update. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS to update prices for negative pressure wound therapy (NPWT) devices given the context of the clinical labor pricing update. The commenter stated that while one database reported typical costs of $400–$600 for single-use disposable NPWT devices, further prices provided by a medical equipment distributor show lower costs incurred by providers paying for PICO, Smith+Nephew's single-use disposable NPWT device. The commenter submitted five invoices for the negative pressure wound therapy, disposable kit (SA131) supply and stated that these updated prices for single-use NPWT devices could be used in future updates of direct cost inputs, which would strengthen the accuracy of Medicare pricing.

Response: We appreciate the submission of invoices from the commenter to update the pricing of the SA131 supply. This kit is currently priced at $208 and we are finalizing an update to a price of $263.25 based on the median of the five submitted invoices from one commenter. We believe that the median value is more reflective of the typical price than the average value as there was a clear outlier amongst the five invoice prices ($248.33, $252.00, $263.25, $284.50, and $340.20).

Comment: Several commenters stated their concerns regarding significant price reductions for several types of radiation therapy equipment: The IMRT treatment planning system (ED033), the HDR Afterload System Nucletron—Oldelft (ER003), and the SRS system SBRT (ER083). Commenters stated that they appreciated CMS' efforts to acquire current pricing information but believed that the recommended prices for these equipment items are below industry standards. Commenters stated that undervaluing equipment inputs has the potential to create access to care issues and potentially reduce the utilization of services that provide high quality patient outcomes.

Response: Although we share the concerns of the commenters about the importance of ensuring accuracy in pricing and beneficiary access to care, the commenters did not submit invoices or provide any other pricing information for the three equipment items in question. In the absence of other pricing

data, we continue to believe that the equipment pricing we established for these items based on our past market-based research reflects the most accurate information for the equipment items in question.

Comment: An anonymous commenter submitted an invoice that they stated could be used to update the pricing of the endovascular laser treatment kit (SA074) supply. The commenter stated that the PE may be overvalued for CPT code 36478, and the cost of $205.00 per kit detailed in this invoice may be more accurately reflective of SA074 kit costs.

Response: We appreciate the invoice submission from the anonymous commenter. The SA074 supply has a current CY 2022 price of $438.60 based on invoices submitted in last year's CY 2021 rulemaking cycle. The new invoice submission is less than half of this price, and when we compared the specific kit in question on the invoices, they described two different products. The CY 2021 invoices described a 65 cm kit while the CY 2022 invoice described a 45 cm version of the same kit. We believe that this explains the disparity in pricing between the different invoices. Since it is unclear to us which of these two products is more typical for use in CPT code 36478, we are maintaining the current CY 2022 price of $438.60 pending availability of additional information. We encourage stakeholders to submit additional invoices to assist in the pricing of the SA074 supply. These invoices can be submitted with public comments in next year's CY 2023 rulemaking cycle or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

Comment: One commenter requested that CMS establish a national physician payment rate for Category III CPT code 0583T, also known as tympanostomy under local anesthesia (Tula). The commenter stated that this device-intensive procedure has inappropriately low physician MAC-posted rates resulting from crosswalks to ENT codes that do not involve use of single-use implantable medical devices provided in the physician office setting. The commenter suggested work RVUs and direct PE inputs for Category III code 0583T to be used in national pricing of the service, and separately submitted six invoices showing prices paid by physicians for the tympanostomy under local anesthesia (Tula) implantable device and related supplies. The commenter requested a price of $995 for the Tula implantable device.

Response: We appreciate the submission of invoices and other pricing information from the commenter regarding Category III CPT code 0583T, but we did not propose to establish national pricing for this service. Category III CPT codes are typically contractor priced since they describe new and emerging technologies. We will review the materials provided by the commenter for potential use in future rulemaking; however, we are not finalizing national pricing for Category III CPT code 0583T or establishing a price for the Tula implantable device at this time.

After consideration of the public comments, we are finalizing the supply and equipment prices as detailed individually above. We note that the supply and equipment prices finalized for CY 2022 represent the fourth and final year of the market-based supply and equipment pricing update.

(2) Invoice Submission

The full list of updated supply and equipment pricing as implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.*

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Stakeholders are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

(3) Autologous Platelet-Rich Plasma (HCPCS Code G0460) Supply Inputs

We did not make any proposals associated with HCPCS code G0460 (*Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment*) in the CY 2021 PFS proposed rule. Following publication of the rule, stakeholders contacted CMS regarding the creation of a new 3C patch system supply, which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds. Stakeholders first sought clarification on how CMS calculated the underlying nonfacility PE RVUs for HCPCS code G0460. Stakeholders also stated that autologous platelet rich plasma administration procedures furnished in clinical trials (including the new 3C patch system) are reported using HCPCS code G0460 and requested that CMS revalue the service to reflect the PEs associated with the new patch system supply. The stakeholders stated that the use of the new 3C patch system will represent the typical case for HCPCS code G0460, and suggested that, therefore, the cost inputs for this supply should be used to establish the RVUs for this code, as the current PFS payment rate is substantially less than the amount it costs to furnish the 3C patch.

We want to clarify that the direct PE inputs for HCPCS code G0460 increased for CY 2021 as a result of the ongoing market-based supply and equipment pricing update. However, there was also a minor decrease in the indirect PE allocation associated with this service for CY 2021, with the net result that the proposed PE RVU coincidentally ended up remaining the same as in the previous year. We also clarify that HCPCS code G0460 is not included in the Anticipated Specialty Assignment for Low Volume Services list, and therefore, was unaffected by low utilization in the claims data. In addition, as a contractor priced service, HCPCS code G0460 is unaffected by inclusion or exclusion from this list.

We share the concerns of the stakeholders that patient access to the 3C patch could be materially impacted if CMS maintains the current PE RVUs for HCPCS G0460. In the CY 2021 PFS final rule, we established contractor pricing for HCPCS code G0460 for CY 2021. We believe that the use of contractor pricing again for CY 2022 will allow us additional time to consider the most appropriate resource inputs and PE RVUs for HCPCS code G0460. We also added the 3C patch system to our supply database under supply code SD343 at a price of $625.00 based on an average of the submitted invoices. We proposed to maintain contractor pricing for CY 2022 for HCPCS code G0460 as we do not currently have sufficient information to establish national pricing. It remains

unclear to us what the typical supply inputs would be for HCPCS code G0460 and whether they would include the use of the new 3C patch system. We believe that it would be more appropriate to maintain contractor pricing for the service, which will allow for more flexibility in pricing. We solicited any additional information that commenters can supply that CMS should consider to establish national payment for HCPCS code G0460.

We did not receive public comments on this proposal and are finalizing contractor pricing for HCPCS code G0460 for CY 2022 as proposed.

d. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Since 2019, we have been updating the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 will be the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Stakeholders have raised concerns that the long delay since clinical labor pricing was last updated has created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of stakeholders have suggested that certain wage rates are inadequate because they do not reflect current labor rate information. Some stakeholders have also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. Since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There has been considerable stakeholder interest in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), stakeholders supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update. We believe it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for this proposal.

We recognize that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we have used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. To account for the employers' cost of providing fringe benefits, such as sick leave, we used the same benefits multiplier of 1.366 as employed in CY 2002. As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected an average hourly wage rate of $14.03, which we multiplied by the 1.366 benefits modifier and then divided by 60 minutes to arrive at the proposed per-minute rate of $0.32.

Table 8 lists our updates to the clinical labor prices. The BLS occupational code used as a source of wage data is listed for each clinical labor type; for the ''blend'' clinical labor types, this may include multiple BLS occupational codes and other clinical labor types which were calculated separately and then averaged together. Clinical labor types without a direct BLS labor category where we are employing a proxy BLS wage rate are indicated with an asterisk in Table 8.

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TABLE 8: Proposed Clinical Labor Pricing Update

Labor Code	Labor Description	Source	Current Rate Per Minute	Updated Rate Per Minute	% Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.32	39%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.39	50%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.50	67%
L032B	EEG Technician	BLS 29-2098	0.32	0.51	59%
L033A	Lab Technician	BLS 29-2010	0.33	0.60	82%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.44	33%
L035A	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.62	77%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.51	38%
L037B	Histotechnologist*	BLS 29-9098	0.37	0.64	73%
L037C	Orthoptist*	BLS 29-1141	0.37	0.85	130%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.59	59%
L037E	Child Life Specialist*	BLS 21-1023	0.37	0.57	54%
L038A	COMT/COT/RN/CST*	BLS 29-2057, BLS 29-2061, L051A, BLS 19-4010	0.38	0.57	50%
L038B	Cardiovascular Technician*	BLS 31-2011	0.38	0.68	79%
L038C	Medical Photographer*	BLS 29-2050	0.38	0.41	7%
L039A	Certified Retinal Angiographer*	BLS 29-2010	0.39	0.60	54%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.64	64%
L039C	Psychometrist*	BLS 21-1029	0.39	0.68	73%
L041A	Angio Technician*	BLS 29-9000	0.41	0.62	51%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.69	68%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.69	68%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.69	64%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.70	67%
L043A	Mammography Technologist*	BLS 29-1126	0.43	0.70	63%
L045A	Cytotechnologist*	BLS 29-2035	0.45	0.81	80%
L045B	Electron Microscopy Technologist*	BLS 29-1124	0.45	1.00	122%
L045C	CORF socialworker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.80	78%
L046A	CT Technologist*	BLS 29-2035	0.46	0.81	76%
L047A	MRI Technologist	BLS 29-2035	0.47	0.81	72%
L047B	REEGT (Electroencephalographic Tech)*	BLS 29-2035	0.47	0.81	72%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.77	64%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.77	64%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.88	43%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.83	66%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.83	66%
L050C	Radiation Therapist	BLS 29-1124	0.50	1.00	100%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	1.00	100%
L051A	RN	BLS 29-1141	0.51	0.85	67%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.84	65%
L051C	RN/CORF	L051A	0.51	0.85	67%
L052A	Audiologist	BLS 29-1181	0.52	0.92	77%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.87	64%
L054A	Vascular Technologist*	BLS 19-1040	0.54	1.07	98%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.90	64%
L056A	RN/OCN*	BLS 29-2033	0.79	0.88	11%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.92	62%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0%
L063A	Medical Dosimetrist*	BLS 19-1040	0.63	1.07	70%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.45	35%
L152A	Medical Physicist	BLS 19-2012 (75th percentile)	1.52	1.80	18%

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We proposed to use the 75th percentile of the average wage data for the Medical Physicist (L152A) clinical labor type because we believe this level

will most closely fit with the historic wage data for this clinical labor type. A Medical Physicist is a specific type of physicist, and the available BLS wage data describes the more general category of physicist which is paid at a lower rate. In this specific case, the 75th percentile more accurately describes the clinical labor type in question based on how it has historically been paid. We also proposed to maintain the current clinical labor pricing for the Behavioral Health Care Manager (L057B) clinical labor type rather than update it. Although the BLS data reflected a decreased clinical labor rate for the Behavioral Health Care Manager labor type, we do not believe that the typical wages have decreased for this clinical labor type given that every other clinical labor type has increased over the past 5 years since the Behavioral Health Care Manager clinical labor type was created. The Behavioral Health Care Manager labor type was initially established in the CY 2017 PFS final rule (81 FR 80350). It seems more likely that we misidentified the proper BLS category for this clinical labor type than that wages have decreased since 2017. We believe that the clinical labor rate for the Behavioral Health Care Manager should be held constant for CY 2022 pending additional public feedback.

We solicited comments on the updated clinical labor pricing. We were particularly interested in additional wage data for the clinical labor types for which we lacked direct BLS wage data and made use of proxy labor categories for pricing. We understand that the clinical labor undertaken by, for example, a Histotechnologist (L037B) is not the same as the clinical labor provided by the Health Information Technologist category of BLS wage data that we employed as a proxy for pricing. Although these occupations are not directly analogous to each other in terms of the work they do, we nonetheless believe that the proposed crosswalks are appropriate in terms of the resulting hourly wage data. We indicated that we would appreciate any additional information that commenters could supply both in terms of direct wage data, as well as identifying the most accurate types of BLS categories that could be used as proxies to update pricing for clinical labor types that lack direct BLS wage data. We isolated the anticipated effects of the clinical labor pricing update on specialty payment impacts by comparing the proposed CY 2022 PFS rates with and without the clinical labor pricing updates in place as shown in Table 9.

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TABLE 9: Anticipated Clinical Labor Pricing Effect on Specialty Impacts

Specialty	Allowed Charges (mil)	New CL Pricing Change
Portable X-Ray Supplier	$95	10%
Family Practice	$6,020	2%
Endocrinology	$508	2%
General Practice	$412	1%
Hand Surgery	$246	1%
Nurse Practitioner	$5,100	1%
Pediatrics	$67	1%
Geriatrics	$192	1%
Orthopedic Surgery	$3,812	1%
Internal Medicine	$10,730	1%
Psychiatry	$1,112	1%
Pulmonary Disease	$1,654	1%
Physician Assistant	$2,901	1%
Neurology	$1,522	1%
Neurosurgery	$811	1%
Plastic Surgery	$382	0%
Optometry	$1,359	0%
Thoracic Surgery	$352	0%
Nurse Anes / Anes Asst	$1,321	0%
Gastroenterology	$1,757	0%
Obstetrics/Gynecology	$636	0%
General Surgery	$2,057	0%
Cardiac Surgery	$266	0%
Physical/Occupational Therapy	$4,973	0%
Ophthalmology	$5,343	0%
Nephrology	$2,225	0%
Clinical Social Worker	$857	0%
Anesthesiology	$2,020	0%
Multispecialty Clinic/Other Phys	$153	0%
Podiatry	$2,133	0%
Clinical Psychologist	$832	0%
Emergency Medicine	$3,077	0%
Total	$97,008	0%
Chiropractic	$765	0%
Physical Medicine	$1,164	0%
Critical Care	$378	0%
Rheumatology	$548	0%
Colon and Rectal Surgery	$168	0%
Cardiology	$6,871	-1%
Infectious Disease	$656	-1%
Other	$48	-1%
Audiologist	$75	-1%
Urology	$1,810	-1%
Nuclear Medicine	$56	-1%
Pathology	$1,265	-1%
Interventional Pain Mgmt	$936	-1%
Radiology	$5,275	-1%
Otolarngology	$1,271	-1%
Dermatology	$3,767	-1%
Hematology/Oncology	$1,707	-2%
Allergy/Immunology	$247	-2%
Independent Laboratory	$645	-3%
Vascular Surgery	$1,293	-4%
Oral/Maxillofacial Surgery	$79	-4%

Specialty	Allowed Charges (mil)	New CL Pricing Change
Radiation Oncology and Radiation Therapy Centers	$1,809	-4%
Interventional Radiology	$499	-5%
Diagnostic Testing Facility	$748	-6%

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The potential effects of the clinical labor pricing update on specialty payment impacts were largely driven by the share that labor costs represent of the direct PE inputs for each specialty. Specialties with a substantially lower or higher than average share of direct costs attributable to labor would experience significant declines or increases, respectively, if this proposal is finalized. For example, the Family Practice specialty had a higher share of direct costs associated with clinical labor, and payments to services comprising the specialty would be expected to increase as a result of this clinical labor pricing update. In contrast, Diagnostic Testing Facilities had a lower share of direct costs that are associated with clinical labor, and payments to services comprising the specialty would be expected to decrease. Other specialty-level payment impacts for the proposed clinical labor pricing changes were driven by changes in wage rates for a clinical labor category that affects a given specialty more than average. One such example would be the proposed increase of 11 percent for Oncology nurses as opposed to the average increase for nurses of 63 percent. We emphasized that these are not the projected impacts by specialty of all the policies we proposed in the proposed rule for CY 2022, only the anticipated effect of the isolated clinical labor pricing update, should this clinical labor pricing update be finalized as proposed.

When updates to our payment methodology based on new data produce significant shifts in payment, we often consider whether it would be appropriate to implement the updates through a phased transition across several calendar years. For example, we utilized a 4-year transition for the market-based supply and equipment pricing update concluding in CY 2022. We are considering the use of a similar 4-year transition to implement the clinical labor pricing update. A multi-year transition could smooth out the increases and decreases in payment caused by the pricing update for affected stakeholders, promoting payment stability. However, a phased transition would delay the full implementation of updated pricing and continue to rely in part on outdated data for clinical labor pricing. We discuss a potential 4-year transition for the clinical labor pricing update as an alternative considered in the Regulatory Impact Analysis (section VI.I of this final rule).

We received public comments on our proposal to update the clinical labor pricing. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to update the clinical labor pricing. Commenters overwhelmingly agreed that the BLS was the most accurate source of wage data and the best source to use for updating the clinical labor pricing. Commenters stated that CMS needs recurring and accurate sources of data to keep PE RVUs up to date and that such data sources should capture the prices of equipment and supplies, wage rates for clinical staff, the types and quantities of direct PE inputs, and specialties' practice costs. Commenters stated that inaccurate prices for PE inputs could lead to distortions in the PE RVUs; for example, updating prices for equipment and supplies but not clinical labor could lead to undervaluing of services that use a high share of clinical labor. Several commenters stated that, after almost 20 years, an update to clinical labor pricing was long overdue. Several commenters urged CMS to update the prices for clinical labor immediately because inaccurate payment rates distort the market for clinician services and further prolonging the necessary improvement in CMS' PE RVU methodology will result in additional, unnecessary delays for an already overdue pricing update. These commenters recognized that this update may negatively impact certain specialties and procedures, but stated that the lack of pricing updates has likely disadvantaged services that rely heavily on clinical labor, such as family medicine, for several years.

Response: We appreciate the support for our proposed policies from the commenters.

Comment: Many commenters supported the proposal to update the clinical labor pricing, but stated that the update should be phased in using a 4-year transition. Commenters stated that the use of a 4-year transition would be consistent with previous PE updates such as the market-based supply and equipment pricing update and the implementation of the bottom-up PE methodology. Commenters stated that the phased in approach would help minimize the reimbursement reductions to specific services which rely heavily on supply and equipment costs that otherwise could prove detrimental to Medicare beneficiary access to services. Commenters stated that these PE decreases coupled with the 3.75 percent reduction in the conversion factor resulting from the expiration of the temporary increase provided under the CY 2021 Consolidated Appropriations Act are difficult for practices to absorb as the country struggles to contain the COVID–19 pandemic, and that mitigating the effects of the clinical labor pricing update through the use of a 4-year transition would help maintain payment stability.

Response: We appreciate the support for the proposed clinical labor update from the commenters, with the additional request that we implement it using a 4-year transition. After consideration of the comments, we agree that the use of a multi-year transition will help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected stakeholders, and promoting payment stability from year-to-year. We believe it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognize that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agree with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. We believe that the use of a 4-year transition in implementing the clinical labor pricing update will help to maintain payment stability, particularly given the ongoing public health emergency (PHE) for COVID–19.

We are finalizing the implementation of the clinical labor pricing update over 4 years to transition from current prices

to the final updated prices in CY 2025. We considered, as an alternative to our proposal, implementing this pricing transition over 4 years, such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. An example of the transition from the current to the fully-implemented new pricing that we are finalizing is provided in Table 10.

TABLE 10: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

Comment: A few commenters requested the use of a 2-year transition as a timetable that they stated would be more equitable to all impacted providers. These commenters stated that if a 2-year timetable was not feasible, they would support a 4-year transition over a 1-year transition.

Response: While we appreciate the support from the commenters for the proposed clinical labor pricing update and the suggestion from some that we use a 2-year transition, we believe that a 4-year transition, which is consistent with the way we have implemented prior significant updates to resource input pricing and the PE methodology, would meet the need to update clinical labor pricing while providing the health care provider community time to adjust to the resulting shifts in payments, especially during the ongoing PHE.

Comment: Many commenters disagreed with the proposal to update clinical labor pricing and urged that the policy should not be finalized, with or without a 4-year transition. These commenters objected to proposed reductions in payment for many types of services, such as but not limited to services in the fields of radiation oncology, peripheral arterial disease, PT/INR home monitoring, flow cytometry, cardiovascular disease, and many others. Commenters stated that the clinical labor pricing update will limit access to care for Medicare patients and will force many Medicare beneficiaries into the facility-based system at a significantly higher cost to the Medicare program and its patients. Commenters stated that this shift in care to the facility-based hospital settings will cause great burdens on an already overwhelmed hospital system, exacerbate market consolidation, and will adversely affect physicians' ability to provide the right care to the right patient at the right time. Commenters stated that patients may have to travel farther and wait longer for care, as well as pay more out-of-pocket since every single case shifted to the facility setting means higher cost-sharing for the affected beneficiary. Commenters emphasized the benefits of office-based care for a variety of services and argued that clinical labor pricing should not be updated as we proposed to help maintain access to office-based care. Several commenters stated that the proposed decrease in payment for certain services will disproportionately affect women's health and racial minorities, with a negative impact on some of the most vulnerable of Medicare's beneficiaries.

Response: We share the concerns expressed by the commenters about the need to ensure continued access to quality and affordable care for all beneficiaries, in both the office and hospital settings. Under section 1848 of the Act, we are required to base payment for services under the PFS on relative resource costs. To accomplish that, it is necessary periodically to update the information on which we base relative values. We believe, and commenters overwhelmingly agreed, that the BLS wage data is the best source to use for clinical labor pricing, and commenters did not identify alternative sources of data that could be used to update pricing. Although we recognize that payment for some services will be reduced as a result of the pricing update due to the BN requirements of the PFS, we do not believe that this is a reason to refrain from updating clinical labor pricing to reflect changes in resource costs over time as suggested by some commenters. There are also other services, such as those primarily furnished by family practice and internal medicine specialties, that will be positively affected by the pricing update, which we anticipate will increase access to care for disadvantaged groups such as women and racial minorities. We also note that for many services that involve proportionally more clinical labor, payment rates were reduced as a result of the prior market-based supply and equipment pricing update, and payment rates will increase with the clinical labor pricing update, due to the same PFS BN requirements. We believe that the ongoing trend of market consolidation and site of service differentials highlight the need to update the overall PE data comprehensively, including a full accounting of indirect/overhead costs, to account for current trends in the delivery of health care, especially with regard to independent versus facility-based practices. We believe that CMS efforts to improve pricing accuracy would improve the sustainability of the Medicare PFS and the broader health system, improve access to care, and reduce inequitable disparities. We believe that the use of a 4-year transition in implementing the clinical labor pricing update will help to maintain payment stability and mitigate potential negative effects on healthcare providers by gradually phasing in the changes over a period of time. We believe that this transition period is also important given that the PHE for COVID–19 is ongoing and industry recovery is likely to take time.

Comment: Many commenters discussed the direct scaling factor used in the calculation of PE RVUs. Commenters stated that updating the clinical labor rates is estimated to increase direct PE costs by 30 percent which would equate to approximately $3.5 billion in total additional direct costs. Commenters noted that the direct scaling factor was proposed to decrease by 24 percent as a result, from 0.5916 in 2021 to 0.4468 in 2022, with the net

effect that Medicare will now reimburse 44 cents on the dollar instead of 59 cents on the dollar for direct costs. Commenters stated that many services require the use of expensive supplies with considerable capital costs that need to be stocked and readily available. Commenters stated that they did not believe the cost of this labor rate update should be borne disproportionately by equipment and supply-heavy services, which are the services least able to accommodate sharp and sudden payment reductions since equipment costs are fixed. Many commenters stated that the proposed policy would place a huge and unfair burden on specialties that require expensive supplies and equipment; commenters stated that the high costs of maintaining this equipment remain the same whether or not the equipment is used. Commenters stated that the proposed policy would result in wildly fluctuating shifts in reimbursement, violating a core principle of the resource-based relative value system which is to stabilize RVUs and reduce fluctuations in year-to-year payments. Commenters stated that if payments change drastically, there is no way to accommodate those shifts through operating expenses without cuts elsewhere, including to staff and services offered. Commenters stated that CMS should explore options to adjust the scaling factor(s) in order to more appropriately reimburse for expenses incurred to treat their beneficiaries.

Response: We appreciate the estimate provided by commenters of the additional spending on direct costs as a result of the proposed clinical labor pricing update. However, we disagree with the commenters that updating the clinical labor pricing to make use of current wage data constitutes an unfair burden or has an inappropriate disproportionate impact on certain services. The PFS is a resource-based relative value payment system that necessarily relies on accuracy in the pricing of resource inputs. Continuing to use clinical labor cost data that are nearly 2 decades old would create distortions in relativity that undervalue many services which involve a higher proportion of clinical labor. As noted previously, payment for services that involve a higher proportion of clinical labor resources was negatively affected by the prior market-based supply and equipment pricing update as a result of the same BN requirements and will now be positively affected by the clinical labor pricing update. We do not agree that updates to pricing for the three categories of direct PE (clinical labor, supplies and equipment), create an unfair burden for individual services. We do agree with commenters that the impact of the proposed clinical labor pricing update is substantial, which is why we believe it is appropriate to use a 4-year transition to implement the pricing update. We believe the use of this transition will help address the concerns of the commenters about stabilizing RVUs and reducing large fluctuations in year-to-year payments.

Comment: Several commenters requested that CMS maintain the CY 2021 direct scaling factor of 0.5916 if the agency chooses to finalize the clinical labor pricing update.

Response: Under our current PE methodology, we calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs does not vary from the aggregate pool of direct PE costs for the current year. (This calculation is described in more detail in the ''PE RVU Methodology'' section earlier in this rule.) In other words, the direct scaling adjustment ensures that the share of direct PE remains constant from year to year. If we continued to maintain the direct scaling factor from a previous calendar year, without making any adjustment to account for the total direct costs increasing as a result of the clinical labor pricing update, the amount of PFS spending allocated to direct PE would increase at the expense of all other spending. This would negatively affect the valuation of many services that have few or no direct PE inputs. It would also result in a substantial negative adjustment to the conversion factor under the statute's BN requirements as the total number of PE RVUs would increase and would need to be offset through the conversion factor. We do not agree that it would be appropriate to maintain the direct scaling factor from a previous calendar year; we did not propose to update our PE methodology and we are not finalizing any changes in the methodology.

Comment: Several commenters suggested that CMS spread the cost of the clinical labor update across both the direct and indirect PE pools. Commenters stated that this suggestion would allocate approximately 27 percent of the additional costs to the direct cost pool and 73 percent to the indirect cost pool. Commenters stated that this change would result in minimal changes in allowed charges for specialties such as general practice and family medicine, as compared with the changes that would result from the proposed approach.

Response: We disagree with the commenters that it would be appropriate to spread the increased spending from the clinical labor pricing update across both the direct and indirect PE pools, as opposed to solely the direct pool as proposed. This suggested change to the PE methodology would have an effect similar to continuing to maintain the direct scaling factor from previous calendar years, that is, the amount of PFS spending allocated to direct PE would increase at the expense of all other spending. In particular, services that have a higher proportion of indirect PE would be negatively affected as increases in the direct PE pool would be subsidized by the indirect PE pool. We do not believe that this would appropriately carry out the statute's directive to value services based on relative resource costs. We did not propose to update our PE methodology and we are not finalizing any changes in the methodology.

Comment: Several commenters suggested that CMS consider scaling the clinical labor and equipment/supply components of the direct PE pool separately. Commenters stated that based on the CY 2014 PFS final rule, it appeared that the clinical labor component of the pool should be weighted at 4.636 percent of PFS expenditures, and should not exceed about 66 percent of the direct cost pool.

Response: We disagree with the commenter that the three components of direct PE (clinical labor, supplies, and equipment) should be should be scaled separately instead of together. This would have the effect of freezing the portion of direct PE allocated to each of the three components; if we were to make this change to the PE methodology, updating the clinical labor pricing would not allocate any additional valuation to clinical labor at all. It would merely shift the relationship between the individual clinical labor types as they were re-priced. The clinical labor component of direct PE has not been updated since 2002, while supply and equipment pricing has been updated more recently. The commenters' suggested change to the PE methodology would lock in place the relativity between direct PE components at a particular time. We believe that this would be inconsistent with the statute's directive to value services based on relative resource costs. As noted above, we did not propose to modify our PE methodology, and we are not finalizing any changes in the methodology.

Comment: Several commenters stated that they had performed an analysis suggesting that the proportion of PFS expenditures allocated to direct PE may have shrunk from the proportion

adopted in 2014. Commenters requested that CMS examine whether, and to what extent, the total PE pool has been reduced over time, and, if so, requested that it be restored.

Response: As explained above, the direct scaling adjustment ensures that the share of direct PE (and therefore, also indirect PE) remains constant from year to year. We can confirm for the commenters that our application of BN adjustments, which is required by statute, has maintained the total PE pool over time.

Comment: Several commenters referred to the decrease in the direct scaling factor and stated that this would cause huge second order effects that are not being considered by CMS. Commenters stated that the result would be a PFS that is ever more out of touch with reality as conversion factors, direct adjustment factors, and other factors make the PFS less and less reflective of what it actually takes to provide services in the office.

Response: We disagree with the commenters that our proposed clinical labor update makes the PFS less reflective of the real-world cost of providing services. We believe that updating clinical labor rates to reflect current pricing has the opposite effect, appropriately improving recognition of current clinical labor costs in the PFS methodology.

Comment: Several commenters stated that the PPIS data which underlie the share of PE allocated to direct PE and indirect PE are outdated, and that it was unreasonable to cap updated direct costs based on direct/indirect cost splits from 2006. Commenters stated that if the updated clinical labor pricing had been in effect in 2006, then direct costs undoubtedly would have constituted a larger proportion of the overall PE pool.

Response: We have no doubt that if the clinical labor pricing in 2006 had been based on BLS wage data from 2019, direct costs would have constituted a larger proportion of the overall PE pool. However, it is inappropriate to make use of wage data from 2019 and compare it to the direct/indirect cost splits from 2006 without also acknowledging that indirect costs such as administrative expenses and office rent have also greatly increased over the intervening span of time. While we share the concerns of the commenters that the PPIS data used in the PE methodology date back more than a decade, we have no evidence at present to indicate that direct costs have increased faster than indirect costs since 2006, or vice versa. As we noted in the CY 2021 PFS final rule (85 FR 84498 through 84499) and again in this rule, the RAND corporation is currently studying potential improvements to our PE allocation methodology and the data that underlie it. We are interested in exploring ways that the PPIS data can be updated; however, we do not believe that this constitutes a reason to refrain from updating the clinical labor pricing.

Comment: Several commenters referenced the BN requirements for the PFS that are included in the statute. Commenters stated that no adjustments to the $20 million threshold for BN have been made to account for new technology in over 30 years. Commenters stated that CMS should publish how the annual $20 million restriction on changes to expenditures could have played a role in the clinical labor updates.

Response: Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve BN. As this is a statutory requirement of the PFS, we are required by law to apply BN adjustments to offset the spending impact of any changes exceeding $20 million; given the roughly $100 billion in spending associated with the PFS, this threshold is exceeded each calendar year by a wide margin. A BN adjustment would be avoided only if updating the clinical labor pricing failed to reach this $20 million threshold. We found that the estimated effect of the proposed clinical labor pricing update was approximately $3.5 billion, with our analysis matching the figure supplied by commenters, which far exceeds the $20 million threshold. Therefore, we were required by statute to make BN adjustments to reflect the expected effects of the clinical labor pricing update. We also note that as the BN requirement is statutory in nature, we do not have discretion to adjust it for new technology or other changes that may have taken place.

Comment: Several commenters urged CMS to use its discretion to waive BN in implementing the proposed update to clinical labor pricing. Other commenters urged CMS to hold harmless the specialties that are bearing the brunt of this proposal and consider alternative ways to update clinical labor pricing. Several commenters stated that updated clinical labor pricing should not be done within the confines of a budget neutral system, unless there were concomitant inflationary updates to the entire fee schedule.

Response: As mentioned above, BN adjustments are a statutory requirement of the PFS. We do not have discretion within the terms of the statute to waive BN or hold individual specialties harmless in implementing the clinical labor pricing update.

Comment: One commenter stated that while CMS has broad discretion to determine and adjust RVUs for physician services, CMS cannot make arbitrary changes to RVUs. The commenter stated that CMS must give a reasoned explanation for adjustments it makes for certain codes, and those explanations must relate to the relative resource use for a particular service. The commenter stated that the requirement to maintain BN does not authorize the agency to ignore the general rule that RVUs, and their individual components, must be based on relative resource use. The commenter stated that unless CMS can articulate how the relative cost of the other PE inputs—like supplies and medical equipment—has gone down, the agency is not authorized to decrease the value of those inputs. The commenter stated that CMS is only authorized to apply a BN adjustment across all RVUs and the BN provisions do not authorize CMS to manipulate the inputs to the two RVU components.

Response: We disagree with the commenter that we have proposed arbitrary changes to the valuation of individual services; we detailed the methodology behind our proposed clinical labor pricing update and provided an opportunity for commenters to submit feedback through notice and comment rulemaking. We believe that updating the clinical labor pricing makes the relative resource use basis dictated by the statute more accurate, not less accurate, for the valuation of services. While the relative resource cost of the other non-clinical labor direct PE inputs, such as supplies and equipment, would in fact decrease for CY 2022 based on our proposed update to clinical labor pricing, they have only decreased in relative terms because the PFS is based on the use of RVUs as part of a budget neutral methodology. We note again that the use of a 4-year transition in implementing the clinical labor pricing update should help to mitigate potential negative effects of these shifts in relative resource costs by spreading them out over a longer period of time.

Comment: Several commenters stated that the specialty impacts tables isolating the effects of the clinical labor pricing update in the CY 2022 PFS proposed rule were misleading. Commenters stated that in reality the negative impact for many services was

much greater than displayed on these tables. Commenters stated that it would be more transparent to share impacts for individual services when they had a potentially large negative effect on providers of office-based procedures with high supply and equipment costs.

Response: Although we share the concerns of commenters regarding the importance of providing transparency in the published data, we disagree that the specialty impacts tables included in the CY 2022 PFS proposed rule were misleading, or that commenters lacked sufficient information about the pricing of individual services. We noted in the CY 2022 PFS proposed rule (86 FR 39532) that the impact tables are for illustrative purposes for aggregate impacts on specialties, and are not meant to be code specific; therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty. This has been a feature of the specialty impact tables published in the PFS for many years, and we believe it is generally well understood by stakeholders. We also note that the proposed RVUs for every HCPCS code were published in Addendum B as part of the CY 2022 PFS proposed rule to allow stakeholders the opportunity to provide comment on the proposed valuations for each code. Due to the thousands of HCPCS codes affected by the clinical labor pricing update, we did not publish a service-level analysis of the pricing update in the preamble, but did include this information in Addendum B for consideration by stakeholders. We will consider suggestions to improve the information available to stakeholders for future rulemaking.

Comment: Many commenters noted that 14 of the 32 clinical labor staff types had proposed valuations using a BLS crosswalk because an exact match was not available. Commenters stated that to maintain transparency CMS should publish the ''other sources'' wage data details for these clinical labor types. Commenters stated that CMS should update specific clinical labor wage rates based on stakeholder comments and data.

Response: We agree with the commenters that stakeholder comments and data will be valuable in updating the clinical labor pricing, and we share the concerns of the commenters regarding transparency in the data used for pricing. As we stated in the proposed rule, we used the national salary data from the Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert for Mammography Technologists as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. In the interest of transparency, Table 11 lists the Salary Expert wage data used for the clinical labor types which did not have direct BLS matches.

TABLE 11: Clinical Labor Types with Other Sources Wage Data

Labor Code	Description	Salary Expert Per-Hour Wage Data
L037B	Histotechnologist	28.06
L037C	Orthoptist	37.41
L037E	Child Life Specialist	25.10
L038B	Cardiovascular Technician	29.69
L038C	Medical Photographer	18.45
L039A	Certified Retinal Angiographer	26.28
L039C	Psychometrist	29.29
L041A	Angio Technician	26.81
L043A	Mammography Technologist	31.07
L045A	Cytotechnologist	36.19
L045B	Electron Microscopy Technologist	44.90
L046A	CT Technologist	33.09
L047B	REEGT (Electroencephalographic Tech)	30.82
L054A	Vascular Technologist	46.36
L056A	RN/OCN	38.81
L063A	Medical Dosimetrist	48.31

Comment: Many commenters stated that CMS proposed to utilize the mean wage data to establish updated clinical labor rates, while the majority of the data inputs for the PFS are based on the median value. Commenters used as an example how RUC recommendations for work RVUs, work times, and direct PE inputs were based on the median or typical case. Commenters requested that CMS use the median wage data, instead of mean wage data, to more accurately capture typical wage rates and to be consistent with the median statistic used for clinical staff time.

Response: We appreciate the feedback from the commenters regarding the use of mean versus median wage data in updating the clinical labor pricing. Based on the feedback from the commenters, we agree that the use of median BLS wage data would be more appropriate than average or mean wage data. We agree that the median value is less susceptible to outlier values, and therefore, better captures the ''typical'' case. We will use the median wage data when finalizing the pricing for the clinical labor update.

Comment: Many commenters disagreed with the proposal to use the same fringe benefits multiplier of 1.366 that was utilized during the previous clinical labor pricing in CY 2002. Commenters stated that using the fringe benefits multiplier rate from 20 years ago was not consistent with CMS' premise for updating the clinical labor pricing which was to maintain relativity

with the recent supply and equipment pricing updates. Commenters stated that the BLS publishes benefits data routinely and that CMS should use a current fringe benefits multiplier; many commenters suggested using a multiplier of 1.296 from the most recent available BLS data.

Response: We agree with the commenters that it would be appropriate to use a more current fringe benefits multiplier as opposed to our proposal to use the same multiplier from 2002. According to a BLS release from June 17, 2021 (USDL–21–1094), the current fringe benefits multiplier for employees in private industry is 1.296, as noted and requested by the commenters. We believe that this will be more appropriate than the proposed fringe benefits multiplier of 1.366 from 2002.

Comment: Many commenters requested that CMS should delay the implementation of the clinical labor pricing update for one year, or finalize a 5-year transition with no update in the first year which was functionally the same request. Commenters stated that the current clinical labor proposal requires additional analysis and modifications prior to implementation and there was further work to be done by both CMS and stakeholders to ensure accurate data are used and appropriate methodological steps are taken for implementation. Some commenters stated that CMS should wait until after the market-based supply and equipment pricing update was concluded before beginning the process of updating clinical labor pricing. Many commenters mentioned the negative impacts of the ongoing COVID–19 PHE and the finalization of updated values for E/M visits in last year's CY 2021 PFS final rule as reasons to delay the clinical labor pricing update for a year.

Response: We disagree that the clinical labor pricing update should be delayed for another year before beginning the 4-year implementation timeline. We do not agree that delaying the pricing update will provide meaningful improvements in our data; commenters overwhelmingly agreed that BLS data was the best choice and did not suggest alternative sources of wage data which would have required additional research. In places where we made use of crosswalks to value individual clinical labor types, commenters provided helpful feedback (see discussion below) and will continue to have the opportunity to provide further engagement over the course of the 4-year implementation timeline. It is not clear to us what further work the commenters believe must be done to ensure appropriate clinical labor pricing given the near-universal support for the use of BLS wage data for the update. While we share the concerns of commenters regarding the effects of the ongoing COVID–19 pandemic, we believe that the use of a 4-year transition in implementing the clinical labor pricing update will help to maintain payment stability and mitigate potential negative effects on healthcare providers. Given that the statute requires PFS payment to be based on relative resource costs, and that the proposed update to clinical labor wages using the latest available BLS data was overwhelmingly supported by commenters, we do not believe that we should delay the transition from outdated pricing from 2002. All of the same issues concerning redistribution of payments through BN will still remain in place whether the clinical labor pricing update begins in CY 2022 or CY 2023.

Comment: One commenter stated that CMS should delay any repricing of clinical labor until it can also collect the latest prices paid for medical equipment and supplies. The commenter stated that this would ensure all updated prices for direct cost inputs used in setting PE payment are factored into Medicare physician rates concurrently.

Response: CY 2022 is the final year of the market-based supply and equipment pricing transition; we proposed to begin implementing the update to clinical labor pricing in this calendar year so that it could take place in conjunction with a portion of the supply and equipment pricing update. We agree with the commenter that it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates.

Comment: Several commenters stated that CMS is currently considering more significant future changes to the PE methodology as explained at a June 16, 2021 Town Hall meeting (further details available on the CMS website at *https://www.cms.gov/medicare/physician-fee-schedule/practice-expense-data-methods*). Commenters stated that given the potential for significant future updates to the data or PE methodology that could also have major impacts, CMS should postpone the update to clinical labor pricing until those changes can be analyzed in combination with other major changes to the PE methodology.

Response: As we noted in the CY 2021 PFS final rule (85 FR 84498 through 84499) and again in this rule, the RAND corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it. We are interested in exploring ways that the PE methodology can be updated; however, we do not believe that this constitutes a reason to refrain from updating the clinical labor pricing or delay the implementation of the pricing update. We will employ a 4-year transition period for the clinical labor pricing update in order to provide payment stability and soften the effects of the pricing update in each calendar year.

Comment: Several commenters stated that the BLS is planning an update to the estimation methodology for the Occupational Employment and Wage Statistics (OEWS) survey next year that may impact their wage data. Commenters stated that although they could not predict the impact of these modifications, it is possible the revised BLS methodology will result in important changes to the hourly wage estimates that CMS proposed to use to update clinical labor pricing. Several commenters requested delaying the implementation of the clinical labor pricing update for one year to make use of updated BLS wage data.

Response: We appreciate the feedback from the commenters regarding ongoing improvements to the BLS methodology for the OEWS. However, we do not agree that this is a sufficient justification for continuing to maintain current clinical labor prices for another year. The BLS routinely updates its wage data and searches for ways to improve the survey methodology. We also note that the commenters who brought this issue to our attention stated that they could not predict the impact of these BLS methodological changes which we believe argues against delaying the pricing update for another year. We believe that the 2019 wage data from the BLS will certainly be an improvement over the current 2002 data, and we will continue to review and evaluate future BLS wage data to consider whether it would be appropriate to propose to incorporate them into the clinical labor pricing update during the course of the 4-year transition period or otherwise through future rulemaking.

Comment: One commenter stated that CMS appeared to have used only the BLS OEWS survey; however, when CMS last updated these data in 2002, CMS also leveraged the BLS National Compensation Survey (NCS). The commenter stated that while the OEWS survey can produce estimates at metropolitan statistical areas (MSAs), the NCS can produce estimates at the national and census region level. The commenter stated that OEWS wage estimates represent only wages and salaries and do not include nonwage

benefits, such as health insurance, retirement contributions, and bonuses; whereas NCS data also includes nonwage benefits. The commenter stated that CMS used the national median wage across all employer types rather than the wage for physician office employers, and the commenter believed that CMS should use the physician office setting of care where possible rather than a median (or average) across all employer types.

Response: We appreciate the feedback from the commenters regarding additional aspects of the wage data provided by the BLS. We are aware that OEWS wage estimates represent only wages and salaries and do not include nonwage benefits, which is why we included a fringe benefits multiplier in our clinical labor pricing update as discussed above. We disagree with the commenter that using the physician office setting of care rather than a median across all employer types would be more accurate for clinical labor pricing; clinical labor is employed in many different sites of service, not solely in the physician office setting. We encourage commenters to submit additional information regarding clinical labor pricing, especially wage data for individual clinical labor types, during future rulemaking, especially over the course of the 4-year transition period for the update to clinical labor pricing.

Comment: Many commenters requested that CMS update pricing data on a more frequent basis for all inputs so that adjustments will not be as dramatic. Commenters stated that more frequent updates would prevent significant redistributive effects to specialties in the future and help ensure stability in payments. Commenters stated that CMS should make year-to-year payment stability a goal of the PFS, and large redistributive impacts on payment should occur infrequently.

Response: We agree with the commenters that the pricing data that underlie the PE methodology should be updated frequently to ensure its accuracy. For this reason, we believe that it is important to begin the transition process of updating the clinical labor pricing for CY 2022. We agree that more frequent updates to all direct PE inputs, clinical labor and supplies and equipment, would help to maintain payment stability across the PFS.

Comment: Several commenters recommended that CMS address the problems related to high-cost supplies by establishing Healthcare Common Procedure Coding System (HCPCS) Level II codes for supplies that exceed $500. Commenters stated that the establishment of individual coding for high cost supplies would help maintain patient access to care in the office setting by offsetting the projected decreases in payment from the clinical labor pricing update.

Response: We did not make any proposals to establish HCPCS Level II codes for high cost supplies. We have received in previous rulemaking cycles a number of prior requests from stakeholders, including the RUC, to implement separately billable alpha-numeric Level II HCPCS codes to allow practitioners to be paid for high cost disposable supplies per patient encounter instead of in connection with payment for the CPT code with which the supplies are furnished. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. (For a discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251)).

Comment: One commenter stated that, as participating practitioners in the Medicare program, audiologists should not be included in the proposed clinical labor pricing update. The commenter stated that they are performing professional services for which they are billing Medicare independently, and should not be assigned any additional clinical labor time for their efforts. The commenter stated that this oversight has created significant rank order anomalies within the audiology code family as included in the proposed rule. The commenter identified several CPT codes which they stated contained significant rank order anomalies and requested again that audiologists be removed from the labor update pool.

Response: We would like to clarify for the commenter that we are proposing to update the rates for individual clinical labor types, not updating the pricing for individual specialties. The statute requires that valuation under the PFS is to be based on relative resource costs; as such, we do not believe that an individual clinical labor type could be priced at one rate when billed by some specialties and at a different rate when billed by other specialties. If the commenter believes that certain CPT codes have rank order anomalies in their valuation, we encourage them to nominate those codes as potentially misvalued for our additional review; see section II.C of this final rule (Potentially Misvalued Services under the PFS) for additional information.

After consideration of the comments detailed above, we are finalizing our proposal to implement the clinical labor pricing update through the use of a 4-year transition, with modifications. Rather than using the proposed BLS fringe benefits multiplier and the BLS mean wage data, in response to public comments, we will apply the BLS private industry fringe benefits multiplier for 2019 and use the BLS median wage data.

We also received a number of comments regarding the pricing of individual clinical labor types which are summarized along with our responses below. We note that, given our final policy to use the BLS median wage data instead of mean as we had proposed, we refer in our responses below to the median wage data.

Comment: Several commenters stated that they supported the proposal to use BLS category 19–1040 (Medical Scientist) for the Vascular Technologist (L054A) clinical labor type. Commenters stated that both vascular technologists and medical dosimetrists play critical roles in independently providing clinically accurate, reproducible and high-quality data for physician decision making. Commenters stated that although they did not have additional wage data to offer, they believed that the proposed crosswalk for the L054A clinical labor type is appropriate in terms of the resulting hourly wage rate and level of technical skill, physical and mental effort, judgment and stress relative to other professions utilizing ultrasound.

Response: We appreciate the support from the commenters for our proposed pricing of the Vascular Technologist (L054A) clinical labor type.

Comment: One commenter stated that they supported the proposed pricing of the Mammography Technologist (L043A), CT Technologist (L046A), and Vascular Technologist (L054A) clinical labor types based on their individual BLS categories.

Response: We appreciate the support from the commenter for our proposed clinical labor pricing.

Comment: Several commenters noted that the Angio Technician (L035A) clinical labor type does not have a direct BLS labor category and CMS proposed using BLS category 29–9000 (Other Healthcare Practitioners and Technical Occupations) at $27.20 as the proxy BLS wage rate. Commenters stated that they believed the Angio Technician was best represented by an advanced level VI certified Radiologic Technologist or an MR technologist. Commenters stated that according to the BLS, the median annual wage for magnetic resonance

imaging technologists was $74,690 in May 2020, and the median annual wage for radiologic technologists and technicians was $61,900 in May 2020. Commenters recommended using BLS category 29–2035 Magnetic Resonance Imaging (MRI) Technologist as the proxy BLS wage rate for the Angio Technician clinical labor type.

Response: We appreciate the additional information provided by the commenters concerning the pricing of the Angio Technician (L035A) clinical labor type. However, we disagree that a Magnetic Resonance Imaging (MRI) Technologist described under BLS category 29–2035 would be the most appropriate choice to use in pricing the L035A clinical labor type. The median hourly wage for a Magnetic Resonance Imaging (MRI) Technologist under this BLS category is $35.30 while the hourly wage data for an Angio Technician that we have from Salary Expert is only $26.81. As such, we disagree that MRI Technologist would be an appropriate crosswalk for valuation. However, in response to the additional certification information provided by the commenters for this occupation, we are modifying our proposed crosswalk. We will instead crosswalk the Angio Technician to the Lab Tech/Histotechnologist (L035A) clinical labor type with a median hourly rate of $26.63 (or an annual rate of $55,390). We believe that this crosswalk better matches the wage data that we have available from Salary Expert for Angio Technicians.

Comment: Several commenters stated that CMS updated the RN/OCN (L056A) clinical labor type in CY 2004, which had been previously updated in 2002, with survey data provided by the American Society of Clinical Oncology (ASCO). Commenters noted that the proposed pricing for the L056A clinical labor type increased by only 11 percent, the third lowest increase among the 50 clinical labor types proposed in the update; and the commenters were concerned that the ASCO wage data were not appropriately captured in the proposed update. Commenters stated that the RN/OCN clinical labor type, which was proposed at a rate only 3.5 percent higher than the regular RN (L051A) clinical labor type, is clearly undervalued and should receive an upward adjustment prior to finalizing the clinical labor pricing update. Commenters urged CMS to delay implementation of the labor price update until they could work with the agency to establish an accurate methodology and labor price inputs for current RN/OCN labor.

Response: We appreciate the additional information provided by the commenter regarding the historical pricing of the RN/OCN (L056A) clinical labor type, and we will be happy to consider any wage data that they can provide. However, we did not receive any additional data from the commenter to be used in pricing the L056A clinical labor type, and in the absence of other information on current wage rates, we believe that our proposed use of BLS category 29–2033 (Nuclear Medicine Technologists) at $37.48 remains the most appropriate accurate pricing for L056A. We welcome the submission of additional pricing data for the RN/OCN clinical labor type in future rulemaking cycles, particularly over the course of the 4-year transition period.

Comment: One commenter provided recommendations on the pricing of several clinical labor types, as indicated in the next 13 comment summaries and responses. The commenter disagreed that BLS category 29–9098 (Health Information Technologists, Medical Registrars, Surgical Assistants, and Healthcare Practitioners and Technical Workers, All Other) at an hourly rate of $28.17 was the correct crosswalk for the Histotechnologist (L037B) clinical labor type. The commenter stated that BLS category 29–2010 (Clinical Laboratory Technologists and Technicians) more accurately describes the clinical staff type associated with Histotechnologists.

Response: We appreciate the additional information provided by this commenter concerning the pricing of the Histotechnologist (L037B) clinical labor type and the others that follow. We reviewed the request from the commenter and we agree that BLS category 29–2010 is a more appropriate crosswalk for the L037B clinical labor type, which has an updated median hourly wage of $25.54. This BLS category is a close match for the wage data that we have from the Salary Expert reference information that we discussed above.

Comment: The same commenter disagreed that BLS category 21–1023 (Mental Health and Substance Abuse Social Workers) at an hourly rate of $24.84 was the correct crosswalk for the Child Life Specialist (L037E) clinical labor type. The commenter stated that a child life specialist was described as a professional armed with a strong background in child development and family systems who promotes effective coping through play, preparation, education, and self-expression activities—not child mental health or substance abuse treatment. The commenter stated that that BLS category 21–1021 (Child, Family, and School Social Workers) more accurately describes the clinical staff type associated with Orthoptists.

Response: We reviewed the request from the commenter and we agree that BLS category 21–1021 is a more appropriate crosswalk for the L037E clinical labor type, which has an updated median hourly wage of $22.78. This BLS category is a close match for the wage data that we have from the Salary Expert reference information that we discussed above.

Comment: The commenter disagreed that BLS category 31–2011 (Occupational Therapy Assistants) at an hourly rate of $29.75 was the correct crosswalk for the Cardiovascular Technician (L038B) clinical labor type. The commenter stated that BLS category 29–2031 (Cardiovascular Technologists and Technicians) was a direct crosswalk for the L038B clinical labor type.

Response: We reviewed the request from the commenter and we agree that BLS category 29–2031 is a more appropriate crosswalk for the L038B clinical labor type, which has an updated median hourly wage of $27.75. This BLS category is a close match for the wage data that we have from the Salary Expert reference information that we discussed above.

Comment: The commenter disagreed that BLS category 29–1126 (Respiratory Therapists) at an hourly rate of $30.75 was the correct crosswalk for the Mammography Technologist (L043A) clinical labor type. The commenter stated that BLS category 29–2034 (Radiologic Technologists and Technicians) more accurately describes the clinical staff type associated with Mammography Technologists.

Response: We reviewed the request from the commenter and we agree that BLS category 29–2034 is a more appropriate crosswalk for the L043A clinical labor type, which has an updated median hourly wage of $29.09. This BLS category is a close match for the wage data that we have from the Salary Expert reference information that we discussed above.

Comment: The commenter disagreed with crosswalking the Certified Surgical Technician (CST) to BLS category 19–4010 (Agricultural and Food Science Technicians) at an hourly rate of $21.37 as part of the blended COMT/COT/RN/CST (L038A) clinical labor type. The commenter stated that BLS category 29–2055 (Surgical Technologist) was a direct crosswalk for the L038A clinical labor type.

Response: We believe that there may have been a misunderstanding on the part of the commenter; we proposed to crosswalk Certified Surgical

Technicians to BLS category 29–2061, not BLS category 19–4010, at a median hourly rate of $22.83. There may have been some confusion regarding the COT and CST clinical labor types in this blend. Nevertheless, we reviewed the request from the commenter and we agree that BLS category 29–2055 is a more appropriate crosswalk for the CST portion of the L038A clinical labor type. This BLS category has a median hourly rate of $23.22 which was very similar to our previous pricing of $22.83. After we ran this updated rate for the CST through the blended methodology for the L038A clinical labor type, the per-minute pricing (including the fringe benefits multiplier) remained unchanged at $0.52.

Comment: The commenter disagreed that BLS category 29–2010 (Clinical Laboratory Technologists and Technicians) at an hourly rate of $26.34 was the correct crosswalk for the Certified Retinal Angiographer (L039A) clinical labor type. The commenter stated that BLS category 29–9000 (Other Healthcare Practitioners and Technical Occupations) or BLS category 29–2057 (Ophthalmic Medical Technician) more accurately described the clinical staff type associated with Certified Retinal Angiographers.

Response: We reviewed the request from the commenter and we agree that BLS category 29–9000 is a more appropriate crosswalk for the L039A clinical labor type, which has an updated median hourly wage of $23.93. The other suggested crosswalk to BLS category 29–2057 had a median hourly wage of $17.76, which did not fit with the data that we had from Salary Expert for Certified Retinal Angiographers; we believe the crosswalk to BLS category 29–9000 is a more appropriate choice.

Comment: The commenter disagreed that BLS category 29–1141 (Registered Nurses) at an hourly rate of $37.24 was the correct crosswalk for the Orthoptist (L037C) clinical labor type. The commenter stated that that BLS category 29–2057 (Ophthalmic Medical Technician) more accurately describes the clinical staff type associated with Orthoptists. The commenter also stated that the L037C clinical labor type is incorrectly assigned to the CPT code 62304. The commenter stated that the correct clinical labor type for CPT code 62304 should be L037D (RN/LPN/MTA), not L037C.

Response: We disagree with the commenter that an Ophthalmic Medical Technician described under BLS category 29–2057 would be the most appropriate choice to use in pricing the L037C clinical labor type. The median hourly wage for an Ophthalmic Medical Technician under this BLS category is $17.76 while the hourly wage data for an Orthoptist that we have from Salary Expert is substantially higher at $37.41. We continue to believe that our crosswalk to BLS category 29–1141 is a more appropriate choice for valuation. While we appreciate the feedback from the commenter, we reviewed CPT code 62304 and we did not find any errors in its clinical labor inputs. We did not propose to change the clinical labor type for CPT code 62304 and we are not finalizing any changes to the clinical labor types of this CPT code at this time.

Comment: The commenter disagreed that BLS category 21–1029 (Social Workers, All Other) at an hourly rate of $29.69 was the correct crosswalk for the Psychometrist (L039C) clinical labor type. The commenter stated that BLS category 31–1133 (Psychiatric Aide) more accurately describes the clinical staff type associated with Psychometrists.

Response: We disagree with the commenter that a Psychiatric Aide described under BLS category 31–1133 would be the most appropriate choice to use in pricing the L039C clinical labor type. The median hourly wage for a Psychiatric Aide under this BLS category is $14.96 while the hourly wage data for a Psychometrist that we have from Salary Expert is substantially higher at $29.29. We continue to believe that our crosswalk to BLS category 21–1029 is a more accurate choice for valuation.

Comment: The commenter disagreed that BLS category 29–9000 (Other Healthcare Practitioners and Technical Occupations) at an hourly rate of $27.22 was the correct crosswalk for the Angio Technician (L041A) clinical labor type. The commenter stated that BLS category 29–2034 (Radiologic Technologists and Technicians) was the previous BLS crosswalk used during the 2002 pricing of clinical labor and remains the correct crosswalk for an angiography technician.

Response: We disagree with the commenter that a Radiologic Technologist described under BLS category 29–2034 would be the most appropriate choice to use in pricing the L041A clinical labor type. The median hourly wage for a Radiologic Technologist under this BLS category is $29.09 and, as we discussed above, the hourly wage data for an Angio Technician that we have from Salary Expert is only $26.81. We are instead crosswalking the Angio Technician to the Lab Tech/Histotechnologist (L035A) clinical labor type with a median hourly rate of $26.63 as described above. We believe that this crosswalk better matches the wage data that we have available from Salary Expert for Angio Technicians. The previous BLS crosswalk may have been the most appropriate choice in 2002 but we have data from Salary Expert suggesting that it is no longer the best option.

Comment: The commenter disagreed that BLS category 29–2035 (Magnetic Resonance Imaging Technologists) at an hourly rate of $35.70 was the correct crosswalk for the Cytotechnologist (L045A) clinical labor type. The commenter stated that BLS category 29–2010 (Clinical Laboratory Technologists and Technicians) was the previous BLS crosswalk used during the 2002 pricing of clinical labor and remains the correct crosswalk for a cytotechnologist.

Response: We disagree with the commenter that the Clinical Laboratory Technologists described under BLS category 29–2010 would be the most accurate choice to use in pricing the L045A clinical labor type. The median hourly wage for a Clinical Laboratory Technologist under this BLS category is $25.54 while the hourly wage data for a Cytotechnologist that we have from Salary Expert is substantially higher at $36.19. We continue to believe that our proposed crosswalk to BLS category 29–2035 is a more appropriate choice for valuation. The previous BLS crosswalk we used in 2002 was based on available information at that time, but we have data suggesting that it is no longer the best option.

Comment: The commenter disagreed that BLS category 29–1124 (Radiation Therapists) at an hourly rate of $44.05 was the correct crosswalk for the Electron Microscopy Technologist (L045B) clinical labor type. The commenter stated that BLS category 29–2010 (Clinical Laboratory Technologists and Technicians) more accurately describes the clinical staff type associated with Electron Microscopy Technologists.

Response: We disagree with the commenter that the Clinical Laboratory Technologists described under BLS category 29–2010 would be the most appropriate choice to use in pricing the L045B clinical labor type. The median hourly wage for a Clinical Laboratory Technologist under this BLS category is $25.54 while the hourly wage data for an Electron Microscopy Technologist that we have from Salary Expert is substantially higher at $44.90. We continue to believe that our crosswalk to BLS category 29–1124 is a more appropriate choice for valuation.

Comment: The commenter disagreed that BLS category 19–1040 (Medical Scientists) at an hourly rate of $46.95 was the correct crosswalk for the

Medical Dosimetrist (L063A) clinical labor type. The commenter stated that BLS category 29–2098 (Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians, All Other) more accurately describes the clinical staff type associated with Medical Dosimetrists.

Response: We disagree with the commenter that the clinical labor described under BLS category 29–2098 would be the most appropriate choice to use in pricing the L045B clinical labor type. The median hourly wage under this BLS category is $20.50 while the hourly wage data for a Medical Dosimetrist that we have from Salary Expert is substantially higher at $48.31. We recognize that BLS category 29–2098 includes Medical Dosimetrists in its heading, however this is an aggregated category that also includes many other miscellaneous types of technicians. If we were to use this category for pricing Medical Dosimetrists, the clinical labor type would be priced significantly lower than its 2002 valuation ($27.67) which we do not believe would be accurate for this profession, especially in the context of the wage data that we have from Salary Expert for the profession. We continue to believe that our crosswalk to BLS category 19–1040 is a more appropriate choice for valuation.

Comment: The commenter disagreed that the 75th percentile of BLS category 19–2012 (Physicists) at an hourly rate of $78.95 was the correct crosswalk for the Medical Physicist (L152A) clinical labor type. The commenter stated that the rationale to use the 75th percentile was based on maintaining the historical wage level for clinical labor type L152A which defeats the purpose of updating clinical labor rates. The commenter stated that BLS category 19–2012 (Physicist) was the highest of several options and would suffice as a crosswalk without using the 75th percentile rate.

Response: We disagree with the commenter that the Physicists described under BLS category 19–2012 would be the most accurate choice to use in pricing the L152A clinical labor type. The median hourly wage for a Physicist under this BLS category is $59.06 while the hourly wage data for a Medical Physicist that we have from Salary Expert is substantially higher at $66.90. While we also have our reservations about the use of 75th percentile wage data from the BLS, we continue to believe that it is a more accurate choice for valuation than BLS category 19–2012.

Comment: Several commenters stated that the BLS wage data for a Physicist are not equivalent or representative of a Medical Physicist, even at the CMS proposed 75th percentile labor rate. Commenters stated that the sophistication and complexity of radiation therapy technology has increased exponentially in the past few decades and as radiation treatments have become more targeted and precise, they have also required increasingly complex equipment and processes. Commenters stated that as the complexity of radiation therapy treatments has grown, the work of ensuring treatment accuracy and patient safety throughout a prescribed course of treatment has also become more demanding in expertise and attention. These commenters recommended that CMS utilize the CY 2020 Professional Survey Report on salary data from the American Association of Physicists in Medicine (AAPM) to determine the updated clinical labor rate per minute for the Medical Physicist clinical labor type. Commenters also noted that CMS utilized the AAPM 2005 salary data, inflated to 2006, when CMS updated the clinical labor wage rates for CY 2002. This report on Medical Physicist salary data was submitted as a public comment and commenters recommended that the Medical Physicist clinical labor rate be updated to $2.25 per minute based on the weighted median salary of certified qualified Medical Physicists multiplied by the CMS proposed benefits factor of 1.366.

Response: We appreciate the submission of this additional wage data specifically for Medical Physicists to supplement the BLS wage data. We agree with the commenters that the BLS wage data for a Physicist is not representative of a Medical Physicist, which was why we proposed to use the 75th percentile of the BLS wage data due to a lack of other sources of information. We agree with the commenters that the submitted AAPM wage data more accurately captures the salary of Medical Physicists and better matches the data that we have from Salary Expert. The submitted AAPM data had an average salary of $205,838 for certified qualified Medical Physicists with a Masters or Ph.D. degree; according to our proposed methodology we divide this by 2080 hours annually for a per-hour rate of $98.96 and a per-minute rate of $1.65. However, since we are finalizing a different fringe benefits multiplier in response to comments (1.296 instead of the proposed 1.366), we arrive at a final adjusted clinical labor rate of $2.14 per minute instead of the $2.25 detailed by the commenters. As noted by the commenters, the L152A clinical labor type is included as part of the blended Medical Dosimetrist/Medical Physicist (L107A) clinical labor type, which we have also updated in response to the new $2.14 pricing.

After consideration of the comments, we are finalizing the clinical labor prices as shown in Table 12.

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TABLE 12: Finalized Clinical Labor Pricing Update

Labor Code	Labor Description	Source	Current Rate Per Minute	Updated Rate Per Minute	Y1 Phase-In Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	0.24	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	0.29	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	0.34	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	0.35	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	0.39	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	0.35	18%
L035A	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.55	0.40	57%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	0.39	19%
L037B	Histotechnologist	BLS 29-2010*	0.37	0.55	0.42	49%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	0.47	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	0.41	46%
L037E	Child Life Specialist	BLS 21-1021*	0.37	0.49	0.40	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055*, L051A, BLS 19-4010	0.38	0.52	0.42	37%
L038B	Cardiovascular Technician	BLS 29-2031*	0.38	0.60	0.44	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0.38	0%
L039A	Certified Retinal Angiographer	BLS 29-9000*	0.39	0.52	0.42	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	0.45	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	0.46	62%
L041A	Angio Technician	L035A*	0.41	0.58	0.45	41%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	0.47	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	0.47	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	0.47	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	0.48	52%
L043A	Mammography Technologist	BLS 29-2034*	0.43	0.63	0.48	47%
L045A	Cytotechnologist	BLS 29-2035	0.45	0.76	0.53	69%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	0.56	98%
L045C	CORF Social worker/Psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	0.51	56%
L046A	CT Technologist	BLS 29-2035	0.46	0.76	0.54	65%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	0.54	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	0.54	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	0.53	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	0.53	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	0.66	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	0.57	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	0.57	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	0.60	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	0.60	78%
L051A	RN	BLS 29-1141	0.51	0.76	0.57	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	0.58	51%
L051C	RN/CORF	L051A	0.51	0.76	0.57	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	0.59	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	0.60	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	0.63	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	0.62	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	0.80	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	0.64	50%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0.57	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	0.70	44%

Labor Code	Labor Description	Source	Current Rate Per Minute	Updated Rate Per Minute	Y1 Phase-In Rate Per Minute	Total % Change
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	1.19	41%
L152A	Medical Physicist	AAPM Data*	1.52	2.14	1.68	41%

* Updated in response to comments.

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We once again isolated the anticipated effects of the clinical labor pricing update on specialty payment impacts by comparing the CY 2022 PFS rates with and without the clinical labor pricing updates in place, including with both the fully implemented pricing update and the first year of a 4-year transition as shown in Table 13.

TABLE 13: Anticipated Final Clinical Labor Pricing Effect on Specialty Impacts

Specialty	Allowed Charges (mil)	Fully Updated	Y1 Phase-In Trans
Portable X-Ray Supplier	$86	9%	2%
Endocrinology	$508	2%	0%
Family Practice	$5,765	2%	0%
General Practice	$375	1%	0%
Hand Surgery	$222	1%	0%
Nurse Practitioner	$5,323	1%	0%
Geriatrics	$177	1%	0%
Internal Medicine	$9,979	1%	0%
Orthopedic Surgery	$3,286	1%	0%
Pediatrics	$56	1%	0%
Physician Assistant	$2,825	1%	0%
Pulmonary Disease	$1,478	1%	0%
Psychiatry	$1,053	1%	0%
Optometry	$1,116	1%	0%
Neurology	$1,362	1%	0%
Obstetrics/Gynecology	$561	0%	0%
Gastroenterology	$1,482	0%	0%
Plastic Surgery	$322	0%	0%
Podiatry	$1,865	0%	0%
Physical/Occupational Therapy	$3,994	0%	0%
Ophthalmology	$4,376	0%	0%
Clinical Social Worker	$881	0%	0%
Nephrology	$2,315	0%	0%
Neurosurgery	$712	0%	0%
Nurse Anes / Anes Asst	$1,075	0%	0%
Clinical Psychologist	$821	0%	0%
Multispecialty Clinic/Other Phys	$138	0%	0%
Total	$87,449	0%	0%
General Surgery	$1,751	0%	0%
Chiropractic	$622	0%	0%
Anesthesiology	$1,687	0%	0%
Critical Care	$366	0%	0%
Emergency Medicine	$2,537	0%	0%
Physical Medicine	$1,036	0%	0%
Cardiac Surgery	$204	0%	0%
Colon and Rectal Surgery	$145	0%	0%
Thoracic Surgery	$304	0%	0%
Cardiology	$6,149	0%	0%
Urology	$1,683	0%	0%
Rheumatology	$543	-1%	0%
Otolarngology	$1,041	-1%	0%
Pathology	$1,069	-1%	0%
Interventional Pain Mgmt	$897	-1%	0%
Infectious Disease	$644	-1%	0%
Nuclear Medicine	$50	-1%	0%
Radiology	$4,417	-1%	0%
Dermatology	$3,462	-1%	0%
Allergy/Immunology	$221	-1%	0%
Other	$54	-2%	0%
Audiologist	$58	-2%	-1%
Hematology/Oncology	$1,742	-2%	-1%
Independent Laboratory	$557	-2%	-1%
Radiation Oncology and Radiation Therapy Centers	$1,666	-3%	-1%
Oral/Maxillofacial Surgery	$73	-3%	-1%

Specialty	Allowed Charges (mil)	Fully Updated	Y1 Phase-In Trans
Vascular Surgery	$1,149	-5%	-1%
Interventional Radiology	$482	-6%	-2%
Diagnostic Testing Facility	$689	-7%	-2%

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We emphasize again that these are not the projected impacts by specialty of all the policies we are finalizing for CY 2022, only the anticipated effect of the isolated clinical labor pricing update (the allowed changes for each specialty therefore may not match the allowed charges listed in the Regulatory Impacts Analysis section of this rule). Several commenters asked CMS to clarify that the 4-year transition would only be implementing the first year of the projected adjustment amount for CY 2022, and not impose some other compounded effect that would deepen the payment reduction. These commenters pointed to Table 135 in the CY 2022 PFS proposed rule (86 FR 39563–39564) and sought assurances that the −1 percent in a 4-year transition would not grow to be a −4 percent by the end of the 4-year transition, rather than the −2 percent listed on the table for the full transition. We are happy to clarify for commenters that these cases, such as applying to the Audiologist specialty in the above table, are caused by rounding and the ''Fully Updated'' column contains the full effects of the entire clinical labor pricing update.

As was the case for the market-based supply and equipment pricing update, the clinical labor rates will remain open for public comment over the course of the 4-year transition period. We welcome additional feedback on clinical labor pricing from commenters in next year's rulemaking cycle, especially any data that will continue to improve the accuracy of our finalized pricing.

e. Establishment of Values for Remote Retinal Imaging (CPT Code 92229), Comment Solicitation for Fractional Flow Reserve Derived From Computed Tomography (CPT Code 0503T), and Comment Solicitation for Codes Involving Innovative Technology

Rapid advances in innovative technology are having a profound effect on every facet of the economy, including in the delivery of health care. Emerging and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program. While new services have emerged over the last several years, it is possible that the COVID–19 PHE could be accelerating the supply and demand for these innovations. Emerging and evolving technologies could be useful tools for improving disparities in care that have been exacerbated by the PHE. Some of these new applications have codes for which innovative technology is substituting for and/or augmenting physician work. For example, the CPT Editorial Panel created CPT code 92229 (*Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral*), a diagnostic test for diabetic retinopathy that uses a software algorithm, and the RUC provided valuation recommendations which included a retinal camera and an analysis fee for remote imaging. In the CY 2021 PFS final rule (85 FR 84629 through 84630), we considered CPT code 92229 to be a diagnostic service under the PFS, contractor-priced it, and stated that we would have ongoing conversations with stakeholders. In the proposed rule, we discussed a proposal to establish RVUs for CPT code 92229, solicited feedback to establish RVUs for CPT code 0503T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model*), and solicited feedback to help us better understand the resource costs for services involving the use of innovative technologies such as software algorithms and artificial intelligence (AI).

In our discussion of CPT code 92229 in the CY 2021 PFS final rule (85 FR 84629 through 84630), we wrote that as the data used in our PE methodology have aged, and more services have begun to include innovative technology such as software algorithms and AI, these innovative applications are not well accounted for in our PE methodology. As described earlier in this section, PE resources involved in furnishing services are characterized as either direct or indirect costs. Direct costs of the PE resources involved in furnish a service are estimated for each code and include clinical labor, medical supplies, and medical equipment. Indirect costs include administrative labor, office expenses, and all other expenses. Indirect PE is allocated to each service based on physician work, direct costs, and a specialty-specific indirect percentage. The source of the specialty specific indirect percentage was the Physician Practice Information Survey (PPIS), last administered in 2007 and 2008, when emerging technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware may not have been typical. Thus, these costs are not well accounted for in the PE methodology.

Consistent with our PE methodology and as we have stated in past PFS rulemaking (83 FR 59557), we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment. In the case of CPT code 92229, the hardware is a retinal camera used for remote imaging. Given that indirect costs are based on physician work, direct costs, and specialty-specific indirect percentages that can include high-cost equipment, our concern is that if we were to consider an analysis fee to be a supply cost, as was recommended by the RUC, it is possible that we would inadvertently allocate too many indirect costs for a supply item that may not require additional indirect expenses. Unlike a piece of equipment, such as the retinal camera, an analysis fee for software does not require physical space in an office or administrative staff hours to maintain it.

However, increasingly, stakeholders have routinely expressed concerns with our policy to consider analysis fees as indirect costs, especially for evolving technologies that rely primarily on these fees with minimal costs in equipment or hardware. In comments in the CY 2021 PFS final rule (85 FR 84629 through 84630) responding to our proposal to price the analysis fee for remote imaging as an indirect cost, stakeholders stated

that there would be no service if the software was not used. There are two aspects that distinguish CPT code 92229 from other services. First, most of the RUC's recommended resource costs for CPT code 92229 were for the analysis fee, rather than high-cost equipment or other supplies that require commensurate indirect costs to accommodate for space or administrative labor. Second, the innovative technology incorporated into the service is a software algorithm, which interprets data collected during the test, either augmenting the work of the physician or NPP performing the test, or in some cases replacing at least some work that a physician would typically furnish. In general, it is possible that physician work time and intensity of furnishing care to patients could be affected as more services that involve innovative technologies such as software algorithms or AI become available.

We finalized a policy to establish contractor pricing for CPT code 92229 (85 FR 84629 through 84630) because analysis fees for software algorithms and AI applications are not well accounted for our PE methodology, and to recognize that practitioners do incur resource costs for purchase and ongoing use of the software. We stated that we would continue to seek out new data sources and have ongoing conversations with stakeholders while also considering other approaches to reflect overall resource costs for these technologies in our PE methodology.

As we described in the CY 2021 PFS final rule (85 FR 84498 through 84499), the RAND Corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it. RAND has found that the PPIS data last collected in 2007–2008 may no longer reflect the resource allocation, staffing arrangements, and cost structures that describe practitioners' resource requirements in furnishing services to Medicare beneficiaries, and consequently may not accurately capture the indirect PE resources required to furnish services to Medicare fee-for-service (FFS) beneficiaries. Our experience with the challenge of accurately accounting for resource costs for innovative and emerging technologies such as ongoing service-specific software costs that are included in CPT code 92229 is another reason we continue to be interested in potentially refining the PE methodology and updating the data used to establish RVUs and payment rates under the PFS. We commonly employ a crosswalk to recognize resource costs when we lack the inputs that we would need to calculate work, PE, and/or malpractice RVUs for a service otherwise. When we use a crosswalk to value a service, we substitute the established RVUs for other services with similar resource costs in the physician office setting to set RVUs and the national payment rates for that particular service.

For CY 2022, we proposed to establish values for CPT code 92229 using our crosswalk approach, and thus this service would no longer be contractor-priced. We continue to believe that the software algorithm present in the analysis fee for CPT code 92229 is not well accounted for in our PE methodology; however, we recognize that practitioners are incurring resource costs for purchase of the software and its ongoing use. We proposed to use a crosswalk that reflects the overall relative resource costs for this service while we continue to consider potentially refining the PE methodology and updating the data we use to establish PE RVUs under the PFS. Specifically, we proposed a crosswalk to CPT code 92325 (*Modification of contact lens (separate procedure), with medical supervision of adaptation*), a PE-only code used for the eye, as we believe it reflects overall resource costs for CPT code 92229 in the physician office setting. We recognize that the services described by CPT code 92325 are not the same as the services in CPT code 92229; however, we believe that the total resource costs would be similar across these two codes. We believe that crosswalking the RVUs for CPT code 92229 to a code with similar resource costs allows CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 92229, which would not typically be considered direct PE under our current methodology. We also solicited comments on our proposal to crosswalk CPT code 92229 to CPT code 92325, and whether other codes would provide a more appropriate crosswalk in terms of resource costs. In addition, as discussed in section II.E of this final rule, we proposed to use our crosswalk approach for CPT code 77089 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk*) and CPT code 77091 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk, technical calculation only*).

We received public comments on our proposal to crosswalk CPT code 92229 to CPT code 92325. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to crosswalk CPT code 92229 to CPT code 92325 to better reflect the overall relative resource costs for this service. Commenters stated that that these services were not clinically similar but the total direct practice cost of CPT code 92325 was similar to the RUC-recommended total direct PE cost for CPT code 92229 and commenters agreed with the CMS proposal to implement relative values for this service. Commenters stated that although many of the MACs have worked with providers to establish pricing, there remains significant variability in payment across MAC jurisdictions and a lack of transparency in the valuation methodology. Commenters stated that this variability in the current MAC pricing can impact provider and beneficiary access to novel and vision-saving technologies. These commenters supported national pricing for CPT code 92229 through the use of the proposed crosswalk code to help provide transparency and facilitate beneficiary access to care. We did not receive comments requesting that CMS return to the contractor pricing finalized for CY 2021 for CPT code 92229.

Response: We appreciate the support for our proposed crosswalk from the commenters.

Comment: Several commenters expressed concern that CMS repeatedly stated that software and analysis fees are not direct expenses. Commenters disagreed and stated that software that is directly attributed to a specific physician service is a direct expense, and furthermore that there are multiple examples of the implementation of such costs. Several comments provided a list of current CPT codes that they stated included software as a direct PE input, such as CPT code 95905 (*Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report*). Several commenters raised the issue of software as a medical device (SaMD) and stated that it should be considered a direct PE expense similar to other medical equipment. Commenters stated that even though SaMD does not require physical space in an office or administrative staff hours

to maintain it, SaMD does require ongoing upgrades, improvements, and security mitigation, as well as the same regulatory oversight by the Food and Drug Administration (FDA) as hardware medical devices. Commenters stated that the legal, regulatory, and financial burdens incumbent of a SaMD manufacturer are no different than those of hardware medical device manufacturers.

Response: We appreciate the detailed feedback from the commenters regarding the issues surrounding software and analysis fees. We agree with the commenters that there have been occasions in the past where we have finalized the inclusion of software as a direct PE expense if it met our criteria as typical and medically necessary for the service in question and could be individually allocable to a particular patient for a particular service. For example, we included the sheer wave elastography software (ED060) as a direct PE input for CPT codes 76981–76983 in CY 2019. In this case, the sheer wave elastography software was an additional resource cost added to the general ultrasound room (EL015) equipment without which the service cannot be performed. We have been more hesitant to classify software, licensing, and analysis fees that are not associated with physical equipment used in the performance of a service as they pose more significant challenges for our traditional PE methodology. Therefore, we wish to clarify that although we have typically considered software costs to be indirect PE under our methodology, as these costs were not individually allocable to a particular patient for a particular service, there have been exceptions to this general principle where software costs have been included directly in the service under review.

As we stated in the proposed rule, we believe that costs associated with software, licensing, and analysis fees are not well accounted for in the PE methodology. Unlike a piece of equipment, such as the retinal camera, an analysis fee for software does not require physical space in an office or administrative staff hours to maintain it. These types of costs were much less prevalent when the Physician Practice Information Survey (PPIS) was last administered in 2007 and 2008 and of course did not exist at all in the case of AI-based services. We remain concerned that if we were to consider software analysis fees and software as a medical device expenses to be direct costs in all cases, we may inadvertently allocate too many indirect costs for supplies that may not require additional indirect expenses. The data underlying the PPIS assumes that direct expenses will require costs associated with physical space and physical maintenance that may not appropriate for these new types of software. However, we do recognize that practitioners are incurring resource costs for purchase of the software and its ongoing use, which is why we proposed the crosswalk to CPT code 92325 to capture these resource costs for CPT code 92229. We believe that the use of this crosswalk and other similar crosswalks are the best way to value services that make use of software, licensing, and analysis fees at the moment while we explore ongoing potential updates to the PE methodology.

Comment: One commenter stated that CMS should consider crosswalks to CPT codes 95249 (*Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording*) and 92977 (*Thrombolysis, coronary; by intravenous infusion*). The commenter stated that these codes are expected to be utilized in primary care and diabetes care settings and reflect similar resource costs.

Response: We appreciate the additional suggested crosswalk codes from the commenter. However, we continue to believe that our proposed crosswalk to CPT code 92325 is a more appropriate choice to use for valuing CPT code 92229 because it more closely matches the RUC-recommended total direct PE costs for CPT code 92229. Although CPT codes 95249 and 92977 share some clinical similarities with CPT code 92229, they both include additional resource costs which would result in an inappropriately higher valuation if we were to employ them as our crosswalk code.

After consideration of the public comments, we are finalizing our proposal to establish values for CPT code 92229 based on a direct crosswalk to CPT code 92325.

We are aware of other services that use similar innovative technologies to those used for the diagnostic test for diabetic retinopathy and trabecular bone score, and that those technologies also are not well-accounted for in our PE methodology. For CY 2018, the AMA CPT Editorial Panel established four new Category III CPT codes for fractional flow reserve derived from computed tomography (FFRCT): CPT code 0501T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report*); CPT code 0502T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission*); CPT code 0503T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model*); and CPT code 0504T (*Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report*). FFRCT is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through coronary CT scans. It uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing or treatment (typically, a coronary angiogram). We understand that FFRCT can show through non-invasive imaging whether a beneficiary has coronary artery disease thereby potentially avoiding an invasive coronary procedure. Medicare began payment for CPT code 0503T in the HOPD setting under the Outpatient Prospective Payment System (OPPS) in CY 2018 (82 FR 59284). For the PFS, we typically assign contractor pricing for Category III codes since they are temporary codes assigned to emerging

technology and services. We followed this established process for Category III codes by assigning and listing them as contractor pricing in Appendix B in the CY 2018 PFS final rule (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1676-F*).

We have since been trying to understand the costs of the PE resource inputs for CPT code 0503T in the physician office setting. In the CY 2021 PFS final rule, we stated that we found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other innovative forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PE methodology; and that our recent reviews for the overall cost of CPT code 0503T have shown the costs in the physician office setting to be similar to costs reflected in payment under the OPPS (85 FR 84630). For the CY 2021 OPPS/ASC final rule, we found that the geometric mean cost reported by HOPDs for the service was $804.35 (85 FR 85943). We believe the costs reported under the OPPS are instructive as they reflect actual costs that hospitals incurred in furnishing the service described by CPT code 0503T to Medicare beneficiaries, and, as we stated in the CY 2021 PFS final rule, we believe that these costs would be similar in the physician office setting. Using the geometric mean costs under the OPPS as a proxy, we then searched for services paid under the PFS that could potentially serve as a crosswalk. Specifically, we looked for services paid under the PFS that include only a TC because CPT code 0503T is a TC-only service, and that have similar total costs to CPT code 0503T. We identified the following potential crosswalks, and solicited public comment on which, if any of them, would be appropriate: CPT code 93455 (*Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography*) and CPT code 93458 (*Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed*). We also solicited comment on whether other codes would provide a more appropriate crosswalk in terms of resource costs.

We received public comments on our comment solicitation for potential crosswalks to use to establish national payment for CPT code 0503T. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to use a crosswalk to recognize resource costs and appropriately pay for CPT code 0503T. These commenters disagreed, however, with the proposal to use costs reported under the OPPS as a proxy to inform our selection of a crosswalk to similarly resourced services under the PFS. Some of these commenters, including the AMA RUC, expressed concern about our reliance on data from the OPPS in establishing relative values for the PFS. These commenters cited Section 4505 of the Balanced Budget Act of 1997 and highlighted what they believed to be requirements for what data CMS should consider in establishing payments under the PFS. Specifically, they stated that CMS must utilize generally accepted cost accounting principles to recognize all staff, equipment, supplies and expenses, not just those which can be tied to specific procedures, and to use actual data on equipment utilization and other key assumptions, as well as to consult with organizations representing physicians regarding methodology. They asserted that any proposal to use the relativity of hospital charge data to determine the relativity of practice costs within a physician office is not consistent with the statutory provisions established by the BBA of 1997. The AMA RUC stated that it would solicit the national specialty societies to determine if RUC recommendations may be developed for this service.

Response: In response to commenters' concerns about our potential use of OPPS cost data, we note that section 1848(c)(2)(N) of the Act authorizes our use of alternative approaches to establishing PE relative values using cost, charge, or other data from suppliers or providers of services in order to ensure accurate valuation of services under the PFS. As previously stated, we believe this is an appropriate approach as our recent reviews for the overall cost of CPT code 0503T have shown the costs in the physician office setting to be similar to costs reflected in payment under the OPPS.

Comment: Some commenters requested that CMS use submitted invoice information, which included a price of $1,100 for furnishing the whole service described under CPT code 0503T, as a direct expense input to establish national payment for CPT code 0503T.

Response: We thank the commenters for the invoice information they provided. We note that, in recent years, these services have been contractor priced, both out of consideration for the relative newness of the technology involved in the services and to allow time for CMS to consider how best to appropriately reflect costs for the service in payments established under the PFS. Stakeholders have worked with MACs to establish payment for the service but have expressed concern with the variability in payments across the different MAC jurisdictions during this time and have continued to urge CMS to establish national payment rates. In response, CMS in recent years has reviewed cost information for this service. Our recent reviews for the overall cost of CPT code 0503T have shown that the costs in the physician office setting are similar to costs reflected in payment under the OPPS (85 FR 84630). We continue to believe the costs and resulting payment reported under the OPPS are instructive as they reflect actual costs that hospitals incurred in furnishing the service described by CPT code 0503T to Medicare beneficiaries. Further, as we stated in the CY 2021 PFS final rule, we believe that these costs would be similar in the physician office setting, given stakeholders' description of the way that this TC-only service is furnished (that is, a technician conducts a proprietary data analysis process at a central facility). In soliciting comments on the appropriate crosswalk for use to establish a PFS payment for this service, we had referenced the CY 2021 OPPS/ASC geometric mean cost of $804.35 for 0503T. We note, however that we finalized an OPPS payment rate of $950.50 for the service based on an assignment to a new technology Ambulatory Payment Classification (APC) in order to provide payment stability and equitable payment for providers as they continue to become more familiar with the proper cost reporting for CPT 0503T and other services that similarly use artificial intelligence technologies. Based on our reference to the underlying OPPS/ASC geometric mean cost data for the service, we had identified CPT code 93455 (*Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with*

catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography) and CPT code 93458 (*Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed*) as potential crosswalks. We had intended in the CY 2022 PFS proposed rule to reference and use the OPPS payment rate to identify an appropriate crosswalk for CPT code 0503T, but due to a technical error, we inadvertently referenced the cost information to identify potential resource-based crosswalks under the PFS. As discussed briefly above, the geometric mean cost information is used under the OPPS to identify an APC assignment based on similarity of cost and clinical characteristics to other services. We believe that using the CY 2021 OPPS payment rate for 0503T ($950.50), as the reference for cost to identify an appropriate crosswalk code under the PFS, which is higher than the underlying geometric mean cost-based information we had proposed ($804.35) to use, strikes the right balance between acknowledging the invoice information we received from commenters and the OPPS payment information informed by hundreds of claims with cost data for the FFRCT service. We reiterate that given stakeholders' description of the way that this TC-only service is furnished (that is, a technician conducts a proprietary data analysis process at a central facility), we believe that the costs for the FFRCT service as reflected in the OPPS payment that we used to identify a suitable resource-based crosswalk, would be similar in the physician office setting. Using the CY 2021 OPPS payment rate (which is based on the geometric mean costs data) as a proxy, we identified the TC for CPT code 93457 (*Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous graft(s) including intraprocedural injection(s) for bypass grafts angiography and right heart catherization*) as a more appropriate crosswalk. After consideration of the public comments, we are finalizing national pricing for CPT code 0503T, based on a valuation crosswalk to the TC of CPT code 93457 (*Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous graft(s) including intraprocedural injection(s) for bypass grafts angiography and right heart catherization*). We intend to continue working with stakeholders to help us better understand the resource costs that should be reflected in payment for services involving the use of innovative technologies, address payment for innovative services (such as CPT code 0503T), and consider how the cost for such services should be accounted for in our PE methodology.

We also more broadly solicited public comment to help us better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. We refer readers to the CY 2022 PFS proposed rule (86 FR 39125) for more detail on the questions we asked the public to consider.

We received public comments on the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. The following is a summary of the comments we received and our response.

Comment: Commenters were unanimously appreciative of the effort to understand and proactively engage on AI topics, and the acknowledgment that AI and innovative technologies are not well accounted for in the current PE methodology. Many commenters noted that the approach to understanding costs and impact on providers, systems, and patients is highly dependent upon the service and circumstances of the clinical encounter, and that it is difficult to broadly assess the impact of innovations on individual components of the RVU for a service. Some commenters encouraged CMS to issue a separate, stand-alone, request for information (RFI) that looks holistically at this issue rather than in the context of a specific payment rule or structure, noting this would help to ensure a broader range of stakeholder views are represented.

Many commenters noted that while there may be one-time or start-up costs associated with implementing an AI-enabled technology or software algorithm, the costs are more likely recurring, and consider these technologies a direct PE instead of an indirect PE. One commenter suggested that the specific AI work and related AI cost should be paid separately under a new code, or added on to the existing code. Another commenter encouraged CMS to exercise flexibility in how it considers costs to allow for a range of cost structures, such as subscription models, per-use costs, device/supply purchases, and AI service purchases, when determining its approach. One commenter noted that the costs associated with innovative technologies should align with the rest of the RBRVS, with staff, supplies and equipment costs resource-based, and with appropriate updates to the PPI Survey to accurately capture these indirect costs. Another commenter encouraged an assessment and analysis of how these and other methodologies for calculating a per-patient cost can accommodate emerging business models for these innovative technologies.

Many commenters disagreed with any characterization of innovative technologies as a replacement for physician work. One commenter stated that the new technologies do not categorically increase or decrease physician work time and intensity, but rather, they change what physicians do. Many commenters referred to the following three broad categories when describing the different roles these technologies play in physician work: (1) Assistive, which enhances clinical management, but does not generate additional physician work; (2) automated, which provides additional insight that informs the physician's actions); and (3) autonomous, which provides diagnosis or clinical management decisions, but does not require physician intervention. Commenters further note that applications in each of these categories can either increase or decrease physician work and intensity. Some commenters noted that technologies such as AI are so nascent or absent in their respective specialties that there are insufficient examples to even illustrate the impact on physician work.

Many commenters noted the potential for these technologies to facilitate more efficient and timely care. A few commenters noted that while these technologies have the potential to increase access to care, beneficiaries in rural areas with limited broadband access could face barriers. One commenter noted that these technologies often require specific hardware, software, broadband and other capabilities that may exceed the resources of a physician, and in turn have an impact on quality and equity. The commenter encouraged CMS to consider policies outside the PFS to mitigate disparities in equitable diffusion and uptake of these

technologies. Some commenters acknowledged that these technologies may foster or perpetuate bias, citing the established literature base on bias in machine-learning algorithms. One commenter noted that the FDA approval process includes an assessment of bias in these technologies. One commenter asserts that while software algorithms and AI improve health care disparities, demonstrated by the diabetic retinopathy example, the potential to worsen or widen health disparities also exists.

Commenters also noted the importance of establishing monitoring and other guardrails to mitigate fraud, waste, and abuse, and to ensure that bias does not lead to compromised patient care.

Response: We thank the commenters for all the information submitted. We will review the many public comments we received on this topic and will also consider how best to continue to engage with all stakeholders as we consider this issue further for potential future rulemaking.

As we described in the CY 2021 PFS final rule (85 FR 84498 through 84499), the RAND Corporation has been studying potential improvements to CMS' PE allocation methodology and the data that underlie it. CMS and RAND hosted a virtual Town Hall meeting on June 16, 2021 and materials are available at *https://www.cms.gov/medicare/physician-fee-schedule/practice-expense-data-methods.* Prior RAND research reports are also available at *https://www.rand.org/pubs/research_reports/RR2166.html* and *https://www.rand.org/t/RR3248.* RAND has issued the results of its final phase of research, available at *www.rand.org/t/RRA1181-1.* This report is also available as a public use file displayed on the CMS website under downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.*

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this final rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), MedPAC, and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.

- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well. Individuals and stakeholder groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox *MedicarePhysisianFeeSchedule@cms.hhs.gov,* with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes''. Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; final rule (76 FR 73052 through 73055) (hereinafter referred to as the ''CY 2012 PFS final rule with comment period''). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 FR 68892) (hereinafter referred to as the ''CY 2013 PFS final rule with comment period''), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (73 FR 38589) (hereinafter referred to as the ''CY 2009 PFS proposed rule''), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2022 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.

- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In the proposed rule, we solicited comments regarding the codes that were nominated by the public and stakeholders as potentially misvalued. In this final rule, we review and summarize the comments we received regarding such codes, and we explain whether we are finalizing such codes as potentially misvalued. We received public nominations for potentially misvalued codes by February 10th and we displayed those nominations on our public website, where we also included the submitter's name and their associated organization for full transparency. Some submissions were for specific, PE-related inputs for codes, and we refer readers to section II.B. of this final rule Determination of PE RVUs for further discussions on PE-related submissions. Discussed below is the summary of this year's submissions under the potentially misvalued code initiative and the comments received from the proposed rule.

A stakeholder nominated CPT code 22551 (*Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex*) ''and common related services'' as potentially misvalued. Citing the CY 2021 PFS final rule (84 FR 84501) where CMS agreed with the public nomination of CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*) as potentially misvalued, and discussed the relationship between CPT code 22867 and CPT code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar*), this stakeholder suggests that there are additional CPT code values related to spine procedures that are in need of contemporaneous review with CPT code 22867. The stakeholder believes that CMS has an interest in reviewing associated anterior cervical discectomy and fusion (ACDF) procedures as well, and suggests that CPT code 22551 ''and common related services'' can result in cumulative RVUs that do not sufficiently reflect physician work, time, or outcomes.

In their submission, the stakeholder expressed concern that there is a discrepancy between the typical total RVUs for codes billed for vertebral fusion procedures performed using three synthetic cage devices with plate and vertebral fusion procedures performed using three allografts with plate. Both methods of vertebral fusion are described by CPT code 22551 (includes a 90-day global period), which has a work RVU of 25.00. Both methods of vertebral fusion involve two units of CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure) (ZZZ global period)*) with a total work RVU of 13.00 (6.50×2); and both methods of vertebral fusion involve 1 unit of CPT code 22846 (*Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure) (ZZZ global period)*) with a work RVU of 12.40. The vertebral fusion method employing three synthetic cage devices with a plate would involve CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure) (ZZZ global period)*) for the insertion of synthetic cage devices for a total work RVU of 12.75 (4.25×3), and CPT code 20930 (*Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)*) with a work RVU of 0.00 (because Medicare considers this code to be bundled into codes for other services). The stakeholder stated that the total work RVUs for the typical vertebral fusion employing three synthetic cage devices with plate would be 63.15 work RVUs.

In contrast, the stakeholder asserted that the vertebral fusion method employing three allografts with plate involves the same set of services and codes (CPT code 22551 (090 global period) and CPT code 22846 (ZZZ global period)), but instead of CPT codes 22853 or 20930, involve CPT code 20931 (*Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure) (ZZZ global period)*) with a work RVU of 1.81. Altogether, the total work RVUs for CPT codes involved in this vertebral fusion method is 52.21. The stakeholder suggested that this difference in total work RVUs, 63.15 versus 52.21, is evidence that these services are misvalued, and that the total work RVUs do not reflect the differences in the amount of work, resources, and intensity between the two vertebral fusion methods.

This stakeholder's description of the potential misvaluation of CPT code 22551 ''and common related services'' differs from the CMS approach to identifying potentially misvalued services by using certain criteria, as described in the beginning of this section. Our determination that one or more codes are potentially misvalued generally revolves around the specific RVUs assigned to an individual code, or several codes within a family of codes. CMS generally does not examine the summed differences in total RVUs based on billing patterns using different codes in different scenarios, representing different physician work, and then comparing the two methods of a procedure, in this case, the use or non-use, of the synthetic cage devices in the vertebral fusion with removal of the disc in the upper spinal column. We do not believe that the stakeholder has provided support for the premise that CPT code 22551 alone is misvalued, or

that any of the codes identified as common related services are misvalued. Therefore, we were not inclined to propose this code as potentially misvalued. However, we solicited comment, including any analysis or studies demonstrating that one or more of these codes meet the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or are otherwise potentially misvalued.

A stakeholder nominated CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) as potentially misvalued, as it has not been valued for payment in the non-facility/office setting. This stakeholder did not include in their submission detailed recommendations for the items, quantities, and unit costs for the supplies, equipment types, and clinical labor (if any), that might be incurred in the non-facility/office setting, all of which are key factors when determining potential valuation or mis-valuation of a service. Medicare claims data for 2018, 2019, and 2020 show that CPT code 49436 is solely performed in the facility ASC setting. We solicited comment, including any analysis or studies demonstrating that this code meets the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or is otherwise potentially misvalued.

A stakeholder nominated CPT code 55880 (*Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance*) as potentially misvalued, as it has not been valued in the non-facility/office setting. This stakeholder also did not include in their submission detailed recommendations for items, quantities, and unit costs for the supplies, equipment types, and clinical labor (if any), that might be incurred in the non-facility/office setting, all of which are key factors when determining valuation or mis-valuation. This stakeholder stated that the advances in High Intensity Focused Ultrasound (HIFU) technology toward the destruction of cancerous tissues in the prostate gland have matured to the point where this procedure is now equally as effective and as safe as the cryoablation procedure described by CPT code 55873 (*Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)*), which is currently valued in the non-facility/office setting (186.69 total RVUs, approximately $6,514) and has been for approximately 10 years. We note that CPT code 55880 was reviewed and valued in the CY 2021 PFS final rule (85 FR 84614 through 84615) in the facility setting only. Accordingly, we do not have enough claims data for this code to make accurate comparisons to similar codes that may be furnished in non-facility settings. In the proposed rule, we explained that there was no case presented that constituted a misvaluation of CPT code 55880, and therefore, we were not inclined to put this code forward as potentially misvalued for CY 2022; however, we solicited comment, including any analysis or studies demonstrating that this code meets the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or is otherwise potentially misvalued.

A stakeholder nominated CPT code 59200 (*Insertion cervical dilator (e.g., laminaria, prostaglandin)*) as potentially misvalued because the direct PE inputs do not include the supply item, Dilapan-S. This stakeholder had sought to establish a Level II HCPCS code for Dilapan-S, but CMS did not find sufficient evidence to support that request. The stakeholder submitted Dilapan-S to be considered as PE supply input to a Level I CPT code(s). This stakeholder seeks to add Dilapan-S to the nonfacility/office PE inputs for CPT code 59200. Specifically, the stakeholder recommends adding 4 rods of Dilapan-S at $80.00 per unit, for a total of $320.00, as a replacement for the current PE supply item, laminaria tent (a small rod of dehydrated seaweed that when inserted in the cervix, rehydrates, absorbing the water from the surrounding tissue in the woman's body), which is currently listed at $4.0683 per unit, with a total of 3 units, for a total of $12.20. We solicited comment, including any analysis or studies demonstrating that this code meets the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or is otherwise potentially misvalued.

A stakeholder nominated CPT codes 66982 through 66986 as potentially misvalued, as they have not been valued in the non-facility/office setting. This stakeholder did not submit other details or reasoning to support their nomination. We note that some of these cataract-related procedures were initially reviewed and valued in CY 2020 PFS final rule (84 FR 62751), and that presently, additional codes in this family are scheduled to be reviewed and valued in this CY 2022 PFS final rule (we refer readers to section II.E. of this final rule, Valuation of Specific Codes). The highest utilization of these cataract codes are CPT code 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique* (*e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery* (*e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation)*) and CPT code 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique* (*e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*). In 2018 and 2019, these services were almost all performed in the ASC facility setting, but based on 2020 claims, the most common setting appears to have shifted to the hospital inpatient or hospital outpatient facility setting. In the proposed rule, we noted that there was no case presented that constituted a misvaluation of CPT codes 66982 to 66986, and therefore, we were not inclined to put this code family forward as potentially misvalued for CY 2022; however, we solicited comment, including any analysis or studies demonstrating that one or more of these codes meet the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources involved in providing a service, or that the code(s) are otherwise potentially misvalued. See Table 14.

TABLE 14: Stakeholders' Nominations of CPT Codes as Potentially Misvalued for CY 2022

CPT	CPT Descriptor
22551	Neck spine fuse&remov bel c2
49436	Embedded ip cath exit-site
55880	Abltj mal prst8 tiss hifu
59200	Insert cervical dilator (PE supply)
66982 to 66986	Cataract codes

In response to the proposed rule, we received public comments on the CY 2022 identification and review of potentially misvalued services. The following is a summary of the comments we received and our responses.

Comment: We received one comment regarding CPT code 22551 ''and other common related services typically billed with CPT 22551'' on the same day of service, with the same patient, with the same provider(s). The commenter stated they believe that this code is not misvalued.

Response: We do not typically look at a collection of services to see if any one combination of services is misvalued against any other combination of services. This is true not just of vertebral fusion procedures, but of any combination of codes that are furnished by a billing physician. We generally only examine the potential misvaluation of a single code, and not a possible mix of multiple codes/services that might be furnished and billed together. Since CPT code 22551 was not nominated as being potentially misvalued for any of the reasons that we have described above in our criteria of being potentially misvalued, we are finalizing our proposal that this code will not be considered as potentially misvalued for CY 2022.

Comment: We received one comment for CPT code 55880, informing us that this service is expected to see further review for valuation recommendations with the AMA RUC in 2022 for possible CY 2024 recommendations to CMS, and that we should reconsider the valuation of CPT code 55880 at that later time.

Response: We appreciate this information, and note that this CPT code is already slated for review by the AMA RUC in the coming year. Therefore, we are finalizing our proposal that CPT code 55880 will not be considered as potentially misvalued for CY 2022.

Comment: We received comments regarding CPT code 59200 concerning the addition of the supply item Dilapan-S, and one of the comments was from the stakeholder that nominated CPT code 59200 as potentially misvalued. The commenters restated that Dilapan-S is not on the list of direct PE supplies for this code, and that the much less costly equivalent item, ''laminaria tent,'' is on the list of direct PE supplies for this code. One commenter cited evidence suggesting an increased risk of infections in using the laminaria tent as compared to Dilapan-S and that Dilapan-S achieves faster cervical ripening for quicker deliveries by 4 hours. This information was not echoed by other commenters and there were no other reasons given as to why Dilapan-S should replace the item laminaria tent and no evidence that Dilapan-S was in any other way a better performing supply that is widely used as a replacement.

Response: Based on these public comments, and the absence of broader support from any additional commenters on this nomination, we are not finalizing CPT code 59200 as potentially misvalued for CY 2022.

Comment: One commenter posited that the drug administration CPT codes 96401 to 96549 are potentially misvalued because claims in that code range are being adjusted by Medicare Administrative Contractors (MACs) and replaced with the less complex CPT codes [96360 to 96379].

Response: These ''Complex Biological Agent Administration'' codes (that is, CPT codes 96401 to 96549 and CPT codes 96360 to 96379) were not nominated as potentially misvalued for our consideration in the CY 2022 PFS proposed rule, and therefore, we did not address them in the proposed rule. As such, they are outside the scope of this CY 2022 PFS rulemaking process. Therefore, we decline to directly address this comment. However, we note that it is not clear to us how the commenter's assertion that MACs are making adjustments to the codes they use in their drug administration claims is relevant to the question of whether the codes are potentially misvalued. If the commenter continues to believe there is a potential code misvaluation, we suggest they consider submitting a nomination that addresses the criteria we use to assess whether a code is potentially misvalued, as explained above, before our February 10th deadline for a future rulemaking cycle.

Comment: We received comments on the nomination of CPT code 49436 only from the nominator of the code. The nominator provided additional documentation that CPT code 49436 can be safely performed in the nonfacility/office setting. The nominator noted that the total Medicare payment amount for this procedure when done in the nonfacility/office setting would be less than when furnished in the HOPD or ASC facility setting. The nominator stated that performing this procedure in the nonfacility/office rather than in an ASC is a significant ease in burden to the practitioner and the patient since there would be no need to coordinate and schedule an ASC time slot, travel to and from the ASC, or incur the cost involved in utilizing the ASC facility. The nominator also states that easing access to this service would promote peritoneal dialysis in the home setting (and may avoid in-center hemodialysis with a central venous catheter). The nominator also noted that dialysis in the home may be favorable to the patient during the public health emergency (PHE) for COVID–19, which imposes social distancing and self-isolation for a measure of safety from the transmission of infection. The nominator states that the PHE for COVID–19 may also be constraining access to ASC operating facilities due to their restricted schedules of operation.

Response: We agree with the nominator that CPT code 49436 can be safely performed in the nonfacility/office setting. We are also aware that the PHE for COVID–19 may also be constraining access to ASC operating facilities where CPT code 49436 is performed, and if this service were to be done in the nonfacility/office setting, there may well be an ease in the burden to the provider and the patient, when trying to coordinate access with the current PHE ASC restricted schedules. We expect that a nonfacility/office valuation for CPT code 49436, would include the similar supplies, equipment, and clinical labor (if any), that is part of

the ASC/Hospital Outpatient facility's service, plus the payment of the physician's work. The sum of these PEs incurred in the nonfacility/office, will likely be less than current amount paid to the ASC/Hospital Outpatient facility and may result in a net savings when CPT code 49436 is provided in the nonfacility/office setting. After considering the additional information provided by the nominator in combination with our above criteria that a code's typical site of service may need to change since it was last valued, we believe it may be appropriate to explore establishing a value for CPT code 49436 in the non-facility/office setting, and therefore, we are finalizing this code as potentially misvalued for CY 2022.

We received no comments recommending that CPT codes 66982 through 66986 should be valued for payment in the non-facility/office setting, and the nominator supplied no reasoning in support of their nomination of these codes as potentially misvalued codes. Since, as we explained in the proposed rule, there is no case presented with this nomination that constitutes a potential code misvaluation, we are finalizing our proposal that these codes will not be considered as potentially misvalued for CY 2022.

We received two comments requesting that CMS establish a national payment rate for Category III CPT code 0583T (*Insertion of ventilating tube in eardrum using an automated tube delivery system under local anesthesia*), also known as tympanostomy under local anesthesia (Tula). This code is currently carrier-priced and was not discussed in the CY 2022 PFS proposed rule. As such, these comments are outside the scope of the CY 2022 PFS rulemaking process, and we will not formally respond to them. However, the commenters are welcome to submit this code by February 10 of the coming year for consideration as potentially misvalued for the CY 2023 PFS proposed rule. See above for more information on how to submit a nomination for a potentially misvalued code.

D. Telehealth and Other Services Involving Communications Technology, and Interim Final Rule With Comment Period for Coding and Payment of Virtual Check-In Services—Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare telehealth services list in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare telehealth services list to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare telehealth services list. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits. Some examples of other clinical benefits that we consider include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treatment.
  - Decreased pain, bleeding, or other quantifiable symptom.
  - Reduced recovery time.
- *Category 3:* In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis following the end of the PHE for the COVID–19 pandemic. This new category describes services that were added to the Medicare telehealth services list during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis will ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare telehealth services list. To add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns for patient safety if the service is furnished as a telehealth service.

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

++ Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare

telehealth services list using the Category 3 criteria described above. In this final rule, we are considering additional requests to add services to the Medicare telehealth services list on a Category 3 basis using the previously described Category 3 criteria.

The Medicare telehealth services list, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2022, requests to add services to the Medicare telehealth services list must have been submitted and received by February 10, 2021. Each request to add a service to the Medicare telehealth services list must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare telehealth services list, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare telehealth services list, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2022

Under our current policy, we add services to the Medicare telehealth services list on a Category 1 basis when we determine that they are similar to services on the existing Medicare telehealth services list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the Medicare telehealth services list that resemble those services already on the Medicare telehealth services list.

We received several requests to permanently add various services to the Medicare telehealth services list effective for CY 2022. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare telehealth services list. The requested services are listed in Table 15.

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TABLE 15: Requests for Permanent Addition – Services Not Proposed for Addition

Service Type	HCPCS	Long Descriptor
Urodynamics	51741	Complex uroflowmetry (e.g., calibrated electronic equipment)
Biofeedback	90901	Biofeedback training by any modality
	90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
	90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)
Neurological & Psychological Testing	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes
	96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
	96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
	96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
Therapy Procedures	97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
	97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97150	Therapeutic procedure(s), group (2 or more individuals)
Physical Therapy Evaluations	97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable

Service Type	HCPCS	Long Descriptor
		assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
Therapy Procedures	97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
Therapy Personal Care	97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
	97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes
	97542	Wheelchair management (e.g., assessment, fitting, training), each 15 minutes
Therapy Tests and Measurements	97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes
	97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
	97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
Personal Care	98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient
	98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients
	98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients
Evaluative and Therapeutic Services	92607	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour
	92608	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)
	92609	Therapeutic services for the use of speech-generating device, including programming and modification

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We remind stakeholders that the criterion for adding services to the Medicare telehealth list under Category 1 is that the requested services are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below, we find that none of the requested services met the Category 1 criterion.

We received a request to permanently add CPT code 51741 (*Complex uroflowmetry* (*e.g., calibrated electronic equipment*)) to the Medicare telehealth services list. This CPT code describes the acquisition of uroflowmetric information and analysis of that information. The code includes a technical component and a professional component. The technical component describes the acquisition of the uroflowmetric information when billed as a standalone service. The professional component describes the analysis for the uroflowmetric information when it is billed as a standalone service. As we have explained in previous rulemaking (see 83 FR 59483), the remote interpretation of diagnostic tests is not considered to be a telehealth service under section 1834(m) of the Act or our regulation at § 410.78. We do not believe that the technical component, which includes acquisition of the uroflowmetric information, will meet the criterion to

be added on a Category 1 basis, because it is not similar to other services on the Medicare telehealth list. Moreover, we do not believe the uroflowmetric information can be accurately and effectively collected using two-way, audio/video communications technology to the degree that will make the results clinically useful. We believe the patient would need to be in the same location as the equipment; thus, making it impracticable to achieve via telehealth. Due to these concerns, we do not believe that the submitted information demonstrates sufficient clinical benefit to support the addition of CPT code 51741 to the Medicare telehealth services list.

We received a request to permanently add several biofeedback, services, CPT codes 90901, 90912, and 90913, to the Medicare telehealth services list. We do not believe these services are similar to Category 1 services on the Medicare telehealth list in that these services describe the application of electrodes directly to the patient's skin and using them to monitor the patient's response. Therefore, we do not believe they meet the criterion for addition to the Medicare telehealth services list on a Category 1 basis. We also believe that proper application of electrodes and monitoring of the patient's response would require the furnishing practitioner to be in the same physical location as the beneficiary. As such, we do not believe these services meet the criteria for addition to the Medicare telehealth list on a Category 2 basis. When we reviewed these biofeedback services on a Category 2 basis, we found that the information supplied with the requests was not detailed enough to determine if the objective functional outcomes (that is, Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs) of the telehealth patients) were similar to that of patients treated in person. Moreover, we believe that the ADLs/IADLs alone are not sufficient to determine if these services, when performed via telehealth, demonstrate a clinical benefit to a patient. We request that stakeholders supply a more comprehensive set of objective data in order to fully illustrate any benefits, to better enable us to evaluate all outcomes.

We received requests to permanently add Neuropsychological/Psychological Testing services, CPT codes 96130–96133 and 96136–96139, to the Medicare telehealth services list. We separately reviewed each of the services in these two code families. In prior years' rulemaking, we have declined to add these services on a Category 1 basis because, in contrast to other services on the telehealth list, these services require close observation by the furnishing practitioner to monitor how a patient responds and progresses through the testing (see 81 FR 80197). We continue to believe that this is the case. All of these codes describe services that involve a very thorough observation and testing process, and require the tester to observe the following: Speed of responses; the ability to adjust focus; written, sometimes manual tasks; following tasks that display the patients' visuospatial mapping abilities, pattern recognition, abstraction, calculation—all while appreciating that the patient may be distracted or aided by environmental cues. The tester must also maintain some subjective amount of flexibility to allow the patient to be in their environment. Additionally, the tester has to maintain professional scrutiny through dynamic tasks. Given all of the above, remote observation by the furnishing practitioner to accomplish the testing in question seems impractical and potentially creates the risk of inaccuracies in diagnosis and subsequent treatment. We note that the information supplied by stakeholders did not address these concerns, and as such, we have concerns over patient safety and the ability of these services to be accurately and thoroughly performed via telehealth to demonstrate a clinical benefit to Medicare beneficiaries. Therefore, we do not believe these services meet the Category 2 criteria for permanent addition to the Medicare telehealth list of services. Consequently, we did not propose to add these services to the Medicare telehealth services list. We encourage stakeholders to submit information addressing the concerns we have stated in any future requests to have these services added to the Medicare telehealth list of services.

We received requests to add Therapy Procedures, CPT codes 97110, 97112, 97116, 97150, and 97530; Physical Therapy Evaluations, CPT codes 97161–97164; Therapy Personal Care services, CPT codes 97535, 97537, and 97542; and Therapy Tests and Measurements services, CPT codes 97750, 97755, and 97763, to the Medicare telehealth services list. In the CY 2017 PFS final rule (81 FR 80198), we noted that section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs) are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We also stated in the CY 2017 PFS final rule that, because these services are predominantly furnished by PTs, OTs, and SLPs, we did not believe it would be appropriate to add them to the Medicare telehealth services list at that time. In a subsequent request to consider adding these services for 2018, the original requester suggested that we might propose these services be added to the Medicare telehealth services list so that payment can be made for them when furnished via telehealth by physicians or practitioners who can serve as distant site practitioners. We stated that, since the majority of the codes are furnished over 90 percent of the time by therapy professionals who are not included on the statutory list of eligible distant site practitioners, we believed that adding therapy services to the Medicare telehealth services list could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth. We continue to believe this to be true; however, we reviewed each therapy service separately, and have categorized them together here for convenience as the same set of information accompanied the request for each of these services.

We determined that these services did not meet the Category 1 criteria for addition to the Medicare telehealth services because they are therapeutic in nature and in many instances involve direct physical contact between the practitioner and the patient. In assessing the evidence that was supplied by stakeholders in support of adding these services to the Medicare telehealth services list on a Category 2 basis, we concluded that it did not provide sufficient detail to determine whether all of the necessary elements of the service could be furnished remotely, and whether the objective functional outcomes of ADL and IADL for the telehealth patients were similar to those of patients receiving the services in person. As we stated above when discussing the request to add certain biofeedback services to the telehealth list, we do not believe ADLs and IADLS alone are sufficient to demonstrate clinical benefit to a Medicare beneficiary. We have enumerated above some examples of the types of clinical benefits we will consider when evaluating services using the Category 2 criterion.

Therefore, we do not believe the supplied information demonstrates that the services meet either the Category 1 or the Category 2 criteria. We did not propose to add these services to the Medicare telehealth services list. We

continue to encourage commenters to supply sufficient data for us to be able to see all measurements/parameters performed, so that we may evaluate all outcomes.

We received requests to add the services in Table 16, and we note that these services are generally not separately payable under the Medicare PFS. Given that these services are not separately payable when furnished in-person, they likewise will not be separately payable when furnished as telehealth. Section 1834(m)(2)(A) of the Act provides that payment for a service when furnished as a telehealth services is equal to the payment when the service is furnished in person. CPT code 90849 has a restricted payment status, indicating that claims must be adjudicated on a case-by-case basis when furnished in-person. Accordingly, any separate payment for that service will require special consideration and not be routine. Therefore, we do not believe this service should be added to the Medicare telehealth list. CPT codes 98960–98962 are bundled services, and therefore, payment for these services is always bundled into payment of other services. For that reason, we did not propose to add them to the Medicare list of telehealth services.

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TABLE 16: Requests for Permanent Addition—Services with Non-paid Status Not Proposed for Addition

Service Type	HCPCS	Long Descriptor	Medicare Payment Status Indicator
Psychotherapy	90849	Multiple-family group psychotherapy	R (Restricted)
Education and Training for Patient Self-Management	98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient	B (Bundled)
	98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients	
	98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients	

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We received requests to temporarily add Neurostimulators, CPT codes 95970–95972, and Neurostimulators, Analysis-Programming services, CPT codes 95983 and 95984, to the Medicare telehealth services list using the Category 3 criteria (see Table 17). In their submission, the requestor noted they would conduct a future study and would submit the study data to CMS at a later date. These services are on the expanded telehealth services list for the PHE, but were not added by CMS on a category 3 basis in the CY 2021 PFS final rule. We do not yet have sufficient information to adjudicate whether these services are likely to meet the category 1 or category 2 criteria given additional time on the Medicare telehealth services list, without having evaluated the full data, and we encourage commenters to submit all available information, when available, for future consideration. As a result, we did not propose to add these services to the Medicare telehealth list of services on a Category 3 basis at this time.

TABLE 17: Requests for Temporary Addition – Services Not Proposed for Addition

Service Type	HCPCS	Long Descriptor
Neurostimulators	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
Neurostimulators, Analysis-Programming	95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
	95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)

We received public comments on the requests to add services to the Medicare telehealth services list. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed disappointment that CMS did not propose to add Neurostimulators, CPT codes 95970–95972, and Neurostimulators, Analysis-Programming services, CPT codes 95983 and 95984, to the Medicare telehealth services list on a Category 3 basis. Commenters stated that, by not adding these services to the Medicare telehealth list on a Category 3 basis, CMS is risking disruption of care for patients who may have become accustomed to receiving these services as telehealth during the PHE.

Some commenters requested that CMS add all codes that were added to the Medicare telehealth services list on an interim basis (in response to the PHE for COVID–19) to the Medicare telehealth list on a Category 3 basis (Table 18), but these commenters did not provide any additional clinical information.

Many commenters opposed CMS' decision not to add CPT codes describing therapy services permanently to the list of Medicare telehealth services. They stated that adding these CPT codes to the list of covered telehealth services would better ensure a seamless transition if additional practitioners, such as physical therapists, become eligible to furnish and bill for telehealth services under Medicare.

Some commenters stated that CMS should maintain payment for Medicare telehealth services at the non-facility, rather than facility payment rates.

Response: We added services temporarily to the Medicare telehealth services list on an emergency basis to allow practitioners and beneficiaries to have access to medically necessary care while avoiding both risk for infection and further burdening healthcare settings during the PHE for COVID–19. The comments provided did not include sufficient clinical information to support adding these services to the telehealth services list. Absent additional clinical information from the commenters, we still believe that these services are not appropriate for addition on either a permanent or Category 3 basis; however, we are continuing to collect information on the use of these services during the PHE for COVID–19, and we invite stakeholders to provide additional information and to submit requests for addition to the telehealth list through our usual process. With regard to the comment requesting Medicare telehealth payment at the non-facility versus facility rate, we refer readers to discussion of this issue in the CY 2017 PFS final rule (81 FR 80199–

80201). Payment for telehealth services using the facility PE RVUs is consistent with our belief that the direct practice expense costs are generally incurred at the originating site where the beneficiary is located, and not by the distant site practitioner. With respect to commenters' concerns about potential disruption of care, we do not agree that this will occur. These services have been included on the Medicare telehealth services list only in response to the PHE for COVID–19. We believe patients and practitioners have a longstanding history of in-person delivery of care. We anticipate that the end of the PHE will not be declared abruptly, and note that healthcare has already begun to transition back to typical, in-person delivery.

After consideration of public comments, we are finalizing our proposal not to add the aforementioned codes to the telehealth list.

c. Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

In the CY 2021 PFS final rule (85 FR 84506), in response to the PHE for COVID–19, we created a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. We included in this category the services that were added during the PHE for COVID–19 for which we believed there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. We recognized that the services we added on a temporary basis under Category 3 will ultimately need to meet the criteria under Categories 1 or 2 in order to be permanently added to the Medicare telehealth services list, and that there was a potential for evidence development that could continue through the Category 3 temporary addition period. We also stated that any service added on a temporary basis under Category 3 will remain on the Medicare telehealth services list through the end of the calendar year in which the PHE for COVID–19 ends.

We added 135 services to the Medicare telehealth list in CY 2020 on an interim basis in response to the PHE for COVID–19 through the interim final rule with comment period (IFC) (March 31st COVID–19 IFC (85 FR 19234–19243) and the subregulatory process established in the May 8th COVID–19 IFC (85 FR 27550–27649). Since the publication of the May 8th COVID–19 IFC, we have added several services to the Medicare telehealth list of services using this subregulatory process (please see *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes* for the list of codes available for telehealth under the PFS). As discussed in the CY 2021 PFS final rule (FR 85 84507), at the conclusion of the PHE for COVID–19, associated waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through the regular notice-and-comment rulemaking process, including the previously established Medicare telehealth services list, as modified by subsequent changes in policies and additions to the telehealth services list adopted through rulemaking. Many services that were temporarily added on an interim basis during the PHE for COVID–19 will not be continued on the list after the end of the PHE for COVID–19.

Numerous stakeholders have continued to note that there is uncertainty about when the PHE for COVID–19 may end, and express concerns that the services added to the telehealth list on a temporary basis could be removed from the list before practitioners have had time to compile and submit evidence to support the permanent addition of these services on a Category 1 or Category 2 basis. To respond to these continuing concerns, we proposed to revise the timeframe for inclusion of the services we added to the Medicare telehealth services list on a temporary, Category 3 basis. Extending the temporary inclusion of these, Category 3 services on the telehealth list will allow additional time for stakeholders to collect, analyze, and submit data on those services to support their consideration for permanent addition to the list on a Category 1 or Category 2 basis.

We proposed to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. We noted that this proposal would allow us time to collect more information regarding utilization of these services during the pandemic, and provide stakeholders the opportunity to continue to develop support for the permanent addition of appropriate services to the telehealth list through our regular consideration process, which includes notice-and-comment rulemaking. By keeping these services on the Medicare telehealth services list through CY 2023, we will facilitate the submission of requests to add services permanently to the Medicare telehealth services list for consideration in the CY 2023 PFS rulemaking process and for consideration in the CY 2024 PFS rule.

We recognize that, during the time between the publication of the CY 2021 PFS final rule and this final rule, practitioners may have used that time to compile new evidence of clinical benefit to support addition to the Medicare telehealth services list on a Category 3 basis, including information that suggests that a certain service will likely meet the Category 1 or Category 2 criteria if provided with more time. We solicited comment on whether any of the services that were added to the Medicare telehealth list for the duration of the PHE for COVID–19 should now be added to the Medicare telehealth list on a Category 3 basis, to allow for additional data collection for submission for CMS to consider as part of the rulemaking process described in prior paragraphs.

We received public comments on the proposed revised timeframe for consideration of services added to the telehealth list on a temporary basis and our comment solicitation on any additional services we should consider under Category 3 criteria. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to maintain services temporarily added to the Medicare telehealth services list on a Category 3 basis through the end of CY 2023. Commenters stated that by extending the inclusion of these services on the telehealth services list through a set date that is not linked to the end of the PHE, CMS is eliminating the unnecessary suspense and confusion that would have come from a more abrupt change. Some commenters suggested that CMS extend the timeframe beyond the end of 2023, if the PHE is extended beyond that point.

Response: We appreciate commenters support for a more definitive timeframe for Category 3 codes to remain available on the Medicare telehealth services list. Consideration of any extensions at this time is outside the scope of this final rule.

Comment: Some commenters requested that CMS add certain therapy, audiology, and speech-language pathology services to the Medicare telehealth list on a Category 3 basis to facilitate the collection of information on how these services can be furnished via telehealth and so that these services may be furnished via telehealth outside of the PHE, billed incident to a physician's professional services. These commenters also suggested that this may also aid in CMS' efforts to continue to gather information on these services

when performed via telehealth. These commenters did not provide any additional clinical information to support their request.

Response: The commenters did not provide any additional clinical information with their request, especially clinical information that would satisfy our criteria for inclusion on the Medicare telehealth list, in any category. We are not finalizing addition of these services to the Medicare telehealth list.

Comment: Some commenters requested that CMS add CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) and HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session) to the Medicare telehealth list on a Category 3 basis. These commenters provided a number of studies on the safety and efficacy of at-home cardiac rehabilitation services.

Response: We agree with commenters that it would be appropriate to add CPT codes 93797 and 93798 and HCPCS codes G0422 and G0423 to the telehealth services list on a Category 3 basis. We also remind commenters that any services added on a Category 3 basis would ultimately need to meet the criteria for addition to the telehealth services list on either a Category 1 or 2 basis in order to be permanently added to the Medicare telehealth services list. In the future, we would expect to see evidence that the risk:benefit ratio of these services when provided via telehealth is clearly in favor of the patient and that the welfare of beneficiaries is not compromised nor are their outcomes diminished. We would also be interested in considering the patient characteristics which allow the treating practitioner to select the most appropriate recipients of these services via telehealth. As the evidence evolves on this subject matter, we welcome further discussion with stakeholders on this topic.

Comment: Many commenters requested that CPT codes 99441–99443 (Telephone evaluation and management services by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment) be added to the Medicare telehealth list on a Category 3 basis. The commenters noted that these codes could be used for mental health services and should be permanently available as part of the expansion of availability of mental health services via telehealth.

Response: We note that for services for the diagnosis, evaluation or treatment of mental health conditions, we are finalizing a policy to revise the definition of ''telecommunications system'' for purposes of section 1834(m) of the Act to allow the use of audio-only technology under certain circumstances, described in detail below, that will allow visits and others services furnished via audio-only technology to be reported as telehealth services with the appropriate modifier. For example, the office/outpatient E/M codes are on the telehealth list permanently and when used to describe care for mental health conditions, will be reportable when furnished via audio-only technology to patients in their homes. Since audio-only telecommunications technology can be used to furnish mental health telehealth services to patients in their homes, the addition of these codes to the telehealth services list is unnecessary for mental health telehealth services. For telehealth services other than mental health care, we continue to believe that two-way, audio/video communications technology is the appropriate, general standard that will apply for telehealth services after the PHE, so we do not believe it would be appropriate for these codes to remain on the telehealth list after the end of the PHE.

After consideration of public comments, we are finalizing as proposed the revised timeframe for inclusion of the services we added to the Medicare telehealth services list on a temporary, Category 3 basis. We will retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. Additionally, we are adding CPT codes 93797 and 93798 and HCPCS codes G0422 and G0423 to the Category 3 Medicare telehealth services list. These services appear on the list of telehealth services on the CMS telehealth website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html* with a status of ''Available through December 31, 2023.''

d. Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

The Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260, December 27, 2020) included a number of provisions pertaining to Medicare telehealth services. The Medicare telehealth statute at section 1834(m)(4)(C) of the Act generally limits the scope of telehealth services to those furnished in rural areas and in certain enumerated types of ''originating sites'' including physician offices, hospitals, and other medical care settings. Section 1834(m)(7) of the Act, (as added by section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018), specifies that the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply, and includes the patient's home as a permissible originating site, for telehealth services furnished to a patient with a diagnosed substance use disorder (SUD) for treatment of that disorder or a co-occurring mental health disorder. Section 123(a) of Division CC of the CAA amended section 1834(m)(7)(A) of the Act to broaden the scope of services for which the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply and for which the patient's home is a permissible originating site to include telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE for COVID–19.[1]

Section 123(a) of the CAA also added subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a telehealth service furnished in the patient's home under paragraph (7) unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. However, section 123(a) of the CAA added a clarification at section 1834(m)(7)(B)(ii) of the Act that the periodic requirement for an in-person item or service does not apply if payment for the telehealth service furnished would have been allowed without the new amendments. As such, the requirement for a periodic

[1] We note that neither the SUPPORT Act nor the CAA amended section 1862 of the Act. Section 1862(a)(4) of the Act and our corresponding regulation at 42 CFR 411.9 prohibit Medicare payment for services that are not furnished within the United States. Both the originating site and the distant site are subject to the statutory payment exclusion.

in-person item or service applies only for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder other than for treatment of a diagnosed SUD or co-occurring mental health disorder, and only in locations that do not meet the geographic requirements in section 1834(m)(4)(C)(i) of the Act or when the originating site is the home of the patient, regardless of geography. We solicited comments on whether we should adopt a claims-based mechanism to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not (in other words, the services for which payment was newly authorized by the CAA amendments, and those for which payment was authorized before the CAA amendments), and if so, what that mechanism should be. In the event that we need to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not, we also solicited comments on whether a clarification should be added to the regulation at § 410.78 as follows (which will take into account the other amendments we proposed to § 410.78):

The requirement that the physician or practitioner must furnish an item or service in person, without the use of telehealth, within a specified time frame shall not apply to telehealth services furnished for treatment of a diagnosed substance use disorder or co-occurring mental health disorder, or to services furnished in an originating site described in paragraphs (b)(3)(i) through (viii) or (xiii) that meets the geographic requirements specified in paragraph (b)(4) other than paragraph (b)(4)(iv)(D).

As we noted above, section 123(a) of the CAA amends section 1834(m)(7)(B)(i)(I) of the Act to prohibit payment for telehealth services under that paragraph unless the physician or practitioner furnished an item or service to the patient in person, without the use of telehealth, within 6 months before the first telehealth service. Thereafter, section 1834(m)(7)(B)(i)(II) of the Act leaves the Secretary discretion to specify the times or intervals at which an in-person, non-telehealth service is required as a condition of payment for these telehealth services. Therefore, in order to implement the new statutory requirement to specify when an in-person service is required, we proposed that, as a condition of payment for a mental health telehealth service described in section 1834(m)(7)(A) of the Act other than services described in section 1834(m)(7)(B)(ii) of the Act (that is, services for which payment was authorized before the CAA amendments), the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of the telehealth service.

We also solicited comments on whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service. We note that the language in the CAA states that the physician or practitioner furnishing the in-person, non-telehealth service must be the same person as the practitioner furnishing the telehealth service. There are several circumstances, however, under which we have historically treated the billing practitioner and other practitioners of the same specialty or subspecialty in the same group as if they were the same individual. For instance, for purposes of deciding whether a patient is a new or established patient, or whether to bill for initial or subsequent visit, practitioners of the same specialty/subspecialty in the same group are treated as the same person. For example, when Physician A and Physician B are of the same specialty and subspecialty and in the same group, if Physician A furnishes an initial critical care service to a patient, and Physician B subsequently furnishes additional critical care services to the same beneficiary for the same condition on the same day, Physician B will bill for a subsequent critical care service rather than an initial critical care visit. As we explain in section II.F of this final rule, because practitioners in the same specialty and same group often cover for one another to provide concurrent services, we believe the total time for critical care services furnished to a patient on the same day by the practitioners in the same group with the same specialty should be reflected as if it were a single set of critical care services furnished to the patient. See section II.F.2 of this final rule for further discussion of our current policies for billing critical care services. Similarly, if Physician A furnished a service to a patient, and then Physician B furnished a service to the patient a few months later, that patient will be considered an established patient with respect to both Physician A and Physician B. For example, Physician B could initiate care management services for the patient as an established patient. An example of guidance to this effect can be found in the Medicare Claims Processing Manual (IOM Pub. 100–04, Chapter 12, § 30.6.7), which defines ''new patient'' as a patient who has not received any professional services, that is, E/M service or other face-to-face service (for example, surgical procedure) from the physician or physician group (same physician specialty) within the previous 3 years, for E/M services.

We note that this manual provision is also consistent with CPT guidance on whether a patient is a new or established patient.[2]

We solicited comments regarding the extent to which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty in that group for treatment of the same condition. This might occur when practitioners in a group cover for each other when a particular practitioner is unavailable or when a practitioner has left the group, but the beneficiary continues to receive services furnished by the group. In addition, fee-for-time compensation arrangements (formerly referred to as locum tenens arrangements), as described in section 1842(b)(6)(D) of the Act, allow for payment to be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if the first physician is unavailable to provide the services, and the services are furnished pursuant to an arrangement that is either informal and reciprocal, or involves per diem or other fee-for-time compensation for such services.

Recognizing the importance of ensuring access to mental health telehealth services for beneficiaries who are unable to see the same practitioner who furnished the prerequisite in-person services due to the practitioner's unavailability, we solicited comments on an alternative policy to also allow the prerequisite in-person, non-telehealth service for certain mental health telehealth services to be furnished by a practitioner in the same specialty/subspecialty in the same group when the physician or practitioner who furnishes the telehealth service is unavailable or the two professionals are practicing as a team.

As amended by the CAA, section 1834(m)(7)(B)(i)(II) of the Act specifies that for subsequent mental health telehealth service, an in-person, non-telehealth service is required at such

[2] American Medical Association. (2020). *CPT 2021 professional edition*. Chicago, Ill.: American Medical Association.

times as the Secretary determines appropriate. We proposed to require that an in-person, non-telehealth service must be furnished by the physician or practitioner at least once within 6 months before each telehealth service furnished for the diagnosis, evaluation, or treatment of a mental health disorder by the same practitioner, other than for treatment of a diagnosed SUD or co-occurring mental health disorder, and that the distinction between the telehealth and non-telehealth services must be documented in the patient's medical record. We are clarifying here that, consistent with the conditions specified in section 1834(m)(7)(B)(i) of the Act, the in-person non-telehealth service requirements apply only to telehealth services furnished to a patient in a home originating site. We distinguish between mental health services furnished for a diagnosed SUD or co-occurring mental health disorder and those furnished to beneficiaries without a SUD diagnosis on the basis of ICD–10 diagnosis codes included on claims when the services are billed. We chose this interval because we are concerned that an interval less than 6 months may impose potentially burdensome travel requirements on the beneficiary, but that an interval greater than 6 months could result in the beneficiary not receiving clinically necessary in-person care/observation. The 6-month interval also matches the specified statutory interval for the initial telehealth service. We believe that a 6-month interval strikes an appropriate balance between these competing considerations, but solicited comments on whether a different interval, whether shorter, such as 3–4 months or longer, such as 12 months, may be appropriate to balance program integrity and patient safety concerns with increased access to care. We noted, however, that regardless of the time interval we establish, the practitioner is not precluded from scheduling in-person visits at a more frequent interval, should such visit be determined to be clinically appropriate or preferred by the patient.

As discussed below in this section of this final rule, ''e. Payment for Medicare Telehealth Services Furnished Using Audio-Only Communications Technology,'' we proposed to revise our regulatory definition of ''interactive telecommunications system'' to permit use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home. Therefore, we solicited comments on whether it would be appropriate to establish a different interval for these telehealth services, for the diagnosis, evaluation, or treatment of mental health disorders, other than for treatment of diagnosed SUD or co-occurring mental health disorder, when furnished as permitted through audio-only communications technology.

In any event, we proposed that there would need to be an in-person visit within 6 months of any telehealth service furnished for the diagnosis, evaluation, or treatment of mental health disorders (other than for treatment of a diagnosed SUD or co-occurring mental health disorder), and the in-person visit would need to be documented in the patient's medical record. Payment would not be made for these telehealth services unless the required in-person service was furnished within 6 months of the telehealth service.

Given the addition of the home of the individual as a permissible originating site for telehealth services for purposes of diagnosis, evaluation, or treatment of a mental health disorder, we proposed to revise our regulation at § 410.78(b)(3) to add a new paragraph (xiv) to identify the home of a beneficiary as an originating site for telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the first day after the end of the PHE as defined § 400.200 of our regulations; and to provide that payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months of the telehealth service. We also proposed to revise our regulation at § 410.78(b)(4)(iv)(D) to specify that the geographic restrictions in § 410.78(b)(4) do not apply to telehealth services furnished for the diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the first day after the end of the PHE as defined in our regulation at § 400.200.

In addition, section 125(c) of the CAA amended section 1834(m)(4)(C)(ii) of the Act to add to the list of permissible telehealth originating sites a rural emergency hospital, which is a new Medicare provider type added by section 125 of the CAA effective beginning in CY 2023.

We also proposed to amend our regulation at § 410.78, Telehealth services, to conform with the statutory change to include rural emergency hospitals as telehealth originating sites beginning in CY 2023. In accordance with section 1834(m)(4)(C)(ii)(XI) of the Act, as added by section 125(c) of the CAA, we proposed to revise § 410.78(b)(3) of our regulations to add a rural emergency hospital, as defined in section 1861(kkk)(2) of the Act, as a permissible originating site for telehealth services furnished on or after January 1, 2023.

We received public comments on the implementation of provisions of the CAA, 2021. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposals to implement sections 123 and 125 of the CAA, 2021.

Many commenters opposed our proposal to require an in-person, non-telehealth visit every 6 months for beneficiaries receiving mental health telehealth services in their home under the amendments made by section 123 of the CAA, 2021. They opined that requiring another in-person visit would be excessive and limit access to services, particularly given the ongoing shortage of mental health practitioners, and that the telehealth practitioner should be able to use professional judgement as to when an in-person interaction is necessary. Some commenters also noted that, during the PHE for COVID–19, there have been no requirements for in-person visits, and this illustrates that the in-person requirement is unnecessary. Other commenters stated that if we do require a subsequent in-person, non-telehealth visit, then the required in-person visit interval should be extended as long as possible, for example at least 12 months. Some commenters also suggested, in keeping with the definition of an established patient, that if CMS were to implement a requirement for in-person services, they should consider an interval of once every 3 years. Other commenters suggested CMS implement a list of exceptions to any in-person visit requirement that could be noted in the medical record, and allow the patient to opt out of the requirement.

Some commenters, such as MedPAC, supported our proposal to require in-person, non-telehealth visits for beneficiaries receiving mental health services via telehealth, stating that this policy would help safeguard beneficiaries and the Medicare program from fraud. MedPAC also noted that this requirement may limit access to mental health services via telehealth, and encouraged CMS to study the impact of this policy and consider adjustments through future rulemaking. MedPAC

also recommended that CMS apply additional scrutiny to outlier clinicians who bill many more telehealth services per beneficiary than other clinicians or who bill for a high number of services in a week or a month, and prohibit ''incident to'' billing for telehealth services provided by any clinician who can bill Medicare directly.

Response: We appreciate the many comments and suggestions regarding our implementation of the amendments made by section 123 of the CAA, especially regarding the frequency with which a beneficiary receiving mental health services in their home through telehealth would need to receive an in-person, non-telehealth service. While we agree with MedPAC and others that requiring an in-person, non-telehealth service for beneficiaries receiving mental health services via telehealth in their home may help to safeguard beneficiaries and the Medicare program from possible program integrity issues we must balance those concerns with concerns raised by commenters about ensuring access to valuable (and underutilized) mental health services. We are also concerned about access to services, particularly given the ongoing shortage of mental health practitioners, and that there is not a ''one size fits all'' model in the management of mental health where some patients may require more frequent in-person visits and some may require less, which is also why we have an exceptions process. Therefore, in response to comments, we are finalizing an interval for the in-person visit requirement of 12 months, rather than the proposed 6-month timeframe.

We note that patients and practitioners should ultimately determine the cadence of meeting during the year, who may decide to meet more often than annually, which is permissible under our policy, as driven by clinical needs on a case-by-case basis. Further, the exceptions process will allow for situations where an in-person annual visit is not needed. CMS will monitor claims data regarding use of telehealth mental health services to identify areas for further investigation and to inform future rulemaking, including situations where there is evidence beneficiaries are potentially experiencing adverse health outcomes or increased difficulty accessing in-person care, or if inappropriate use or billing of telehealth mental health services is suspected.

We also agree with commenters that there may be specific circumstances when an in-person visit requirement within 12 months of each mental health telehealth service furnished in a beneficiary's home may be inadvisable or impracticable for an individual beneficiary. If the patient and practitioner consider the risks and burdens of an in-person service and agree that, on balance, these outweigh the benefits (such as the opportunity to assess in-person body language or conducting a physical exam to monitor for medication side effects), and the practitioner documents the basis for that decision in the patient's medical record, then the in-person visit requirement is not applicable for that 12-month period. Therefore, we are finalizing our proposed policy with a modification to require, in general, that after the first mental health telehealth service in the patient's home, there must be an in-person, non-telehealth service within 12 months of each mental health telehealth service—but to allow for limited exceptions to the requirement. Specifically, if the patient and practitioner agree that the benefits of an in-person, non-telehealth service within 12 months of the mental health telehealth service are outweighed by risks and burdens associated with an in-person service, and the basis for that decision is documented in the patient's medical record, the in-person visit requirement will not apply for that particular 12-month period. For example, situations in which the risks and burdens associated with an in-person service may outweigh the benefit could include, but are not limited to instances when an in-person service is likely to cause disruption in service delivery or has the potential to worsen the patient's condition(s). The risks and burdens associated with an in-person service could also outweigh the benefit if a patient is in partial or full remission and only requires a maintenance level of care. Other examples of such instances may include the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the patient's condition, creating undue hardship on self or family, or if it is determined that the patient is at risk for disengagement with care that has been effective in managing the illness. Practitioners must also document that the patient has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies. Practitioners must note the exception for any applicable 12-month interval. We note that there is no exception to the statutory requirement that the physician or practitioner must furnish to the beneficiary an in-person, non-telehealth service within 6 months prior to initiation of mental health services via telehealth.

Comment: Many commenters agreed with the alternative policy we considered to allow the required in-person, non-telehealth service to be furnished by another physician or practitioner of the same specialty and subspecialty in the same group as the practitioner who furnishes the mental health telehealth service to the beneficiary if the practitioner who furnishes the telehealth service is unavailable.

Response: We are adopting the alternative policy discussed in the proposed rule to allow a clinician's colleague in the same subspecialty in the same group to furnish the in-person, non-telehealth service to the beneficiary if the original practitioner is unavailable. This is also consistent with longstanding policy, which defines an established patient as an individual who receives professional services from the physician/NPP or another physician of the same specialty and subspecialty who belongs to the same group within the previous three years, for purposes of billing for E/M services.

Comment: A few commenters provided suggestions as to how CMS would distinguish between mental health services provided to beneficiaries in their homes via telehealth that co-occur with a SUD (and therefore, would not be subject to the requirement for an in-person, non-telehealth visit every 6 months) and those that are not co-occurring with a SUD. A few commenters stated that use of a mental health or behavioral health diagnosis code(s) on the claim (for which no substance use disorder code is reported), place of service is home, and for which modifier 95 is used would identify a mental health telehealth visit that is newly covered under the CAA.

Response: We will consider these suggestions and undertake future rulemaking as necessary. We note that we are not finalizing any changes to our policies regarding payment for telehealth services furnished for treatment of a patient with a diagnosed SUD or co-occurring mental health disorder, although we are clarifying that these telehealth services are considered mental health services for purposes of the audio-only policy we are finalizing as discussed in the section that follows below.

Comment: A few commenters requested that CMS implement a broad definition of the term ''home'' in terms of mental healthcare delivery site, as a strict definition would only serve to exacerbate existing socioeconomic barriers and reduce access to care for an already underserved and vulnerable patient population. For example, some

patients may not have access to traditional living space, as they may be living in places such as shelters and transitional housing or lack access to housing entirely. According to these commenters, requiring patients to access telehealth from their own residence creates an unnecessary barrier to telehealth services and may reinforce health inequities for individuals of lesser financial means. Commenters further pointed out that, for privacy reasons, a beneficiary may not be comfortable receiving mental health services in their home and may wish to receive mental health services in a temporary location, such as a car or other private location.

Response: Our definition of home, both in general and for this purpose, can include temporary lodging, such as hotels and homeless shelters. We clarify that for circumstances where the patient, for privacy or other personal reasons, chooses to travel a short distance from the exact home location during a telehealth service, the service is still considered to be furnished ''in the home of an individual'' for purposes of section 1834(m)(4)(C)(ii)(X) of the Act.

After consideration of public comments, we are finalizing the proposed amendments to our regulation at § 410.78, Telehealth services, to implement the amendments made by section 123 of the CAA as explained above, with some modifications. We are finalizing amendments to § 410.78(b)(3) and (4) to add the home of a beneficiary as an originating site for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders, to specify that the geographic restrictions do not apply to these services, to add the conditions of payment requiring an in-person, non-telehealth visit within 6 months of the mental health telehealth service in the patient's home, and to add the exception for subsequent mental health telehealth services when the risks and burdens outweigh the benefits of this requirement. Specifically, we are modifying the proposed amendments to clarify that payment will not be made for a telehealth service furnished under § 410.78(b)(3)(xiv) unless the following conditions are met:

(1) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service;

(2) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, at least once within 6 months of each subsequent telehealth service described in this paragraph, with exceptions as noted above.

(3) The requirements of paragraph (2) may be met by another physician or practitioner of the same specialty and subspecialty in the same group as the physician or practitioner who furnishes the telehealth service, if the physician or practitioner who furnishes the telehealth service described under this paragraph is not available.

We are also finalizing our proposal to add a rural emergency hospital, as defined in section 1861(kkk)(2) of the Act, as a permissible originating site.

We are also clarifying that, as proposed, our definition of home can include temporary lodging such as hotels and homeless shelters as well as locations a short distance from the beneficiary's home.

e. Payment for Medicare Telehealth Services Furnished Using Audio-Only Communications Technology

Section 1834(m) of the Act outlines the requirements for Medicare payment for telehealth services that are furnished via a ''telecommunications system,'' and specifies that, only for purposes of Medicare telehealth services through a Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term ''telecommunications system'' includes asynchronous, store-and-forward technologies. We further defined the term, ''telecommunications system,'' in the regulation at § 410.78(a)(3) to mean an interactive telecommunications system, which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communications between the patient and distant site physician or practitioner.

During the PHE for COVID–19, we used waiver authority under section 1135(b)(8) of the Act to temporarily waive the requirement, for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology. Therefore, for certain services furnished during the PHE for COVID–19, we make payment for these telehealth services when they are furnished using audio-only communications technology. Emergency waiver authority is no longer available after the PHE for COVID–19 ends, and telehealth services will again be subject to all statutory and regulatory requirements.

In the CY 2021 PFS final rule (85 FR 84535), we noted that we continued to believe that our longstanding regulatory definition of ''telecommunications system'' reflected the intent of statute and that the term should continue to be defined as including two way, real-time, audio/video communications technology.

Historically, we have not proposed any permanent modifications to the definition of ''interactive telecommunications system'' to allow for use of audio-only communications technology due to our interpretation of the statutory requirements, as well as concerns over program integrity and quality of care. Specifically, we were concerned that the use of audio-only communications technology for Medicare telehealth services could lead to inappropriate overutilization, and believed that video visualization of the patient generally was necessary to fulfill the full scope of service elements of the codes included on the Medicare telehealth list. We believe it is reasonable to reassess these concerns, given the now widespread utilization during the PHE for COVID–19 of Medicare telehealth services furnished using audio-only communications technology. Based upon an initial review of claims data collected during the PHE for COVID–19, which describe audio-only telephone E/M services, we observed that the audio-only E/M visits have been some of the most commonly performed telehealth services during the PHE, and that most of the beneficiaries receiving these services were receiving them for treatment of a mental health condition. Given the generalized shortage of mental health care professionals (*https://bhw.hrsa.gov/data-research/review-health-workforce-research*), and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, we believe beneficiaries may have come to rely upon the use of audio-only communications technology in order to receive mental health services, and that a sudden discontinuation of this flexibility at the end of the PHE could have a negative impact on access to care.

As explained above, section 123 of the CAA removes the geographic restrictions for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder, and adds the patient's home as a permissible originating site for these telehealth services. We also believe that mental health services are different from

most other services on the Medicare telehealth services list in that many of the services primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to provision of the service. While we continue to believe that two-way, audio/video communications technology is the appropriate, general standard for telehealth services, and that there may be particular instances where visual cues may help a practitioner's ability to assess and treat patients with mental health disorders, especially where opioids or mental health medications are involved (for example, visual cues as to patient hygiene, or indicators of self-destructive behavior), we note that stakeholders have suggested to us that the availability of telehealth services for mental health care via audio-only communications technology will increase access to care. This is especially true in areas with poor broadband infrastructure and among patient populations that do not wish to use, do not have access to, and/or are unable to utilize devices that permit a two-way, audio/video interaction. Our preliminary analysis of Medicare claims data, as well as information provided to us by stakeholders on the popularity of these services, indicates that use of interactive communications technology for mental health care will likely continue to be high even beyond the circumstances of the COVID–19 pandemic. According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth during the PHE for COVID–19, utilization of telehealth for many professional services spiked around April 2020 and has diminished over the ensuing months. In contrast, preliminary analysis of Medicare claims data suggests that, for many mental health services that were permanently and temporarily added to the Medicare Telehealth list, there is a steady utilization trend from April 2020 and thereafter. Furthermore, as described above, according to preliminary analysis of claims data which examined utilization by diagnosis, the codes for audio-only E/M services have been highly utilized during the PHE, particularly for beneficiaries with mental health conditions.

Given these considerations, we now believe that it will be appropriate to revisit our regulatory definition of ''interactive telecommunications system'' beyond the circumstances of the PHE to allow for the inclusion of audio-only services under certain circumstances. Therefore, we proposed to amend our regulation at § 410.78(a)(3) to define interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. We believe this proposal is consistent with the expansion of at-home access to mental health telehealth services in section 1834(m)(7) of the Act, as amended by section 123 of the CAA, which required that the beneficiary must have received a Medicare-paid (or payable), in-person item or service from the physician or practitioner furnishing the mental health services through telehealth within 6 months of the first mental health telehealth service. We proposed to adopt a similar, ongoing requirement that an in-person item or service must be furnished within 6 months of such a mental health telehealth service. We reiterate that our policy to permit audio-only telehealth services is limited to services where the home is the originating site. This is because the other enumerated telehealth originating sites are medical settings that are far more likely to have access to reliable broadband internet service. When a patient is located at one of these originating sites, access to care is far less likely to be limited by access to broadband that facilitates a video connection. In contrast, access to broadband, devices, and user expertise to enable a video connection is less likely to be available in the patient's home. As described in prior paragraphs, we also believe that mental health services are distinct from other kinds of services on the Medicare telehealth list in that many of the services do not necessarily require visualization of the patient to fulfill the full scope of service elements

We also proposed to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communication technology, in instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. We believe that this requirement will ensure that mental health services furnished via telehealth are only conducted using audio-only communications technology in instances where the use of audio-only technology is facilitating access to care that would be unlikely to occur otherwise, given the patient's technological limitations, abilities, or preferences. In the interests of monitoring utilization and program integrity concerns for audio-only telehealth services furnished under the terms of this exception, we proposed to create a service-level modifier that would identify these mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. The use of this modifier will also serve to certify that the audio-only telehealth service meets the requirements for the exception specified in § 410.78(a)(3), including that the furnishing physician or practitioner has the capacity to furnish the service using interactive two-way, real-time audio/video communications technology, but instead used audio-only technology under the conditions specified in the regulation.

We proposed to amend our regulation at § 410.78(a)(3) to specify that an interactive telecommunications system can include interactive, real-time, two-way audio-only technology for telehealth services furnished for the diagnosis, evaluation, or treatment of a mental health disorder as described under paragraph (b)(4)(D), under the following conditions: The patient is located in their home at the time of service as described at § 410.78 (b)(3)(xiv); The distant site physician or practitioner has the technical capability at the time of the service to use an interactive telecommunications system that includes video; and the patient is not capable of, or does not consent to, the use video technology for the service.

We solicited comments on these proposals, as well as what, if any, additional documentation should be required in the patient's medical record to support the clinical appropriateness of providing audio-only telehealth services for mental health in the event of an audit or claims denial. Additional required documentation could include information about the patient's level of risk and any other guardrails that are appropriate to demonstrate clinical appropriateness, and minimize program integrity and patient safety concerns.

We solicited comment on whether, for purposes of the proposed audio-only mental health telehealth services exception, we should exclude certain higher-level services, such as level 4 or 5 E/M visit codes, when furnished alongside add-on codes for psychotherapy, or codes that describe psychotherapy with crisis. We solicited comment on whether the full scope of service elements for these codes could be performed via audio-only communications technology. However, we also noted that maintaining the

availability of these services through audio-only communications technology might give patients access to care needed to address their higher level or acute mental health needs in instances where they are unable to access two-way, audio/video communications technology.

We received public comments on the payment for Medicare telehealth services furnished using audio-only communications technology. The following is a summary of the comments we received and our responses.

Comment: Commenters were very supportive of our proposal to allow for mental health services to be furnished using audio-only communications technology. A few commenters, while supportive of the use of audio-only communications technology during the PHE, urged CMS to further study and evaluate the safety and effectiveness of the audio-only modality for various levels of care and treatments to determine appropriateness of continuing payment after the PHE expires.

Some commenters requested that CMS allow office/outpatient E/M services furnished via telehealth to be conducted via audio-only communications technology, at least through the end of year in which the PHE ends. Some commenters requested that CMS clarify that SUD services are considered mental health services for purposes of the expanded definition of ''interactive telecommunications system'' to include audio-only services under § 410.78(a)(3), as well as to ensure that the periodic in-person non-telehealth visit requirements would not apply when audio-only communications technology is used for services for the treatment of a SUD or co-occurring mental health disorder to established patients with a SUD diagnosis. Other commenters suggested that CMS allow all Medicare telehealth services, not just mental health services, to be conducted via audio-only communications technology. Some commenters requested that CMS permit audio-only communications technology to be used to furnish psychological and neuropsychological testing evaluation (CPT codes 96130–96133) and Health Behavior Assessment and Intervention (HBAI) services (CPT codes 96156–96171) as these services do not require visualization of the patient. Some commenters expressed disappointment that CMS did not propose to continue payment beyond the PHE for COVID–19 for CPT codes 99441–99443, which describe audio-only office/outpatient visits, as the commenter believes these services are also important for beneficiaries who do not have access to two-way, audio/video communications technology.

Response: As we explain above, we continue to believe that mental health services are different from most other services on the Medicare telehealth services list in that they primarily involve verbal conversation where visualization between the patient and the furnishing physician or practitioner may be less critical to provision of the service. We continue to believe that office/outpatient E/M visits furnished via telehealth that are not for the diagnosis, evaluation, or treatment of a mental health disorder are most appropriately furnished via an interactive telecommunications system that includes two-way, audio/video communications technology. We would like to clarify that SUD services are considered mental health services for purposes of the expanded definition of ''interactive telecommunications system'' to include audio-only services under § 410.78(a)(3). CMS used waiver authority under section 1135(b)(8) of the Act to waive the video requirement under the regulation at § 410.78(a)(3) during the pandemic for certain behavioral health and/or counseling services, and this waiver expires with the expiration of the PHE. We proposed to amend the definition of interactive telecommunications system to include audio-only technology only for certain mental health telehealth services; and we continue to believe that, except for those mental health services and outside the circumstances of the PHE, it is appropriate to continue the current policy of defining ''interactive telecommunications system'' as technology that allows two-way, real-time interactive audio and video communications.

Regarding telephone E/M services CPT codes 99441, 99442, and 99443, please see above for a discussion of these services These telephone E/M codes will remain on the telehealth services list temporarily through the end of the PHE for COVID–19.

Comment: A few commenters suggested other conditions for which audio-only communications technology could be appropriate, such as neurologic services in treatment for headache, seizure, dementia, pain, along with adherence and side-effect follow-up. Other commenters stated that audio-only technology could also be used for other conditions such as patients with chronic pain or for provision of MNT services.

Response: As stated earlier, we continue to believe that mental health services are different from other services because they principally involve verbal exchanges between patient and practitioner. We note that the home is not a permissible originating site for the vast majority of telehealth services; that the geographic limitations for telehealth originating sites apply outside the circumstances of the PHE; and that, when telehealth services are furnished in an originating site other than the patient's home, the facility/office that serves as the originating site should have available broadband/video to allow the patient the ability to have real-time, audio/video interaction with their physician/practitioner. Additionally, given that payment for Medicare telehealth services under section 1834(m) of the Act is at the same rate as for in-person services, we have some concerns about making sure that the telehealth service provided is a sufficiently close substitute for what the patient would get in an in-person service. As such, we are not expanding the scope of Medicare telehealth services for which audio-only communications technology may be used to include services other than those furnished in the home to diagnose, evaluate or treat a mental health condition.

Comment: Commenters supported the proposal to create a service-level modifier to identify mental health telehealth visits ''furnished to a beneficiary in their home using audio-only communications technology.'' Some commenters stated that the creation of a service-level modifier to identify telehealth services furnished using audio-only would help facilitate further study of the use of audio-only technology for telehealth services.

Some commenters did not support additional documentation requirements for audio-only visits beyond those already required, while others recommended that CMS require practitioners to document the reason the beneficiary declined to participate in a live, two-way video visit and specify if it was due to lack of access, the inability to use the technology, or the patient's unwillingness to consent.

A few commenters suggested that CMS remove the requirement that the practitioner have access to two-way, audio/video communications technology in order to furnish audio-only telehealth services, stating that practitioners in rural areas may not have access to reliable broadband and should not be precluded from providing audio-only telehealth services due to this lack of access.

Response: We appreciate commenters' concerns. However, we continue to believe that, because a telehealth service

is generally analogous to and must include the elements of the in-person service, it is generally appropriate to continue to require the use of two-way, real-time audio/video communications technology to furnish the service. Therefore, we are maintaining the requirement that distant site physicians and practitioners must have the technical capability to use an interactive telecommunications system that includes two-way, real-time, interactive audio and video communications at the time that an audio-only telehealth service is furnished. With regard to documentation requirements, we are finalizing a requirement that the reason for using audio-only technology to furnish a telehealth service must be documented in the patient's medical record.

Comment: A few commenters provided examples of services that they believe should not be conducted via audio-only communications technology. These included: Level 4 and 5 office visits as well as services describing psychotherapy for crisis (CPT codes 90839–90840), group psychotherapy (CPT code 90853), psychological and neuropsychological testing (CPT codes (96130–96133 and 96136–96139), psychological and neuropsychological testing), and Applied Behavior Analysis Therapy (CPT codes 97151–97157).

Other commenters stated that there should be no restrictions on furnishing higher level mental health telehealth visits to patients in the home via audio-only technology.

In response to our statement regarding utilization of CPT codes 99441–99443 (telephone E/M services), a few commenters requested the agency share with the public the audio-only utilization data that has been collected during the public health emergency to provide stakeholders with a better understanding of how these services have been utilized outside of the treatment of mental health conditions.

Response: We would like to thank commenters for their support and suggestions. We continue to believe that real-time, audio-video telehealth interactions are the standard for Medicare telehealth services in most instances. We will continue to consider how the delivery of certain services via telehealth impacts patient care, and we encourage stakeholders to submit requests with supporting documentation using our process for the addition or removal of services on the Medicare telehealth services list. Regarding CPT codes 99441–99443, which describe telephone E/M services, please find our discussion earlier in this preamble. In response to the request for utilization data on audio-only telehealth services furnished during the PHE for COVID–19, we refer readers to publicly available utilization data (an example available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems*).

After consideration of public comments, we are finalizing as proposed creation of a service-level modifier for use to identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. We are also amending our regulation at § 410.78(a)(3) to specify that an interactive telecommunications system can include interactive, real-time, two-way audio-only technology for telehealth services furnished for the diagnosis, evaluation, or treatment of a mental health disorder as described under paragraph (b)(4)(iv)(D), under the following conditions: The patient is located in their home at the time of service as described at § 410.78 (b)(3)(xiv); the distant site physician or practitioner has the technical capability at the time of the service to use an interactive telecommunications system that includes video; and the patient is not capable of, or does not consent to, the use of video technology for the service. We are also clarifying that SUD services are considered mental health services for purposes of the amended definition of ''interactive telecommunications system'' to include audio-only services under § 410.78(a)(3). We anticipate that this will have a positive impact on access to care for mental health conditions and contribute to overall health equity.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Expiration of PHE Flexibilities for Direct Supervision Requirements

Under section 1861 of the Act and at § 410.32(b)(3) of the regulations, Medicare requires certain types of services to be furnished under specific levels of supervision of a physician or practitioner, including diagnostic tests, services incident to physician services, and other services. For professional services furnished incident to the services of a billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), requirements for immediate availability and accessibility of a physician are considered to be satisfied if the physician meets the requirements for direct supervision for physician office services at § 410.26 and for hospital outpatient services at § 410.27. Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service, and we have interpreted this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability.

Through the March 31st COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In that rule, we also solicited comment on issues related to the policy allowing virtual provision of direct supervision, specifically whether there should be any additional guardrails or limitations put in place to ensure patient safety/clinical appropriateness, beyond typical clinical standards, and whether we should consider potential restrictions to prevent fraud or inappropriate use. We also stated that we will consider this and other information as we contemplate future policy regarding use of communications technology to satisfy supervision requirements, as well as the best approach for safeguarding patient safety while promoting use of technology to enhance access.

We also noted that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their own professional services. This is discussed in the March 31st COVID–19 IFC (85 FR 19246). This is especially relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners can only bill Medicare directly for telehealth services under telehealth waivers that are effective only during the PHE for COVID–19. We note that sections 1834(m)(4)(D) and (E) of the Act specifies the types of clinicians

who may furnish and bill for Medicare telehealth services, and include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act.

We solicited information on whether this flexibility should be continued beyond the later of the end of the PHE for COVID–19 or CY 2021. Specifically, we solicited comments on the extent to which the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology is being used during the PHE, and whether physicians and practitioners anticipate relying on this flexibility after the end of the PHE. We solicited comments on whether this flexibility should potentially be made permanent, meaning that we would revise the definition of ''direct supervision'' at § 410.32(b)(3)(ii) to include immediate availability through the virtual presence of the supervising physician or practitioner using real-time, interactive audio/video communications technology without limitation after the PHE for COVID–19, or if we should continue the policy in place for a short additional time to facilitate a gradual sunset of the policy. We solicited comment on whether the current timeframe for continuing this flexibility at § 410.32(b)(3)(ii), which is currently the later of the end of the year in which the PHE for COVID–19 ends or December 31, 2021, remains appropriate, or if this timeframe should be extended through some later date to facilitate the gathering of additional information in recognition that, due to the on-going nature of the PHE for COVID–19, practitioners may not yet have had time to assess the implications of a permanent change in this policy. We also solicited comment regarding the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time audio/video technology for only a subset of services, as we recognize that it may be inappropriate to allow direct supervision without physical presence for some services, due to potential concerns over patient safety if the practitioner is not immediately available in-person. We also solicited comments on, if this policy to be made permanent, whether a service-level modifier should be required to identify when the requirements for direct supervision were met using two-way, audio/video communications technology.

We received public comments on the expiration of PHE flexibilities for direct supervision requirements. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported continuing to allow requirements for direct supervision of services to be met through virtual presence using telecommunications technology beyond the PHE. They stated that COVID–19 may not be completely eradicated for at least a year after the end of the PHE, and that health professionals will need time to recover from the pandemic's effects. Other commenters stated that CMS should permanently modify the definition of direct supervision to include the presence of the supervising practitioner via real-time, interactive audio/video technology in certain cases. Some commenters encouraged CMS to create a service-level modifier for purposes of identifying advanced practice provider involvement in care and requested that CMS consult with specialty societies as this change is developed.

Some commenters supported use of a service-level modifier to identify services furnished under direct supervision where the supervising physician was available through two-way, audio/video communications technology.

Some commenters specifically requested that CMS maintain the flexibility for the supervising physician to be available using two-way, audio/video when a nurse practitioner is furnishing a behavioral health service, as these are services that do not require a physical exam.

MedPAC, while supportive of our extension of this policy through the year in which the PHE ends, stated two concerns about making it permanent after the PHE in the absence of evidence about its effects on safety, quality, and spending. First, allowing clinicians to supervise ''incident to'' services virtually could pose a safety risk to beneficiaries because the clinician would not be physically available to help the individual being supervised, if necessary, which is important if the service is a complex procedure. Second, allowing virtual supervision could potentially enable a clinician to supervise many individuals at multiple locations at the same time. It could be difficult for a clinician to address urgent, clinical needs while virtually supervising many people at multiple locations simultaneously. This scenario could also lead to higher spending by allowing clinicians to bill for more ''incident-to'' services during a single day.

Some commenters stated that, if CMS were to make this policy permanent, certain services should be precluded, such as complex drug therapies or anesthesia services.

Response: We thank commenters for their input and will consider addressing the issues raised by these comments in future rules or guidance, as appropriate.

b. Interim Final Provisions in the CY 2021 PFS Final Rule

In the CY 2021 PFS final rule (85 FR 84536), we finalized the establishment of HCPCS code G2252 (Brief communication technology-based service, *e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*) on an interim basis. We stated that, given the widespread concerns expressed by commenters about the continuing need for audio-only conversations with patients and our determination that we will not continue to pay for audio-only E/M visits after the conclusion of the PHE (see 85 FR 84533 through 84535 for further discussion of that policy), we believed it will be expedient to establish additional coding and payment for an extended virtual check-in, which could be furnished using any form of synchronous communications technology, including audio-only, on an interim basis for CY 2021. We stated that we believed establishing payment for this service on an interim basis will support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. In that rule, we finalized a direct crosswalk to CPT code 99442, the value of which we believe most accurately reflects the resources associated with a longer service delivered via synchronous communications technology, which can include audio-only communications. Commenters supported the creation and interim final adoption of this service. Commenters stated that, as beneficiaries and practitioners may be reluctant to return to primarily in-person services post-PHE, payment for a longer virtual check-in will be necessary to account for circumstances where more time is spent determining whether an in-person visit is needed beyond the 5–10 minutes accounted for by HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care*

professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion). Commenters also supported valuing HCPCS code G2252 through a direct crosswalk to CPT code 99442. We agree with commenters that additional time may be needed to assess the necessity of an in-person service given concerns over exposure to illnesses beyond the duration of the PHE for COVID–19 and that current coding may not accurately reflect that time. Based on support from commenters, we proposed to permanently adopt coding and payment for CY 2022, HCPCS code G2252 as described in the CY 2021 PFS final rule.

We received public comments on the interim final provisions in the CY 2021 PFS final rule. The following is a summary of the comments we received and our responses.

Comment: Commenters supported CMS' finalizing separate coding and payment for a longer virtual check-in.

Some commenters, including the AMA RUC, supported valuing HCPCS code G2252 through a direct crosswalk to the value of CPT code 99442 but recommended that CMS work with the CPT Editorial Panel to editorially revise CPT codes 99441–99443 so that the CPT codes may be consistently reported by all payors to describe audio-only services.

Some commenters stated that CMS should create a parallel code to HCPCS code G2252 billable by those practitioners who cannot independently bill for E/M services. Commenters pointed out that, in the CY 2021 PFS final rule, CMS implemented a similar policy for HCPCS codes G2010 and G2012.

Response: With regard to HCPCS code G2252 being billable by those practitioners who cannot independently bill for E/M services, we appreciate commenters bringing this issue to our attention, and we will consider these comments for future rulemaking.

After consideration of public comments, we are finalizing our proposal to permanently establish separate coding and payment for the longer virtual check-in service described by HCPCS code G2252 for CY 2022 using a crosswalk to the value of CPT code 99442, as proposed. As described in the CY 2021 PFS final rule (85 FR 84536), we believe that the value of CPT code 99442 most accurately reflects the resources associated with a longer service delivered via synchronous communications technology, which can include audio-only communications. This is consistent with our approach to valuing the virtual check-in service (HCPCS code G2012), which used CPT code 99441 as the basis for valuation. In the case of HCPCS code G2252 and CPT code 99442, both codes describe 11–20 minutes of medical discussion when the practitioner may not necessarily be able to visualize the patient, and is used when the acuity of the patient's problem is not necessarily likely to warrant a visit, but when the needs of the particular patient require more assessment time from the practitioner. In the case of HCPCS code G2252, the additional time would be used to determine the necessity of an in-person visit and result in a work time/intensity that is similar to the crosswalk code.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00.

For telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The originating site facility fee for telehealth services furnished in CY 2022 is $27.59.

The MEI increase for CY 2022 is 2.1 percent and is based on the most recent historical percentage increase of the MEI for the second quarter of 2021 (2.3 percent), and the most recent historical productivity adjustment for calendar year 2020 (0.2 percent).

Therefore, for CY 2022, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is $27.59. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period is shown in Table 18.

TABLE 18: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.C. of this final rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's

recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of

the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2022 PFS proposed rule and those comments are summarized below.

Comment: Several commenters disagreed with our reference to older work time sources, and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of

time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time are not accounted for in a recommended work RVU, we believe we have an obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs.

We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this CY 2022 PFS final rule, CPT codes 63053 (*Laminectomy, facetectomy, or foraminotomy* (*unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]*), *during posterior interbody arthrodesis, lumbar; each additional segment*), 67335 (*Placement of adjustable suture(s) during strabismus surgery, including postoperative adjustment(s) of suture(s)*), 80504 (*Pathology clinical consultation; for a moderately complex clinical problem, with review of patient's history and medical records and moderate level of medical decision making. When using time for code selection, 21–40 minutes of total time is spent on the date of the consultation*), and 99425 (*Principal care management services, for a single high-risk disease; additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*) all share the same intraservice and total work time of 30 minutes. However, these codes have very different proposed work RVUs of 2.31 and 3.23 and 0.91 and 1.00 respectively. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors employed in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

We also clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regard to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters discouraged the use of valuation of codes based on work RVU increments. Commenters stated that this methodology for valuing codes inaccurately treats all components of the physician time as having identical intensity and would lead to incorrect work valuations. Commenters stated that CMS should carefully consider the clinical information justifying the changes in physician work intensity provided by the RUC and other stakeholders.

Response: We believe the use of an incremental difference between the work RVUs of codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon the incremental work RVU difference between the code and another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between the work RVUs of codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not believe that it is necessary for codes to share the same site of service, patient population, or utilization level in order to serve as an appropriate crosswalk.

Comment: Several commenters stated that they were concerned about CMS' lack of consideration for compelling evidence that services have changed. Commenters stated that CMS appeared to dismiss the fact that services may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services. Commenters stated that CMS' failure to discuss compelling evidence does not reflect the long history of reviewing potentially misvalued codes, first through the statutorily mandated 5-year review processes and more recently from continuous annual reviews. Commenters stated that CMS has discussed compelling evidence in rulemaking since the inception of the RBRVS and has informed public commenters to consider compelling evidence to identify potentially misvalued codes. Commenters requested that CMS address the compelling evidence submitted with the RUC recommendations when the agency does not accept the RUC's recommended work RVUs.

Response: The concept of compelling evidence was developed by the RUC as part of its work RVU review process for individual codes. The RUC determines whether there is compelling evidence to justify an increase in valuation. The

RUC's compelling evidence criteria include documented changes in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the service. While we appreciate the submission of this additional information for review, we emphasize that the RUC developed the concept of compelling evidence for its own review process; an evaluation of ''compelling evidence,'' at least as conceptualized by the RUC, is not part of our review process, as our focus is the time and intensity of services, in accordance with the statute. With that said, we do consider changes in technology, patient population, and other compelling evidence criteria, as such evidence may affect the time and intensity of a service under review. For example, new technology may cause a service to become easier or more difficult to perform, with corresponding effects on the time and intensity of the service. However, we are under no obligation to adopt the same review process or compelling evidence criteria as the RUC. We instead focus on evaluating and addressing the time and intensity of services when reviewing potentially misvalued codes because section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service.

Comment: A commenter stated that there has been a disparate impact on the valuation of cardiothoracic services over the past decade. The commenter stated that CMS has taken a prejudicial approach to services from this specialty over the period 2009–2019 by making refinements to the RUC's recommended work RVUs at a higher percentage than all other specialties.

Response: We disagree with the commenter that there has been any prejudicial approach to the valuation of services from the cardiothoracic specialty or any other specialty. We value services on an individual case-by-case basis using time and intensity as directed by the statute. When the recommended work RVUs from the RUC do not appear to account for significant changes in time, we have employed different approaches (such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation) to identify potential values that reconcile the recommended work RVUs with the recommended time values. We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, and the dominant specialty of the service under review is not part of our work valuation methodology.

Comment: Several commenters raised the issue of the refinement panel which was last reformed in CY 2016. Commenters stated that the refinement panel was not obsolete and was not mutually exclusive with the change to include all proposed valuations in each year's proposed rule. Commenters stated that for two decades, the refinement panel process was considered by stakeholders to be an appeals process and its elimination discontinued CMS' reliance on outside stakeholders to provide accountability through a transparent appeals process. Commenters requested that CMS consider these issues and create an objective, transparent and consistently applied formal appeals process that would be open to any commenting organization.

Response: We did not propose any changes to the refinement panel and we are not finalizing any changes to the refinement panel for CY 2022. As we stated in the CY 2016 PFS final rule (80 FR 70917–70918), the refinement panel was established to assist us in reviewing the public comments on CPT codes with interim final work RVUs and in balancing the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. We did not believe that the refinement panel had generally served as the kind of ''appeals'' or reconsideration process that some stakeholders envisioned in their comments. We also believe that the refinement panel was not achieving its intended purpose. Rather than providing us with additional information, balanced across specialty interests, to assist us in establishing work RVUs, the refinement panel process generally served to rehash the issues raised and information already discussed at the RUC meetings and considered by CMS. In contrast to the prior process of establishing interim final values and using a refinement panel process that generally was not observed by members of the public, we continue to believe that the current process of proposing the majority of code values in a proposed rule, giving the public the opportunity to comment on those proposed values, and then finalizing those values in a final rule offers greater transparency and accountability.

We also note that we did not finalize our proposal to eliminate the refinement panel completely in CY 2016. We retain the ability to convene refinement panels for codes with interim final values under circumstances where additional input provided by the panel is likely to add value as a supplement to notice and comment rulemaking. We also remind stakeholders that we have established an annual process for the public nomination of potentially misvalued codes. This process, described in the CY 2012 PFS final rule (76 FR 73058), provides an annual means for those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking to bring those codes to our attention.

Comment: Several commenters requested that CMS use the interim RUC recommendations from the April 2021 meeting for several code families which had previously been reviewed at the October 2020 RUC meeting or the January 2021 RUC meeting. Commenters stated that the earlier RUC recommendations were made on an interim basis and requested an expedited review of the recommendations from the April 2021 RUC meeting; the RUC resubmitted its recommendations for these code families as part of its comment submission.

Response: We finalized a policy in the CY 2015 PFS final rule to make all changes in the work and MP RVUs and the direct PE inputs for new, revised, and potentially misvalued services under the PFS by proposing and then finalizing such changes through notice and comment rulemaking, as opposed to initially finalizing changes on an interim final basis (79 FR 67602 through 67609). As we stated when promulgating the CY 2015 PFS final rule, this approach has the significant advantage that the RVUs for all services under the PFS are established using a full notice and comment procedure, including consideration of the RUC recommendations, before they take effect, providing the public the opportunity to comment on a specific proposal prior to it being implemented. We continue to believe that this is a far more transparent process which assures that we have the full benefit of stakeholder comments before establishing values. Since we did not make proposals on the code families in question using the RUC's recommendations from the April 2021 meeting, we would be forced to finalize valuation for these codes on an interim

final basis, without the opportunity for public comment. This would contradict the policy that we finalized in the CY 2015 PFS final rule, and we do not believe that it would serve the interests of transparency. Although we will consider any information submitted by stakeholders for valuation during the comment period, as we do for all codes which are subject to notice and comment rulemaking, we will formally review the recommendations from the April 2021 RUC meeting next year as part of the CY 2023 PFS rulemaking cycle.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. We also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 21 contains a list of codes and descriptors for which we proposed work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2021. The finalized work RVUs, work time and other payment information for all CY 2022 payable codes are available on the CMS website under downloads for the CY 2022 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 22 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), we addressed certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We noted that for each refinement, we indicated the impact on direct costs for that service. We noted that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In the proposed rule, we also noted that many of the refinements listed in Table 21 of the proposed rule resulted in changes under the $0.35 threshold and were unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2022 are displayed in the CY 2022 direct PE input files, available on the CMS website under the downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the CY 2022 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the

portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

Comment: Several commenters stated that CMS is proposing to refine the facility pre-service clinical labor times for major procedures to conform to the 000-day or 010-day global period standards for ''Extensive use of clinical staff'' despite the RUC recommendation of standard 090-day preservice clinical labor times. Commenters stated that these procedures are performed under general anesthesia in the facility setting and require specialized supplies and equipment and pre-operative coordination between multiple specialists necessitating office clinical staff time typical of 90-day global procedures performed in the facility setting. Commenters stated that reassignment of global periods for select codes does not negate the fact that a major procedure is a major procedure and the pre-service facility clinical staff time for a major procedure is independent of the global period assignment. Commenters stated that each procedure should be evaluated on a case-by-case basis.

Response: We agree with the commenters that the direct PE inputs for each service should be evaluated on a case-by-case basis based on our criteria of what would be reasonable and medically necessary in the typical case. We reviewed the individual codes in question and concluded that the use of 000-day or 010-day global period standards for ''Extensive use of clinical staff'' would be most typical in these cases. As we noted under the Standardization of Clinical Labor Tasks (section II.B) part of this final rule, we continue to believe that setting and maintaining clinical labor standards provides greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For additional discussion, we direct readers to the individual code families affected by our proposed preservice clinical labor times (CPT codes 46020 and 46030 and CPT codes 61736 and 61737).

We refer readers to section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2022 we received invoices for several new supply and equipment items. Tables 23 and 24 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 23 and 24 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies

the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2022 are available on the CMS website under downloads for the CY 2022 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under paragraph (t)(2)(D) of such section, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such TC for such year. As required by the section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2022, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined above for purposes of this cap. Beginning for CY 2022, we proposed to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0633T (*Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material*), 0634T (*Computed tomography, breast, including 3D rendering, when performed, unilateral; with contrast material(s)*), 0635T (*Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast, followed by contrast material(s)*), 0636T (*Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)*), 0637T (*Computed tomography, breast, including 3D rendering, when performed, bilateral; with contrast material(s)*), 0638T (*Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast, followed by contrast material(s)*), 0648T (*Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session*), 0649T (*Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)*), 77089 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk*), 77090 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk, technical preparation and transmission of data for analysis to be performed elsewhere*), 77091 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk, technical calculation only*), 77092 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk interpretation and report on fracture risk only, by other qualified health care professional*), 91113 (*Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report*), and 93319 (*3D echocardiographic*

imaging and postprocessing during transesophageal echocardiography or transthoracic echocardiography for congenital cardiac anomalies for the assessment of cardiac structure(s) (eg, cardiac chambers and valves, left atrial appendage, intraterial septum, interventricular septum) and function, when performed). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap.

We did not receive public comments on this proposal. We are finalizing the addition of the services listed above to the list of codes to which the OPPS cap applies, as proposed.

4. Valuation of Specific Codes for CY 2022

(1) Anesthesia for Cardiac Electrophysiologic Procedures (CPT Code 00537)

In October 2019, the RUC reviewed CPT code 00537 (*Anesthesia for cardiac electrophysiologic procedures including radiofrequency ablation*) and recommended that the code be surveyed for the October 2020 meeting. This service was identified by the RUC via the high volume growth screen for services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. Additionally, at the October 2019 RUC meeting, the RUC approved an anesthesia reference service list (RSL) and a method to assess the relativity among services on the anesthesia fee schedule that uses a revised building block methodology and a regression line analysis. The RUC has stated that the revised building block methodology generates ''proxy RVUs'' that are then compared against the RSL regression line to assess relativity among anesthesia services. The RUC has indicated that their primary and approved method for anesthesia base unit valuation continues to be the anesthesia survey results, and that the building block and regression line analysis are used as a supplemental validation measure.

The RUC recommended a valuation of 12 base units for CPT code 00537. We disagree with the RUC-recommended valuation of 12 base units for CPT code 00537. After performing a RUC database search of codes with similar total times and post-induction period procedure anesthesia (PIPPA) times, 12 base units appears to be on the very high range. We proposed a valuation of 10 base units supported by reference codes CPT code 00620 (*anesthesia for procedures on the thoracic spine and cord, not otherwise specified*) and CPT code 00600 (*Anesthesia for procedures on cervical spine and cord; not otherwise specified*), which both have a valuation of 10 base units. CPT code 00620 has a very similar total time of 235 minutes and CPT code 00600 has a higher total time of 257 minutes and the same base unit value of 10, which indicates that this is an appropriate valuation. Additionally, we note that the survey total time for CPT code 00537 increased from 150 to 238 minutes, resulting in a survey result 25th percentile valuation of 10 base units.

We proposed the RUC-recommended direct PE inputs for CPT code 00537.

Comment: Commenters disagreed with the proposed valuation of 10 base units for CPT code 00537 and stated that CMS should instead finalize the RUC-recommended valuation of 12 base units. Commenters disagreed with CMS using reference codes CPT code 00620 (*anesthesia for procedures on the thoracic spine and cord, not otherwise specified*) and CPT code 00600 (*Anesthesia for procedures on cervical spine and cord; not otherwise specified*) as a basis for the valuation of 10 base units. Commenters stated that CMS ignored the reference codes chosen by the RUC and instead used reference codes that were not surveyed, which makes the time source unknown. They also stated that CMS ignored the validation measures that the RUC used to support their recommendations and that CMS only considered the total times of the reference codes and not all inputs of time, such as post induction time. Additionally, commenters stated that they believe CMS did not consider the intensity of the service for CPT code 00537, as the supporting reference codes have a lower intensity and are not clinically similar.

Response: We disagree and continue to believe that using multiple methodologies for identifying potential base units for anesthesia services is appropriate. Codes are, and have been over many years, often valued by comparisons to codes with similar times, including the total time of a service. Therefore, we consider total time to be an appropriate measure for comparison. We also use reference codes to validate a base unit valuation. When using reference codes to support a proposed valuation, we do not consider them as a direct ''cross-walk'' between the CPT code that is being revalued and the chosen reference code. Instead, a reference code is used as a supportive check in validating times. For CPT code 00600 and CPT code 00620, we believe that the similarities in time, as well as the base unit value of 10 being the survey 25th percentile result, make them appropriate reference codes. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparison to one another. We do not agree that codes must share the same patient population, utilization, age of the CPT code, or survey tool to serve as an appropriate reference code. We do consider clinical information associated with the intensity of a physician's work provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same clinical aspects of work to serve as an appropriate reference code. For CPT code 00537, we considered the intensity of the service as it relates to other CPT codes on the fee schedule, the total time of the service, as well as aspects of time compared to supporting reference codes to determine the base unit valuation for this CPT code. For additional information regarding our use of supporting reference codes and our use of time inputs as a tool for comparison, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2. of the final rule).

Comment: We received one comment in support of our proposed valuation for CPT code 00537.

Response: We acknowledge and appreciate the support of a base unit valuation of 10 for CPT code 00537.

After consideration of these public comments, we are finalizing the base unit valuation and direct PE inputs for CPT code 00537 as proposed.

(2) Anesthesia Services for Image-Guided Spinal Procedures (CPT Codes 01937, 01938, 01939, 01940, 01941, and 01942)

In 2017, the RUC identified CPT code 01936 (*Anesthesia for percutaneous image guided procedures on the spine and spinal cord; therapeutic*) as possibly needing refinement due to inaccurate reporting via the high-volume growth screen. The Relativity Assessment Workgroup reviewed data on what procedures were reported with this anesthesia code. In October 2019, the Workgroup reviewed this service and recommended that it be referred to the CPT Editorial Panel to create more granular codes. In October 2020, the CPT Editorial Panel replaced CPT codes 01935 and 01936 with six new codes to report percutaneous image-guided spine and spinal cord anesthesia procedures. These CPT codes are 01937 (*Anesthesia for percutaneous image-guided*

injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic), 01938 (*Anesthesia for percutaneous image guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral*), 01939 (*Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic*), 01940 (*Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral*), 01941, (*Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures*) (*e.g., Kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic*) and 01942 (*Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures* (*e.g., Kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral*).

We proposed the RUC-recommended valuation of 4 base units for CPT codes 01937, 01938, 01939, and 01940.

We disagreed with the RUC-recommend valuation of 6 base units for CPT codes 01941 and 01942. After performing a RUC database search of codes with similar total times and post-induction period procedure anesthesia (PIPPA) times, 6 base units for CPT codes 01941 and 01942 appeared to be a high valuation. We proposed a valuation of 5 base units for both codes supported by a reference code, CPT code 00813 (*Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum*). CPT code 00813 has a valuation of 5 base units with a higher PIPPA time of 40 minutes, as well as a higher total time of 70 minutes. The RUC noted that CPT codes 01941 and 01942 should have a higher base unit valuation than the other similar codes within this family due to the complex nature of these procedures that have a more intensive anesthesia process. The RUC supported their recommendation with a crosswalk code, CPT code 00732 (*Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ECRP)*). CPT code 00732 has a valuation of 6 base units, a total time of 100 minutes, and a PIPPA time of 65 minutes. CPT codes 01941 and 019427 have a total time of 58 minutes and a PIPPA time of 20 minutes. We agreed that a more complex procedure may require a higher base unit valuation within a code family; however, given the disparity in total and PIPPA time, we disagreed with the use of this crosswalk code to support a valuation of 6 base units and instead proposed a valuation of 5 base units supported by reference CPT code 00813, which has higher times and the same base unit valuation.

We proposed the RUC-recommended direct PE inputs for all six codes in the family.

Comment: Commenters disagreed with the proposed valuation of 5 base units for CPT code 01941 and CPT code 01942 and stated that CMS should finalize the RUC-recommended base unit of 6 for both CPT codes. Commenters disagreed with our use of CPT code 00813 (*Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum*) as a reference code for the proposed valuation of 5 base units for CPT code 01941 and CPT code 01942. Commenters stated that from a clinical perspective, the RUC's reference code was more appropriate and similar in complexity.

Response: We disagree that a supporting reference code must have similar clinical features. We believe that other methods of comparison, such as total and intra-service time, can also be used to reach appropriate valuations when clinical features are disparate. The relativity of the PFS allows for comparisons amongst all codes. We also do not consider supporting reference codes as direct ''cross-walks''. We use supporting reference codes to further validate valuations that are based on comparisons of time and intensity, but not necessarily clinical similarities. The higher total and post induction times for our chosen reference code, with a base unit value of 5, make it an appropriate code for purposes of comparison with CPT code 01941 and CPT code 01942 to reach a base unit valuation. Additionally, we note that the RUC chose the survey 25th percentile result or lower for every other CPT code in this family, but for CPT code 01941 and 01942 they chose a survey result value that is above the 25th percentile. We believe that using the survey 25th percentile of 5 base units is appropriate to maintain consistency within the family for purposes of valuation and that a base unit valuation of 5 will also account for the increase in intensity of CPT code 01941 and CPT code 01942. For additional information regarding our use of supporting reference codes, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2. of this final rule).

After consideration of these public comments, we are finalizing the base unit valuation and direct PE inputs for this code family as proposed.

(3) Closed Treatment of Nasal Bone Fracture (CPT Codes 21315 and 21320)

We agreed with the RUC's recommendation to change CPT codes 21315 (*Closed treatment of nasal bone fracture; without stabilization*) and 21320 (*Closed treatment of nasal bone fracture; with stabilization*) to 000-day global period codes from 010-day global period codes to account for the degree of swelling within 10 days post-procedure, and because the patient can remove their own splint at home for CPT code 21320. For CPT codes 21315 and 21320, we disagreed with the RUC-recommended work RVUs of 2.00 and 2.33, respectively, as we believe these values do not adequately reflect the surveyed reductions in physician time and the change to a 000-day global period from a 010-day global period for these CPT codes. We proposed a work RVU of 0.96 for CPT code 21315 and 1.59 for CPT code 21320 based on the reverse building block methodology to remove the RVUs associated with the 010-day global period and the surveyed reductions in physician time. We believe that the proposed work RVU of 0.96 for CPT code 21315 adequately accounts for the 50 percent decrease in intraservice and postservice time, a 31-minute decrease in total time, and a change to a 000-day global period which will allow for separately billable E/M visits as medically necessary. We believe that the proposed work RVU of 1.59 for CPT code 21320 adequately accounts for the 5-minute decrease in intraservice time, 3-minute decrease in total time, and 48 percent decrease in postservice time. Absent an explicitly stated rationale for an intensity increase for CPT codes 21315 and 21320, we proposed to adjust the work RVU to reflect significant decreases in surveyed physician time.

The global period changes from 010-day to 000-day allow for separately billable E/M visits relating to CPT codes 21315 and 21320, therefore we removed RVUs that we believed were attributable to the currently bundled E/M visits totaling 1.30 RVUs for CPT code 21315 and 0.35 RVUs for CPT code 21320. CPT code 21315 is currently bundled with one post-operative follow up office visit, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low*

level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter). CPT code 21320 is currently bundled with half of a post-operative follow up office visit, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter*). We do not believe the RUC adequately accounted for the loss of these E/M visits in their recommended work RVUs for CPT codes 21315 and 21320. The RUC's recommendations also seem to dismiss the significant changes in surveyed physician time, without a persuasive explanation of a significant increase in IWPUT that results from the RUC's recommended work RVUs for CPT codes 21315 and 21320. We believe the surveyed decreases in physician time in conjunction with the loss of the post-operative visits for CPT codes 21315 and 21320 merit decreases in the work RVUs from the current work RVUs.

We considered using a modified total time ratio methodology given the age and potentially flawed methodology used to arrive at the current valuation. The modified total time ratio calculation does not include the loss of 8 minutes of post-operative time attributable to the change from a 010-day global period to a 000-day global period for CPT code 21320 and loss of 23 minutes of post-operative time for CPT code 21315. This modified time ratio methodology reflects how the physician time is changing in the pre-, intra-, and postservice periods when a code's global period is changing, given that E/M services can be billed as medically necessary and appropriate for a 000-day global code. The total time ratio between the current and proposed total times for CPT code 21315, excluding the 23 minutes of post-operative time in the current total time, equals 1.64. We arrived at 1.64 by modifying the original total time ratio equation to equal the proposed new total time divided by the current time, less any time attributable to the post-operative global period, then multiplied by the current work RVU. The current total time for CPT code 21315 without the 23 minutes of post-operative time that will be lost by going from a 010-day to a 000-day global period code is 76 minutes, therefore, the modified total time ratio = (68 minutes/(99 minutes − 23 minutes)) * 1.83 = 1.64. When using the original total time ratio methodology for CPT code 21315, it shows a 31 percent decrease in total time [(68 minutes − 99 minutes)/99 minutes = −0.31], whereas the modified methodology shows that there is only an 11 percent decrease in newly proposed pre-, intra-, and postservice time from the current times [(68 minutes − 76 minutes)/76 minutes = −0.11].

The same modified total time ratio methodology could be applicable to CPT code 21320. The current total time for CPT code 21320 without the 8 minutes of post-operative time that will be lost by going from a 010-day to a 000-day global period code is 70 minutes, therefore, the modified total time ratio = (75 minutes/(78 minutes − 8 minutes) * 1.88 = 2.01. The modified methodology shows that the pre-, intra-, and postservice time is increasing by 7 percent for CPT code 21320, whereas the original methodology, which accounts for the loss of the 8 post-operative minutes in the total time ratio, shows a 4 percent decrease in total time that would indicate the need for a work RVU decrease. We recognize that we have not previously used a modified total time approach to consider work RVU values when there is a change in the global period for a service in conjunction with significant surveyed changes to the pre-, intra-, and postservice times; therefore, we solicited comment on application of the modified total time ratio approach to value services that have a global period change and significant surveyed physician time changes. We believe this methodology may account for the loss of post-operative visits and the surveyed changes in the pre-, intra-, and postservice times in this unique situation.

Comment: Commenters stated that CMS did not address the compelling evidence submitted with the RUC recommendations for CPT codes 21315 and 21320. Commenters stated that CMS dismisses the fact that services may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services, and CMS only proposes blanket reductions instead of considering how a service may have changed or increased over time. Commenters requested that CMS address the compelling evidence submitted with the RUC recommendations when the agency does not accept the RUC's recommended work RVUs.

Response: The concept of compelling evidence was developed by the RUC as part of its work RVU review process for individual codes. The RUC determines whether there is compelling evidence to justify an increase in valuation. The RUC's compelling evidence criteria include documented changes in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the service. While we appreciate the submission of this additional information for review, we emphasize that the RUC developed the concept of compelling evidence for its own review process; an evaluation of ''compelling evidence,'' at least as conceptualized by the RUC, is not part of our review process, as our focus is the time and intensity of services, in accordance with the statute. With that said, we do consider changes in technology, patient population, and other compelling evidence criteria, as such evidence may affect the time and intensity of a service under review. For example, new technology may cause a service to become easier or more difficult to perform, with corresponding effects on the time and intensity of the service. However, we are under no obligation to adopt the same review process or compelling evidence criteria as the RUC. We instead focus on evaluating and addressing the time and intensity of services when reviewing potentially misvalued codes because section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service.

Comment: Commenters disagreed with our reference to older work time sources, and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs to the newly surveyed work time and work RVUs as recommended by the RUC, particularly with regards to the removal of RVUs that we believed were attributable to the global period. Commenters unanimously disagreed with the subtraction of the increased CY 2021 office/outpatient E/M work RVUs of 0.70 and 1.30 for CPT codes 99212 and 99213, respectively, to arrive at our proposed work RVUs for CPT codes 21315 and 21320.

Response: The global period changes from 010-day to 000-day allow for separately billable E/M visits relating to CPT codes 21315 and 21320, therefore we removed RVUs that we believed

were attributable to the currently bundled E/M visits totaling 1.30 RVUs (when billed separately) for CPT code 21315 and 0.35 RVUs (when billed separately) for CPT code 21320. We used the reverse building block methodology to calculate the proposed work RVUs, which accounts for the longstanding time and intensity associated with CPT code 99212 and CPT code 99213 for bundled office visits in the surgical global period, rather than the increased CY 2021 office/outpatient E/M work RVUs of 0.70 and 1.30 for CPT codes 99212 and 91213, respectively, as commenters suggested. In the proposed rule, we stated that CPT code 21315 is currently bundled with one post-operative follow up office visit, CPT code 99213. When separately furnished, practitioners could bill for a total of 1.30 work RVUs, as the post-operative follow up office visit would no longer be bundled in the global period, therefore the practitioner could bill for the increased CY 2021 office/outpatient E/M value. CPT code 21320 is currently bundled with half of a post-operative follow up office visit, CPT code 99212. When separately furnished, practitioners could bill for the increased CY 2021 office/outpatient E/M value a total of 0.35 work RVUs for the half of a post-operative follow up office visit, CPT code 99212, as the half of a post-operative follow up office visit would no longer be bundled in the global period. We continue to believe that the RUC did not adequately account for the removal of these E/M visits as a result of the global period changes in their recommended work RVUs for CPT codes 21315 and 21320.

We believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comments: Commenters opposed our proposed work RVUs for CPT codes 21315 and 21320 and urged us to finalize the RUC-recommended work RVUs for these codes. Commenters stated that CMS' reverse building block, total time ratio, and modified total time ratio calculations ignore magnitude estimates as indicated by physicians who perform these services and compromise the correct relativity of these services. Commenters also stated that CMS' calculations ignore and discount the intensity of these services.

Response: We disagree with the commenters and continue to believe that reverse building block and time ratio calculations are appropriate methods for identifying potential work RVUs for PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys which suggests that the amount of time involved in furnishing the service has changed significantly. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2.), as well as a comprehensive discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). We note that the modified total time ratio discussed above was not used to arrive at the valuation for CPT codes 21315 or 21320, but was discussed solely to seek comment on a potential approach to value services that have a global period change and significant surveyed physician time changes.

We continue to believe that using the reverse building block methodology to calculate a proposed work RVU of 0.96 for CPT code 21315 and 1.59 for CPT code 21320 was appropriate. Based on the aforementioned references to section II.E.2. and the CY 2017 PFS final rule (81 FR 80273 through 80274) and consideration of the comments, we are finalizing the work RVUs for CPT codes 21315 and 21320 as proposed. We believe the work RVU of 0.96 for CPT code 21315 adequately accounts for the 50 percent decrease in intraservice and postservice time, a 31-minute decrease in total time, and a change to a 000-day global period which will allow for separately billable E/M visits as medically necessary for CPT code 21315. We also believe that the work RVU of 1.59 for CPT code 21320 adequately accounts for a 5-minute decrease in intraservice time, 3-minute decrease in total time, 48 percent decrease in postservice time, and a change to a 000-day global period which will allow for separately billable E/M visits as medically necessary for CPT code 21320.

We are also finalizing the RUC-recommended direct PE inputs without refinements and the surveyed physician times for CPT codes 21315 and 21320 as proposed.

(4) Insertion of Interlaminar/Interspinous Device (CPT Code 22867)

We proposed the RUC-recommended work RVU of 15.00 for CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*). The RUC did not recommend changes to the current PE inputs, and we did not propose any changes to the current PE inputs.

Comment: Several commenters stated that they supported the proposal of the RUC-recommended work RVU 15.00 for CPT code 22867.

Response: We appreciate the support from the commenters for our proposed RUC-recommended work RVU of 15.00 for CPT code 22867.

Comment: Some commenters expressed appreciation for the acceptance of the new, higher work RVU of 15.00, but urged consideration of adding additional work RVUs to the adjusted value to represent the physician work and intensity of CPT code 22867. The commenters stated that CPT code 22867 includes the work of an open laminectomy, which is coded as CPT code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar*). One commenter stated that a work RVU of 19.62 would be more appropriate for CPT code 22867. This work RVU was derived by adding the work RVU of CPT code 63047, valued at 15.37, to the work RVU of add-on CPT code 22853 (*Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*), valued at 4.25. Other commenters asserted that a work RVU of 20.00 is more appropriate.

Commenters stated that new research was available as of July 1, 2021 that suggests CPT code 22867 requires more physician work than CPT code 63047 alone.

Response: We appreciate the additional information, but we continue to believe that the original survey results and RUC's reaffirmed value for CPT code 22867 accurately reflect the time and intensity of CPT code 22867. At the January 2021 meeting, the RUC agreed that a third survey would not be useful at the time and agreed to reaffirm the January 2016 RUC recommendations. Although we will consider any information submitted by stakeholders for valuation during the comment period, as we do for all codes which are subject to notice and comment rulemaking, the newly available research was not discussed in the proposed rule, and CMS did not broach the topic of the amount of physician work that factors into CPT code 22867 versus CPT code 63047 alone. Further, CMS did not propose a work RVU of 20.00 for CPT code 22867, therefore the public has not had notice or the opportunity to comment on this potential policy. Lastly, the AMA RUC did not review or consider the validity of the assertions in the research in their recommendations for CPT code 22867. We continue to believe that this is important to be transparent and have the full benefit of stakeholder comments before establishing values, so we are not finalizing a work RVU of 20.00 for CPT code 22867. We expect that new research would be considered in any future recommendations or rulemaking.

After consideration of the comments, we are finalizing the proposed work RVU of 15.00 for CPT code 22867.

(5) Treatment of Foot Infection (CPT Codes 28001, 28002, and 28003)

Through a screen of codes with 010-day global period service with more than one post-operative follow-up office visit, the RUC identified this family of major surgical codes that did not have consistent global periods. The RUC conducted a survey of these codes as 000-day globals for their April 2020 meeting, and the review was postponed until October 2020. CPT code 28001 (*Incision and drainage, bursa, foot*) (work RVU of 2.78 with 31 minutes of intraservice time) currently has a 010-day global period with one post-operative follow-up office visit, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*). Survey results from podiatrists and orthopedic surgeons yielded a median work RVU of 2.00 with 17 minutes of preservice evaluation time, 3 minutes of preservice positioning time, 5 minutes of preservice scrub/dress/wait time, 20 minutes intraservice time, and 15 minutes immediate postservice time for a total of 60 minutes total time. We proposed the RUC-recommended work RVU of 2.00 and the surveyed physician times for this 000-day global code.

CPT code 28002 (*Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space*) (work RVU of 5.34 with 30 minutes of intraservice time) currently has a 010-day global period with two post-operative follow-up office visits, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family*); and a half day hospital discharge CPT code 99238 (*Hospital discharge day management; 30 minutes or less*). For CPT code 28002, the RUC recommended 30 minutes of preservice evaluation time, 5 minutes of preservice positioning time, 15 minutes of preservice scrub/dress/wait time, 30 minutes of intraservice time, and 20 minutes of immediate postservice time, for a total of 100 minutes total time. The RUC recommended a work RVU of 3.50 and the surveyed physician times for this 000-day global code.

We note that the result from the survey's 50th percentile work RVU was 3.73 and that the survey's 25th percentile work RVU was 2.80. As this CPT code is converting from a 010-day global to a 000-day global we find the reference CPT code 43193 (*Esophagoscopy, rigid, transoral; with biopsy, single or multiple*) as a more suitable value of 2.79 work RVUs with a similar 30 minutes of intraservice physician time and 106 minutes of total time. We proposed a work RVU of 2.79 for CPT code 28002 and we proposed the RUC surveyed physician times for this 000-day global code.

CPT code 28003 (*Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas*) currently has a 090-day global period with two post-operative follow-up office visits, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*); three post-operative follow-up office visits, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family.*); one post-operative CPT code 99231 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit*); one post-operative CPT code 99232 (*Subsequent hospital care, per day, for the evaluation and*

management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit), and one hospital discharge CPT code 99238 (*Hospital discharge day management; 30 minutes or less*), for a total of eight post op follow-up visits, across five types of E/M and hospital care codes. For CPT code 28003, the RUC recommends 40 minutes of preservice evaluation time, 10 minutes of preservice positioning time, 15 minutes of preservice scrub/dress/wait time, 45 minutes of intraservice time, and 20 minutes of immediate postservice time, for a total time of 130 minutes. We proposed the RUC-recommended work RVU of 5.28 and surveyed physician times for this 000-day global code.

In order to complete the adjustments for making these Treatment of Foot Infection codes consistent as 000-day global codes, the RUC adjusted the PE inputs for these codes to reflect their proposed global periods from 010 and 090-day globals to 000-day global, and to reflect the use of more typical supplies, equipment, and clinical labor employed now, than what was necessary a decade ago. Some relatively small valued supply items were removed, while other items were added, and clinical labor times were largely adjusted to remove minutes from the post-operative follow-up office visit times in the 010 and 090-day global codes. We proposed all of the PE refinements as recommended by the RUC for these codes.

Comment: Commenters supported CMS' proposal to adopt the AMA RUC-recommended work RVU of 2.00 for CPT code 28001 and work RVU of 5.28 for CPT code 28003, in this family of codes. However, commenters objected to the CMS proposed work RVU of 2.79 for CPT code 28002, as the AMA RUC recommended a higher work RVU of 3.50. Commenters stated that a work RVU of 2.79 for this code is too low and does not reflect the work intensity of CPT code 28002. Commenters objected to CMS' consideration of the physician work value 25th percentile survey result, which has a work RVU of 2.80. Commenters noted that the AMA RUC's 50th percentile survey result—a work RVU of 3.73—was too high, indicating that the AMA RUC recommend work RVU should fall somewhere between these two percentiles.

Response: We note that the current work RVU for CPT code 28002 as a 010-day global code with 30 minutes of intra-service time and 163 minutes of total time is 5.34. Since the AMA RUC recommended that this family of codes (Treatment of Foot Infection (CPT codes 28001, 28002, and 28003)) be revised to 000-day globals, any post-op follow-up visits included with CPT code 28002 and this family of codes, would be billed separately. We would expect that total time for CPT code 28002 would be revised to reflect this change. Specifically, CPT code 28002, a 010-day global code, is bundled with two E/M visits: CPT code 99213 (0.97 work RVUs and 23 minutes total time) and one half-day CPT code 99238 Hospital Discharge Day service (1.28 work RVUs and 38 minutes total time). Removing these postoperative services from the bundle should change the total time of CPT code 28002 from 163.0 minutes to 100.0 minutes.

Removing the post-op follow-up visits from the total time of CPT code 28002 results in a total time decrease of 65 minutes, but the AMA RUC recommended adding 2 minutes to the procedure's pre-positioning time, which nets to removing 63 minutes from current total of 163 minutes to a new total time of 100 minutes. This is a reduction of about 39 percent from the current total time for CPT code 28002. CPT code 99213 has a work RVU of 0.97. CMS multiplies this work RVU by two post-op visits, which totals 1.94, and the half-day Hospital discharge of CPT code 99239 is 0.64 work RVUs (1.28 divided by 2). CMS adds 1.94 and 0.64 work RVUs to get 2.58 work RVUs. Subtracting 2.58 work RVUs from the original 5.34 work RVUs for CPT code 28002 is 2.76 work RVUs. This 2.76 value, plus the survey's 25th percentile level work RVU of 2.80, and the comparator CPT code 43193 with a work RVU of 2.79, in combination suggests that the proposed work value of 2.79 is a proper valuation for CPT code 28002. This value maintains a proper relative relationship of work RVUs and time within this family of codes.

Comment: Commenters suggested alternative cross walk codes for CPT code 28002 that differed from the comparator code proposed by CMS (CPT code 43193). Specifically, they suggested CPT codes with the same 000-day global periods and the same intra-service minutes but with much higher work RVUs. The AMA RUC specifically suggested several codes as alternative crosswalks, including CPT code 31287 (*Nasal/sinus endoscopy, surgical, with sphenoidotomy;* with a work RVU of 3.50, 30 minutes of intra-service time, and 86 minutes of total time), CPT code 41530 (*Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session;* with a work RVU of 3.50, 20 minutes intra-service time, and 95 minutes total time), CPT code 52334 (*Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde*; with a work RVU of 3.37, 30 minutes intra-service time, and 75 minutes total time), CPT code 43194 (*Esophagoscopy, rigid, transoral; with removal of foreign body(s);* with a work RVU of 3.51, 30 minutes of intra-service time, and 107 minutes total time) and CPT code 58558 (*Biopsy and/or removal of polyp of the uterus using an endoscope;* with a work RVU of 4.17, 30 minutes of intra-service time, and 106 minutes total time), all of which are varying in levels of work and intensity, but all equal in intra-service times.

Response: The AMA RUC recommended a median intra-service time of 20 minutes for CPT code 28001, which is a reduction from 31 minutes, which is indicative of a reduction in this procedure's work intensity. The AMA RUC recommended median intra-service time for CPT code 28002 remains the same at 30 minutes, and indicates that the work intensity for this procedure has not changed. The AMA RUC recommended median intra-service time of 45 minutes for CPT code 28003 is a reduction from 53 minutes, which indicates a reduction in this procedure's work intensity. The AMA RUC has not recommended an increase in median intra-service time for any of the codes in this family, which indicates that work intensity for these codes is not increasing. Even so, the AMA RUC has recommended that physician time be added back to these services in pre-times and in immediate post-times. CMS' comparator CPT code 43193 accounts for these increases in pre-service and immediate post service minutes, whereas the example comparison codes that the AMA RUC has recommended, do not, and we believe them to be a less suitable match than CPT code 43193. CPT code 28002 maintains its intra-service time and is not changing its intensity to justify a higher work RVU as recommended by the AMA RUC.

Comment: One commenter stated that CMS' decision to reduce the work RVU for CPT code 28002 for CY 2010 unfairly

devalued CPT code 28002, and that CMS is further perpetuating that undervaluation now. This commenter stated that a flawed assumption about the site of service for CPT code 28002 was based on early 2009 data indicating that this service was performed in the inpatient setting 49.2 percent of the time. Subsequent utilization information indicated that the service was actually performed over 50 percent of the time in the inpatient setting. The commenter stated that this incorrect assumption led to the inclusion of only a half-day CPT code 99238 hospital discharge day for CPT code 28002's post-op services and a recommended reduction of 10 percent in work RVU. The commenter offered recent Medicare utilization claims for CPT code 28002 suggesting that the service is furnished in the inpatient setting over 60 percent of the time, which likely indicates that it was probably always an inpatient procedure, and that the CY 2010 work RVU reduction was unjustified because CMS assumed that this service was performed in the inpatient setting less than half of the time.

Response: The values for CPT code 28002 were finalized in CY 2010 and have been the basis of payment ever since then. Even if the AMA RUC agreed that CPT code 28002 was performed more often in the inpatient setting as compared to the outpatient setting in 2010, and recommended a full day hospital discharge instead of a half day discharge and reduced the payment for CPT code 28002, we still cannot say what their recommended final valuation might have been back then. CMS expects that any changes in valuation that reflect new information would come to CMS in the form of AMA RUC recommendations and if there was a flaw in the CY 2010 final valuation, commenters would have flagged this code for CMS review sooner, as 11 years have passed since CY 2010. CPT code 28002's current conversion to 000-day global code from a 010-day global code, makes the original half-day CPT code 99238 hospital discharge assignment irrelevant, since 000-day global codes do not have post-service discharge activities, and include no post-service follow-up visits.

After review of comments, we are finalizing the proposed work RVU value of 2.79 for CPT code 28002, as well as our proposal of the AMA RUC-recommended work RVUs for the other two codes in the family: CPT code 28001 and CPT code 28003. We are also finalizing the direct PE inputs recommended by the AMA RUC for all three CPT codes, as proposed.

(6) Percutaneous Cerebral Embolic Protection (CPT Codes 33370)

CPT code 33370 (*Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)*) was created in October 2020, by the CPT Editorial Panel as a new add-on code to report transcatheter placement and subsequent removal of cerebral embolic protection device(s). The CPT Editorial Panel also added instructions to report the new code in the Aortic Valve guidelines. The RUC reviewed the survey results for the new add-on code and noted that the survey respondents likely overvalued the physician work involved in performing this service, with a 25th percentile work value of 3.43. The RUC recommends a work RVU of 2.50 for CPT code 33370.

We proposed the RUC-recommended work RVU of 2.50 for CPT code 33370. This is a facility-based add-on code with no direct PE inputs.

Comment: Commenters stated that they were pleased that CMS accepted the RUC-recommended values for CPT code 33370.

Response: We are finalizing a work RVU of 2.50 for this code as proposed.

(7) Exclusion of Left Atrial Appendage (CPT Codes 33267, 33268, and 33269)

In May 2020, the CPT Editorial Panel approved the creation of three new codes to describe open and thoracoscopic left atrial appendage management procedures when performed as stand-alone procedures or in conjunction with other procedures. The codes represent new technology and surgical techniques that may be used to treat atrial fibrillation at the time of another surgical procedure and include CPT code 33267 (*Exclusion of left atrial appendage, open, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip*), CPT code 33268 (*Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)*), and CPT code 33269 (*Exclusion of left atrial appendage, thoracoscopic, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip*)). CPT codes 33267 and 33269 are 090-day global codes while CPT code 33268 is a ZZZ global code.

In October 2020, the RUC reviewed and recommended work and PE values for the three new codes. Recommended work values include 18.50 RVUs for CPT code 33267, 2.50 work RVUs for CPT code 33268, and 14.31 work RVUs for CPT code 33269.

We proposed the RUC-recommended work RVUs for the three new codes. We also proposed the RUC-recommended direct PE inputs for CPT codes 33267 and 33269. We note that CPT code 33268 has no direct PE inputs.

Comment: A few commenters supported our decision to propose the RUC-recommended valuations on the proposed values for the three new Exclusion of the Left Atrial Appendage codes.

Response: We thank commenters for their feedback. We are finalizing the proposed values for the codes: 18.50 RVUs for CPT code 33267, 2.50 work RVUs for CPT code 33268, and 14.31 work RVUs for CPT code 33269. We are also finalizing the direct PE inputs as proposed for all three codes.

(8) Endovascular Repair of Aortic Coarctation (CPT Codes 33894, 33895, and 33897)

In October 2020, the CPT Editorial Panel created CPT codes 33894 (*Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches*) and 33895 (*Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; not crossing major side branches*) to report endovascular stent repair of coarctation of the thoracic or abdominal aorta; and CPT code 33897 (*Percutaneous transluminal angioplasty of native or recurrent coarctation of the aorta*) to report trans-liminal angioplasty for repair of native or recurrent percutaneous coarctation of the aorta. For CY 2022, the RUC recommended a work RVU of 21.70 for CPT code 33894, a work RVU 17.97 for CPT code 33895, and a work RVU 14.00 for CPT code 33897.

We disagree with the RUC-recommended work RVUs for the CPT code family of 33894, 33895, and 33897. We found that the recommended work RVUs for these CPT codes were high when compared to other codes with similar time values. Therefore, we proposed the RUC survey 25th percentile of 18.27 as the work RVU for 33894, we proposed a work RVU of

14.54 for 33895, and we proposed a work RVU of 10.81 for 33897.

When we reviewed CPT code 33894, we found that the recommended work RVU was high compared to other codes with similar time values. The RUC survey 25th percentile of 18.27 falls within the range of RVUs with similar intra service time. This is supported by the reference CPT codes we compared to CPT code 33894 with intra service time similar to the 134 minutes of intra service time for CPT code 33894; reference CPT code 37231 (*Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed*) has a work RVU of 14.75 with 135 minutes of intra service time, and CPT code 93590 (*Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve*) has a work RVU of 21.70 with 135 minutes of intra service time. We note that the RUC-recommended RVU of 21.70 is a crosswalk from CPT code 93590 and is the highest value code within the range of reference codes we reviewed with similar intra service time. Again, we believe the RUC survey 25th percentile of 18.27 is a more appropriate value overall than 21.70 when compared to the range of codes with similar intra service time.

The RUC-recommended RVU of 17.97 for CPT code 33895 was higher than other codes with the same 120 minutes of intra service time and similar total time. Although we disagree with the RUC-recommended work RVU for 33895, we concur that the relative difference in work between CPT codes 33894 and 33895 is equivalent to the RUC-recommended interval of 3.73 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we proposed a work RVU of 14.54 for CPT code 33895, based on the RUC-recommended interval of 3.73 RVUs below our proposed work RVU of 18.27 for CPT code 33894.

The RUC-recommended work RVU of 14.00 for CPT code 33897 was higher than other codes with the same 90 minutes of intra service time and similar total time and we believe it will be more accurate to propose a work RVU that maintains the 3.73 incremental difference between the codes in this family. Therefore, for CPT code 33897, we proposed a work RVU of 10.81 which also continues the 3.73 incremental difference used between CPT codes 33894 and 33895, instead of the RUC incremental difference of 3.97 between CPT codes 33895 and 33897. Although the work RVU of 10.81 we proposed for CPT code 33897 is lower than the RUC recommendation, the 3.73 incremental difference between CPT codes 33895 and 33897 we proposed is more generous than the RUC incremental difference of 3.97 between CPT codes 33895 and 33897.

We proposed no direct PE inputs for the CPT code family of 33894, 33895, and 33897, as recommended by the RUC. These services are provided exclusively in the facility setting.

Comment: Commenters disagreed with our proposal and stated that we did not provide any clinical foundation for the proposed alternate value of CPT code 33894 and that we made no acknowledgement that this service is for pediatric patients with congenital defects and the extra work that goes into working with these special patients. Also, there are no 000-day global services with similar times. Some commenters stated that our use of CPT code 37231 as a reference code for CPT code 33894 was not suitable since it has 81 fewer minutes of total time. Commenters stated that beyond having similar intra-service time, reference CPT code 37231 has few similarities to CPT code 33894 and is a service that is less intensive to perform than CPT code 33894. In addition, commenters noted that CPT code 37231 is vastly different than CPT code 33894. The other reference code we used for CPT code 33894 was CPT code 93590, and commenters noted that CPT code 93590 was the code that the RUC had recommended to use as a direct work RVU crosswalk. Code 93590 has much less total time than CPT code 33894, though it was used by the RUC as a crosswalk due to the lack of services with similar total times.

Response: We continue to believe that the RUC-recommended work RVU of 21.70 for CPT code 33894 was high when compared to other codes with similar time values, and that the RUC survey 25th percentile work RVU of 18.27 is appropriate for CPT code 33894. We did use other 000-day Global services within a range of 120 to 135 minutes of intra-service time, and 203 to 223 minutes of total time, in our comparisons. Such comparison codes included reference CPT code 37231 on the low end of the range and CPT code 93590 on the high end of the range. The 25th percentile work RVU of 18.27 falls within the range of RVUs with similar intra-service time and total time. A direct work RVU crosswalk from CPT code 93590 would have put CPT code 33894 at the top end of the reference code range between CPT codes 37231 and 93590.

We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparison to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Commenters stated that relative to adult patients with normal cardiac anatomy, the pre-service evaluation time for pediatric patients with congenital defects includes additional time to discuss a patient's procedure with the parent. Commenters went on to say that similarly, the post-procedure work includes additional time to explain the pathology of the child to the parent. Also, commenters stated that congenital heart programs are now required to enter hemodynamic data and other procedural details into national registries which can add significant post procedure work time. By solely comparing CPT code 33894 to adult patient population services with much lower total times, commenters argue that we are not providing adequate consideration for the additional work or that a pediatric population with congenital defects is a more intense and complex patient population. In addition, commenters said we did not provide any discussion regarding the clinical attributes of CPT code 33894 or any of the reference codes and strongly recommended that we accept the RUC-recommended work RVU of 21.70 for CPT code 33894.

Response: We continue to believe that the RUC-recommended work RVU of 21.70 for CPT code 33894 was high when compared to other codes with similar time values, and that the RUC survey 25th percentile of 18.27 is appropriate for CPT code 33894. Regarding consideration of the clinical attributes and the complexity of working with the pediatric population for CPT code 33894, the review we conducted included the RUC-recommended work RVU, intensity, time to furnish the preservice, intra-service, and post-service activities, as well as other components of the service that contributed to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, other public commenters, medical literature,

as well as a comparison with other codes within the PFS, and consultation with other physicians and health care professionals within CMS and the Federal Government. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As stated in the response above, we also continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Commenters disagreed with our proposed work RVU of 14.54 for CPT code 33895, which was calculated by subtracting the 3.73 incremental difference between the RUC-recommend work RVUs for CPT codes 33894 and 33895 from our proposed work RVU of 18.27 for CPT code 33894 (18.27 − 3.73 = 14.54). Commenters noted that our rejection of the RUC-recommended work RVU of 21.70 for 33894 is flawed, and therefore, the proposed work RVU of 14.54 for 33895 instead of the RUC-recommended work RVU of 17.97 is inaccurate.

Response: In the responses above, we address the work RVU of 18.27 that we proposed for CPT code 33894. Although we disagreed with the RUC-recommended work RVU for CPT code 33895, we concurred that the relative difference in work between CPT codes 33894 and 33895 is equivalent to the RUC-recommended interval of 3.73 RVUs. Therefore, the work RVU of 14.54 for CPT code 33895 is valid, based on the RUC-recommended interval of a 3.73 reduction in RVUs below our proposed work RVU of 18.27 for CPT code 33895.

Comment: Commenters disagreed with our proposal to continue to use the 3.73 incremental difference between the other codes in this family (CPT codes 33894 and 33895) to calculate the proposed work RVU of 10.81 for CPT code 33897. Commenters said the RUC recommendation of a work RVU of 14.00 for CPT code 33897 does not have that increment with the other services in this family so CMS' rationale does not make sense, and the incremental difference between the other codes in this family should not be used as the basis to derive a new value for CPT code 33897.

Response: The 3.73 incremental difference is based on the RUC-recommended incremental difference between CPT codes 33894 and 33895. We believe that it is appropriate to have the same incremental difference of 3.73 between all three codes in the family. Therefore, we applied the same 3.73 increment to the work RVUs for 33895 and 33897 which resulted in our proposed work RVU of 10.81 for CPT code 33897. The RUC recommended incremental difference between CPT codes 33895 and 33897 was 3.97, which would have resulted in a lower proposed work RVU for 33897 if we had applied that same incremental difference to our proposed work RVU of 14.54 for CPT code 33895. Using the RUC-recommended incremental difference between CPT codes 33895 and 33897 would have brought our proposed work RVU for CPT code 33897 down to 10.57 instead of 10.81.

We believe the use of an incremental difference between codes is a valid methodology for setting work RVUs, especially in valuing services within a family of codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes.

Comment: Commenters stated that in general, CMS' review process for this code family and the reference code comparison seemed like CMS selecting an arbitrary and capricious value from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity between work RVUs. Also, commenters stated that CMS did not provide any clinical foundation for the proposed alternate value and made no acknowledgement that this service is for pediatric patients with congenital defects. Further, commenters thought that CMS did not provide a discussion regarding the clinical attributes of the surveyed procedure or any of the reference codes.

Response: We clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regard to clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. We also refer readers to the discussion of this subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2.) for more information.

After consideration of the public comments, we are finalizing the proposed work RVU of 18.27 for CPT code 33894, the work RVU of 14.54 for CPT code 33895, and the work RVU of 10.81 for CPT code 33897. There are no direct PE inputs for the CPT code family of 33894, 33895, and 33897, as these services are provided exclusively in the facility setting.

(9) Harvest of Upper Extremity Artery (CPT Codes 33509 and 35600)

In May 2020, the CPT Editorial Panel created CPT code 33509 (*Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic*) to describe endoscopic radial artery harvest via an endoscopic approach, and CPT code 35600 (*Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, open*) was modified to only include an open approach for the upper extremity harvesting procedure. The RUC also stated that CPT codes 33509 and 35600 are almost always exclusively performed in conjunction with coronary artery bypass grafting (CABG) procedures. For CY 2022, the RUC-recommended a work RVU of 3.75 for CPT code 33509 and a work RVU of 4.00 for CPT code 35600.

We disagree with the RUC-recommended RVUs for the CPT code family of 33509 and 35600. We found that the recommended work RVUs for these CPT codes were high when compared to other codes with similar

time values. Therefore, we proposed 3.34 as the work RVU for 33509 and we proposed a work RVU of 3.59 for 35600.

We disagree with the RUC-recommended work RVU for CPT code 33509 and we proposed an RVU of 3.34 which is a direct work RVU crosswalk from CPT code 35686 (*Creation of distal arteriovenous fistula during lower extremity bypass surgery (non-hemodialysis) (List separately in addition to code for primary procedure)*). The RUC-recommended value of 3.75 is higher than other codes with similar intra service time and total time. This is supported by the reference CPT codes we compared to CPT code 33509 with the same 35 minutes of intra service time and 35 minutes of total time as CPT code 33509; reference CPT code 74713 (*Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation (List separately in addition to code for primary procedure)*) has a work RVU of 1.85, and CPT code 35686 has a work RVU of 3.34.

Although we disagree with the RUC-recommended work RVU for CPT code 35600, we concur that the relative difference in work between CPT codes 33509 and 35600 is equivalent to the RUC-recommended interval of 0.25 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we proposed a work RVU of 3.59 for CPT code 35600, based on the RUC-recommended interval of 0.25 RVUs above our proposed work RVU of 3.34 for CPT code 33509.

We proposed no direct PE inputs for the CPT code family of 33509 and 35600 as recommended by the RUC. These services are provided exclusively in the facility setting.

The RUC acknowledged that CPT codes 33509 and 35600 are almost always exclusively performed in conjunction with coronary artery bypass grafting (CABG) procedures. Such codes are designated as add-on procedures and are assigned a ZZZ-day global period (that is, code related to another service and is always included in the global period of the other service). The RUC also requested that the global period for both CPT codes 33509 and 35600 be an XXX-day global period (that is, global concept does not apply) and not a ZZZ-day global period as is customary for add-on codes. The RUC stated that an XXX-day global period would allow the individual that performs the harvest of upper extremity artery procedure (often separate from the surgeon performing the base CABG procedure) to report it under their own provider number. The RUC noted that it is often a nurse practitioner (NP) or physician's assistant (PA) who performs the harvest procedure. However, the RUC surveyed CPT codes 33509 and 35600 using reference codes with the ZZZ-day global period. Therefore, we believe it is appropriate to use that same ZZZ-day global period for CPT codes 33509 and 35600, and we proposed to assign the ZZZ-day global period to CPT codes 33509 and 35600 for CY 2022. Through our scrutiny of comparing the code descriptions of codes with matching intra service times, we find much more clinically coherent similarities with codes with a ZZZ-day global period (procedures complementary, and sometimes necessary, to complete a larger procedure) than codes with an XXX-day global period.

However, we were compelled to understand more about the billing circumstances presented by the RUC and stakeholders that have presented this approach for CPT codes 33509 and 35600 to CMS for consideration. We solicited comments and requested information that could inform why CPT codes 33509 and 35600 should have an XXX-day global period instead of the ZZZ-day global period that is customary for add-on codes.

Comment: Commenters disagreed with our proposed work RVU of 3.34 for CPT code 33509 and stated that unlike reference CPT codes 35686 and 74713, CPT code 33509 is typically performed by a separate practitioner than the one that is performing the base procedure. Also, there were concerns that we did not take into consideration the intraoperative evaluation, the total physician work, and the intensity associated with the procedure, which also contributed to the RUC's recommendation for a value that is higher than other procedures with similar intra and total times.

Response: We disagree with the commenters regarding our use of CPT codes 35686 and 74713 as reference codes to determine our proposed work RVU of 3.34 for CPT code 33509. Whether or not the practitioner performing CPT code 33509 is the same practitioner who performed the base procedure or is a separate practitioner does not change the work RVU for this procedure. For CPT code 33509, we proposed an RVU of 3.34 which is a direct work RVU crosswalk from CPT code 35686. When we looked at codes with the same 35 minutes of intra-service time and 35 minutes of total time as CPT code 33509, reference CPT code 35686 had the highest RVU of the codes with the same 35 minutes of intra-service time and total time.

Comment: Commenters stated that the reference code CMS used, CPT code 35686, as a direct work RVU crosswalk for CPT code 33509 has not been reviewed by the RUC or CMS in 20 years and has virtually no volume. Furthermore, the reference code that CMS cited as support for their proposal—CPT code 74713—is an imaging code that has no clinical similarities to the survey code.

Response: We disagree with the commenters' statement that CPT code 35686 should not be used as a reference code because it has not been reviewed in 20 years and has low utilization. We also disagree with the commenters' statement that CPT code 74713 should not be used as a reference code because it is not a service similar to CPT code 33509. We agree that it is important to use the recent data available regarding time, and we acknowledge that when many years have passed since work time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes are a very important element in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been underestimated or overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times and it undermines the validity of the allocation of indirect PE RVUs to physician specialties across the PFS. Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting process are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily

obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Commenters disagreed with our proposed work RVU of 3.59 for CPT code 35600 based on the increment of 0.25 between the RUC-recommended values of CPT codes 33509 and 35600, and stated that we did not list any specific reference codes for this service to support our proposed work RVU of 3.59. Commenters also stated that our proposed work RVU of 3.59 lowers the intensity to an amount well below that of the other surgical add-on procedures, and that the RUC's recommended RVU of 4.00 was already leading to a decrease of 19 percent even though the surveys supported the same intra and total time for CPT code 35600 which has a higher valuation of 4.94.

Response: Although we disagreed with the RUC-recommended work RVU for CPT code 35600, we concurred that the relative difference in work between CPT codes 33509 and 35600 is equivalent to the recommended interval of 0.25 RVUs. Therefore, the work RVU of 3.59 for CPT code 35600 is valid, based on the recommended interval of a 0.25 increase in RVUs above our proposed work RVU of 3.34 for CPT code 33509. Also, as stated in our response above, for CPT code 33509, the reference codes we used were CPT codes 35686 and 74713. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. We apply various methodologies to identify several potential work RVU values for individual codes. We also refer readers to the discussion of this subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2.) for more information.

Comment: Two commenters responded to our request for information regarding the RUC's request that the global period for both CPT codes 33509 and 35600 be an XXX-day global period (that is, global concept does not apply) and not a ZZZ-day global period as is customary for add-on codes. The commenters both provided very similar information, and stated that the rationale for assigning an XXX global period instead of a ZZZ add-on global period for CPT codes 33509 and 35600, even though these services are almost exclusively performed in conjunction with an arterial Coronary arterial bypass graft (CABG) procedure, is that an XXX global would allow the individual who performs the harvest of an upper extremity artery procedure (often separate from the surgeon performing the base CABG procedure and not the first assistant) to report it under their National Provider Identifier (NPI) number. The societies involved in surveying CPT codes 33509 and 35600 had also indicated that sometimes a separate physician or other qualified health professional (QHP), typically a PA or NP, performing these codes is not part of the same practice as the surgeon performing the CABG procedure or is not the first assistant at surgery for the CABG procedure. Therefore, there would be no established mechanism for paying this practitioner for their work.

Similarly, commenters stated if the physician or QHP who performs the upper extremity artery harvest is in the same practice but is not the first assistant at surgery for the CABG surgery, they have no mechanism to report an add-on code since they are not reporting the base arterial CABG code. In both situations, the individual performing CPT codes 33509 or 35600 does not have a primary code to report with it, which would result in these codes being denied for payment. In many cases, even if the individual performing CPT codes 33509 and 35600 is the first assistant at surgery and reports an arterial CABG procedure with an appropriate assistant at surgery modifier (-80, -82 or -AS), the add-on code, which is only reported by the assistant at surgery, is not recognized by payers. Commenters noted that by assigning an XXX-day global period to these codes and valuing them as ZZZ-day global codes, the individual that performs CPT codes 33509 and 35600 can report these codes without also having to report an arterial CABG code, thereby ensuring that the practitioner performing the service is reimbursed at the appropriate rate (for example, physician vs NP or PA). The reason that the two codes were surveyed using a reference service list with ZZZ-day global codes is to ensure that the codes were valued in the same manner as an add-on code with no pre or post service work included in the procedure. Commenters stated that this is the case because, as CMS points out, they are worded in the same manner as other add-on codes and only include the additional work of harvesting the upper extremity artery. While these codes are in essence an add-on code, they are unique in that the additional intra-operative work represented by the procedures is typically performed by individuals that specialize in harvesting the grafts for CABG procedures. These individuals may or may not be associated with the same practice as the surgeon performing the procedure, and it is often the only service that individual provides for the case.

In addition, commenters stated that when referencing that the harvest procedure is almost always performed with a CABG procedure, CMS noted that ''. . . such codes are designated as add-on procedures and are assigned a ZZZ-day global period (that is, a code related to another service and is always included in the global period of the other service).'' However, commenters stated that is not the case for services that are performed by a separate provider than the surgeon performing the primary procedure. A relatively recent example of services like this are the separate practitioner moderate sedation CPT code 99155 (*Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intraservice time, patient younger than 5 years of age),* 99156 *(Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intraservice time, patient age 5 years or older),* and 99157 *(Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intraservice time (List separately in addition to code for primary service)*) which CMS assigned an XXX-day global period.

Response: We solicited comments and requested information that could inform why CPT codes 33509 and 35600 should have an XXX-day global period instead of the ZZZ-day global period that is customary for add-on codes, and received two comments. After reviewing

the comments, it remains unclear that the solution to a billing issue which does not seem to affect the majority of the practitioners billing for these add-on services is to revise the global period for CPT codes 33509 and 35600 in order to bypass our existing standard policies and payment procedures. For instance, CPT code 35600 has been in use as a ZZZ-day global period code since 2001, and we are unaware of any information from stakeholders suggesting that they were unable to get their claims paid because of the ZZZ-day global period in the past. We are concerned that assigning an XXX-day global period instead of a ZZZ-day global period for CPT codes 33509 and 35600 would be inconsistent with current standard policies and payment procedures. These codes are not relative to the other services with an XXX-day global period. We find much more clinically coherent similarities with ZZZ-day global codes (procedures complementary, and sometimes necessary, to complete a larger procedure) than XXX-day global period codes. A ZZZ-day global add-on code is a code that is related to another service and is always included in the global period of the other service. (Note: Physician work is associated with intra-service time and in some instances the post service time.) Both commenters also agreed that CPT codes 33509 and 35600 are, in essence, add-on procedures. Therefore, we believe that a ZZZ-day global period is appropriate for both of these codes because they would not be done on their own, and would always be performed with another surgical procedure. Codes with ZZZ-day global periods are always listed separately in addition to the primary procedure and included in the global period of the other service, while the global period concept does not apply to codes with an XXX-day global period. However, we also believe there may be another solution to the billing issue described by the two commenters. Instead of altering the global periods for these codes, we suggest that stakeholders consider coding options that describe when a different practitioner is performing the add-on procedure, the same way the practitioner performing the preoperative or postoperative care during the global period of a surgery can be distinguished from a different practitioner who performed that surgery through the use of modifiers. This would be similar to the example provided by the commenters who highlighted how the separate practitioner moderate sedation CPT codes 99155, 99156, and 99157 were created. Unlike the descriptions for CPT codes 33509 and 35600, the descriptions for CPT codes 99155, 99156, and 99157 specifically state that these codes identify situations in which moderate sedation services are provided by a practitioner who is not performing the diagnostic or therapeutic service that the sedation supports. Also, we note that while CPT codes 99155 and 99156 both have an XXX-day global period, CPT code 99157 has a ZZZ-day global period and not an XXX-day global period as stated by the commenters.

After consideration of the public comments, we are finalizing the proposed work RVU of 3.34 for CPT code 33509 with a ZZZ-day global period, and the proposed work RVU of 3.59 for CPT code 35600 with a ZZZ-day global period. There are no direct PE inputs for this CPT code family, as these services are provided exclusively in the facility setting.

(10) Needle Biopsy of Lymph Nodes (CPT Code 38505)

CPT code 38505 (*Biopsy or excision of lymph node(s); by needle, superficial (eg, cervical, inguinal, axillary)*) was identified in October 2019 as Harvard Valued with a utilization of over 30,000 claims. In January 2020, the RUC recommended that the code be surveyed for October 2020 RUC meeting. The RUC recommended increasing the work RVU to 1.59 which is the survey 25th percentile, acknowledging a change in the service, which now involves larger tissue samples, as well as a change in technology, and a change in the dominant specialty now reporting the service.

We proposed the RUC-recommended work RVU of 1.59 for CPT code 38505. We also proposed the RUC-recommended direct PE inputs for this code.

Comment: One commenter suggested that we give the primary specialties that use CPT code 38505 time to investigate and identify the root cause of the claim submission, provide appropriate education to their practitioners regarding appropriate use criteria, and present that data to the RUC subcommittee or workgroup for evaluation.

Response: We believe this comment is directed towards the RUC. We will consider any future RUC recommendations for the work RVU for CPT code 38505 when they are submitted.

Comment: Commenters appreciated that CMS proposed the RUC-recommended work RVU and direct PE inputs for CPT code 38505.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing the proposed work RVU of 1.59 for CPT code 38505. We are also finalizing the RUC-recommended direct PE inputs for code 38505 without refinement.

(11) Drug Induced Sleep Endoscopy (CPT Codes 42975)

CPT code 42975 (*Drug induced sleep endoscopy; with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing; flexible, diagnostic*) is a new code created to report drug induced sleep endoscopy (DISE) flexible, diagnostic. The RUC recommended, and we agree, that the survey 25th percentile for the work RVU of 1.90 accurately reflects the typical physician work necessary to perform this service.

Since this is a drug induced sleep endoscopy, we proposed CPT code 31575 (*Diagnostic laryngoscopy*) as the endoscopic base code for CPT code 42975 because the description of the proposed CPT code is the same as what is described for CPT code 31575 with the additional component of the patient being sedated. The procedure is performed with a flexible endoscope or laryngoscope. CPT code 42975 is not an add-on code, it has a 0-day global period. The endoscopic base code that it is using is a specific type of multiple procedure discount that applies to some endoscopy codes.

We proposed the RUC-recommended work RVU of 1.90 for CPT code 42975. We also proposed the RUC-recommended direct PE inputs for this code.

Comment: Commenters appreciated that CMS proposed the RUC-recommended work RVU of 1.90 and the RUC-recommended direct PE inputs for CPT code 42975.

Response: We thank commenters for their support.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 1.90 and the RUC-recommended direct PE inputs for CPT code 42975 as proposed.

(12) Per-Oral Endoscopic Myotomy (POEM) (CPT Codes 43497)

In May 2020, the CPT Editorial Panel created a new CPT code 43497 (*Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM]*) to describe a Per-Oral Endoscopic Myotomy (POEM), which involves the visualization and dissection of the esophageal muscle layers via an endoscope to treat esophageal motility disorders such as achalasia. This

procedure accomplishes a comparable myotomy to what traditional open and laparoscopic myotomy (Heller) accomplishes. POEM utilizes an endoscope and specially designed dissecting, cutting, and cauterizing instruments to create a long submucosal tunnel beginning in the mid-esophagus and extending several centimeters into the cardia. For CY 2022, the RUC recommended a work RVU of 15.50 for CPT code 43497.

We disagreed with the RUC-recommended work RVU for CPT code 43497 and proposed a work RVU of 13.29 based on a direct work RVU crosswalk from CPT code 36819 (*Arteriovenous anastomosis, open; by upper arm basilic vein transposition*). CPT code 36819 has the same 120 minutes of intra service time as CPT code 43497, and has 283 minutes of total time, which is 2 minutes more than the 281 minutes of total time than for 43497. The RUC used CPT codes 43279 (*Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed*) and 43180 (*Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (e.g., Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed*) as reference codes for CPT code 43497. However, the intra service time of 150 minutes and total time of 404 minutes for the RUC reference CPT code 43279, and intra service time of 60 minutes and total time of 201 minutes for the RUC reference CPT code 43180, are not adequate comparisons since they do not have similar time values to those of CPT code 43497. Therefore, we believe the proposed work RVU of 13.29 for CPT code 43497 based on a direct work RVU crosswalk from CPT code 36819 is a better representation of the work being performed and is more appropriate based on the same intra service time and similar total time.

We proposed the RUC-recommended direct PE inputs for CPT code 43497 without refinement.

Comment: Commenters disagreed with our proposal to crosswalk the work RVU of 13.29 from CPT code 36819 to CPT code 43497. The commenters stated that crosswalking to CPT code 36819 based on time alone is inappropriate and fails to consider the physician work necessary to perform this service. Beyond comparing the time similarities, it is unclear whether any other criteria were used to identify the CMS recommended work RVU as CMS did not include any clinical comparisons or quantifiable inputs. Also, commenters stated that CMS failed to provide justification on why the survey data was ignored in the analyses used to determine the work RVU for this service. Most importantly, commenters noted that CMS does not provide a rationale that would warrant the work RVU to fall below the survey 25th percentile from a robust survey. They said that a crosswalk based on time alone is not an appropriate justification for any code, especially a new code.

Response: We believe that the proposed work RVU of 13.29 for CPT code 43497 is appropriate. CPT code 36819 was reviewed in 2013 and has the same intra-service time of 120 minutes and 2 additional minutes of total time than the 281 minutes of total time for CPT code 43497, and is close to an exact crosswalk. We compared CPT code 43497 to the other codes with the same 120 minutes of intra-service time and with total times ranging from 271 to 291 minutes. We found the work RVUs ranged from a low of 5.90 (represented by CPT code 33220 (*Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator) with 276 minutes of total time*) to a high of 17.71 (represented by CPT code 58572 (*Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g*) with 271 minutes of total time). The RUC recommended RVU of 15.50 was high in comparison to the range of RVUs for the comparison CPT codes with the same intra-service time and similar total times, therefore we believe this work RVU crosswalk from CPT code 36819 to CPT code 43497 is a valid crosswalk. Also, the Total Time Ratio of 12.62 between the 2nd key reference code of CPT code 43180 and CPT code 43497 supports a value closer to 13.00 RVUs. The survey data ranged from a minimum value of 5.00 to a maximum value of 39.00. We looked at the RUC survey 25th percentile value of 15.50, which is also the RUC-recommended work RVU. We also looked at the 25th percentile value of each of the surveys listed on the RUC Summary Report, and note that there was a wide range of 25th percentile values shown, ranging from 12.00 to 21.00. Our proposed work RVU crosswalk of 13.29 for CPT code 43497 from CPT code 36819 is above the lowest 25th percentile value that was provided in the RUC Summary Report, and is closer to the Total Time Ratio of 12.62 described above. We believe this provides additional support for a work RVU that is closer to 13.00, and therefore, our proposed work RVU of 13.29 for CPT code 43497 is appropriate.

Comment: Commenters stated that CPT code 43497 should have a work RVU value of 15.50 based on the RUC's 119 survey results and physician input, and that a work RVU of 15.50 accurately reflects the physician work necessary to perform this service. They noted that the flawed crosswalk work RVU of 13.29 for CPT code 43497 creates inconsistencies within the RBRVS as the intensity level for CPT code 43180 would be higher if the proposed work RVU is accepted.

Response: We believe the RUC-recommend work RVU of 15.50 for CPT code 43497 is high in comparison to the range of work RVUs for the comparison CPT codes with the same intra-service time and similar total times, and therefore, we believe this work RVU crosswalk from CPT code 36819 to CPT code 43497 is a valid crosswalk. CPT code 36819 has the same intra-service time of 120 minutes and 2 additional minutes of total time than the 281 minutes of total time for CPT code 43497, and is close to an exact crosswalk. We compared CPT code 43497 to the other codes with the same 120 minutes of intra-service time and with total times ranging from 271 to 291 minutes. We found the work RVUs ranged from a low of 5.90 (represented by CPT code 33220 with 276 minutes of total time) to a high of 17.71 (represented by CPT code 58572 with 271 minutes of total time). Also, the Total Time Ratio of 12.62 between the 2nd key reference code of CPT code 43180 and CPT code 43497 supports a value closer to 13.00 RVUs. Therefore, we believe that the proposed work RVU of 13.29 for CPT code 43497 is appropriate.

Comment: Commenters stated that the reference CPT codes 43279 and 43180 provided by the RUC were never meant to be crosswalk codes; they are reference codes that act as bookends to demonstrate how the value of CPT code 43497 falls appropriately between them thereby maintaining relativity. It is logical that the survey takers migrated towards CPT codes 43279 and 43180 as the top two key reference services based on their familiarity with these procedures and the disease states treated by these procedures. Commenters stated that the reference codes are intended to act as supporting rationale to demonstrate relativity within the PFS. Commenters assert that CPT codes 43279 and 43180 are representative of this concept in that they demonstrate the validity of the 15.50 RVU recommendation for 43497, which falls between the established RVUs of CPT code 43279, the longer more intense procedure, and CPT code 43180, the shorter less intense procedure. Also, there are numerous codes with a similar intra-service time

and intensity with higher work RVUs that CMS could have selected as a more appropriate crosswalk for CPT code 43497. Commenters believe that a work RVU of 15.50 most accurately reflects the physician work and intensity necessary to perform this service.

Response: We believe the RUC-recommended work RVU of 15.50 is high. We compared CPT code 43497 to the other codes with the same 120 minutes of intra-service time and with total times ranging from 271 to 291 minutes. We found the work RVUs ranged from a low of 5.90 (represented by CPT code 33220 with 276 minutes of total time) to a high of 17.71 (represented by CPT code 58572 with 271 minutes of total time). Therefore, we believe the work RVU crosswalk from CPT code 36819 to CPT code 43497 is appropriate. CPT code 36819 has the same intra-service time of 120 minutes and 2 additional minutes of total time than the 281 minutes of total time for CPT code 43497, and is close to an exact crosswalk. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regard to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. We also refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2.)

Comment: Commenters stated that CMS' recommendation to crosswalk CPT code 43497 to 36819 is based only on time and fails to take into consideration the difference in intensity between the procedures. CPT code 36819 represents one of many codes that CMS could have selected to use as a crosswalk based on time. Value is based on multiple factors including procedure time, technical skill required, physical effort involved, mental effort and judgment, and stress due to the potential risks to the patient. Commenters stated that if CMS were to truly have considered intensity in addition to time, the selected crosswalk should have reflected this consideration by selecting a code with similar intensity. A search of the RUC database for 90-day global codes with 120 minutes of intra- service time yields 235 CPT codes with an intra-service work per unit of time (IWPUT) ranging from -0.036 to 0.1983. CMS' recommended work RVU of 13.29 for CPT code 43497 creates a rank-order anomaly in the intensities of related procedures.

Response: We continue to believe that crosswalking the work RVU of 13.29 from CPT code 36819 to CPT code 43497 is appropriate. CPT code 36819 has the same intra-service time of 120 minutes and 2 additional minutes of total time than the 281 minutes of total time for CPT code 43497, and is close to an exact crosswalk for CPT code 43497. In general, CMS considers a variety of factors when we review the RUC recommendations as indicated in the response above. Again, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2.).

Comment: Commenters disagreed with crosswalking the work RVU of CPT code 36819 to CPT code 43497 and urged CMS to accept the RUC-recommended RVU of 15.50 for CPT code 43497. CPT code 36819 is an open, three-dimensional procedure with a multi-person surgical team using a wide field of view, operating on an upper extremity with local anesthesia from nerve block. Also, CPT code 36819 is not an endoscopic procedure, involves completely different work and has an IWPUT of 0.0755. The IWPUT of CPT code 43497 is significantly higher at 0.091.

Response: We continue to believe that the RVU of 13.29 for CPT code 43497 based on a crosswalk from CPT code 36819 is more appropriate than the RUC-recommended work RVU of 15.50. CPT code 36819 has the same intra-service time of 120 minutes and 2 additional minutes of total time than the 281 minutes of total time for CPT code 43497, and is close to an exact crosswalk for CPT code 43497. In more general terms, we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

After consideration of the public comments, we are finalizing the proposed work RVU of 13.29 for CPT code 43497. We are also finalizing the RUC-recommended direct PE inputs for CPT code 43497 without refinement.

(13) Placement-Removal of Seton (CPT Codes 46020 and 46030)

For CPT codes 46020 (*Placement of seton*) and 46030 (*Removal of anal seton, other marker*), we disagree with the RUC-recommended work RVUs of 3.50 and 2.00, respectively, as we believe these values do not adequately reflect the surveyed reductions in physician time for CPT code 46020 and the change to a 000-day global period from a 010-day global period for these CPT codes. Instead, we proposed a work RVU of 1.86 for CPT code 46020 and 1.48 for CPT code 46030 based on a reverse building block methodology.

The survey showed that total time and intraservice time are decreasing for CPT code 46020 by 26 minutes and 5 minutes, respectively. We believe the surveyed decreases in physician time in conjunction with the loss of the post-operative visits for CPT code 46020 merit a decrease in work RVU from the current work RVU.

We note that the proposed work RVU of 1.48 for CPT code 46030 falls between CPT code 57410 *(Pelvic examination under anesthesia (other than local))*, which has a work RVU of 1.75, and CPT code 64487 *(Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed))*, which has a work RVU of 1.48. Both of these bracketing reference codes have identical intraservice times and similar total time values. While we understand that total time is going up for CPT code 46030, this increase is a result of significant increases to evaluation, positioning, and scrub, dress, wait preservice times,

which is mostly low-intensity physician work.

We agree with the RUC's recommendation to change CPT codes 46020 and 46030 to 000-day global period codes from 010-day global period codes to account for the highly variable follow-up care for these services, but we note that the differences in RUC-recommended work RVUs and our proposed work RVUs largely reflect the change in global period and loss of physician time to provide the E/M services. The global period changes from 010-day to 000-day allow for separately billable E/M visits relating to CPT codes 46020 and 46030, therefore we removed RVUs that we believed were attributable to the currently bundled E/M visits totaling 2.04 RVUs for CPT code 46020 and 0.35 RVUs for CPT code 46030. CPT code 46020 is currently bundled with two post-operative follow up office visits, CPT code 99212 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter),* and a half hospital discharge CPT code 99238 (*Hospital discharge day management; 30 minutes or less*). CPT code 46030 is currently bundled with half of a post-operative follow up office visit, CPT code 99212 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter).* We do not believe the RUC adequately accounted for the loss of these E/M visits in their recommended work RVUs for CPT codes 46020 and 46030.

The RUC proposed the standard 090-day preservice times for the clinical labor activities CA001, CA002, CA003, CA004, and CA005 for CPT code 46020 in the facility. We note that the RUC recommended 090-day preservice clinical labor times despite surveying the service as a 000-day service. We disagree with the RUC-recommended 090-day preservice clinical labor times as we believe 000-day services should have times consistent with 000-day services, not 090-day services. However, we recognize there is time needed to coordinate this service. Therefore, we proposed the following standard clinical labor times for extensive use of clinical staff for a 000-day global code for CPT code 46020 in the facility:

- Complete preservice diagnostic and referral forms (CA001) 5 minutes.
- Coordinate pre-surgery services (including test results) (CA002) 10 minutes.
- Schedule space and equipment in facility (CA003) 5 minutes.
- Provide preservice education/obtain consent (CA004) 7 minutes.
- Complete pre-procedure phone calls and prescription (CA005) 3 minutes.

We also proposed to refine the direct PE input for Coordinate post-procedure services (CA038) to 0 minutes from the RUC-recommended 3 minutes to align with 000-day standards instead of 090-day standards for CPT code 46020.

For CPT code 46030, the RUC recommended the standard 000-day extensive use of clinical staff preservice times for clinical activities CA001, CA002, CA003, CA004, and CA005 in the facility and non-facility settings. Preservice times for 000-day codes are presumed to be zero unless there is sufficient justification that preservice time is warranted. We do not agree that sufficient justification was presented to warrant preservice time in the non-facility setting, therefore, we proposed the following standard clinical labor times for use of clinical staff in the non-facility setting. We also proposed the standards for minimal use of clinical staff in the facility setting, as we recognize there is time needed to coordinate this service for CPT code 46030:

- Complete preservice diagnostic and referral forms (CA001) 0 minutes for non-facility and 3 minutes for facility.
- Coordinate pre-surgery services (including test results) (CA002) 0 minutes for non-facility and 3 minutes for facility.
- Schedule space and equipment in facility (CA003) 0 minutes for non-facility and 3 minutes for facility.
- Provide preservice education/obtain consent (CA004) 0 minutes for non-facility and 3 minutes for facility.
- Complete pre-procedure phone calls and prescription (CA005) 0 minutes for non-facility and 3 minutes for facility.

We also proposed to refine the direct PE input for Coordinate post-procedure services (CA038) to 0 minutes from the RUC-recommended 3 minutes to align with 000-day standards instead of 090-day standards for CPT code 46030.

Comment: Commenters opposed the use of reverse building block methodology and stated that the calculations of work RVUs for these CPT codes were not transparent. Commenters stated that we removed work RVUs based on the CY 2021 E/M increased work RVU of 0.70 for CPT code 99212. Commenters also stated that CPT code 46020 was originally misvalued. Commenters disagreed with our reference to older work time sources, and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: The global period changes from 010-day to 000-day allow for separately billable E/M visits relating to CPT codes 46020 and 46030; therefore, we removed RVUs that we believed were attributable to the currently bundled E/M visits totaling 2.04 RVUs (when billed separately) for CPT code 46020 and 0.35 RVUs (when billed separately) for CPT code 46030 using the reverse building block methodology. Reverse building block methodology accounts for the longstanding times and work RVU associated with CPT code 99212 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter)* for bundled office visits in the surgical global period, rather than the increased CY 2021 office/outpatient E/M work RVU of 0.70 for CPT code 99212, as commenters suggested. The longstanding times and work RVUs accounted for in the reverse building block methodology are 16 minutes and 0.48 work RVUs for CPT code 99212 and 38 minutes and 1.28 work RVUs for CPT code 99238. Therefore, we did not subtract the increased CY 2021 office/outpatient E/M work RVU of 0.70 for CPT code 99212 as the commenters suggested. CPT code 46020 is currently bundled with two post-operative follow up office visits (CPT code 99212) and a half hospital discharge day (CPT code 99238). In CY 2022, when the currently bundled visits in the global period are furnished, practitioners could bill for a total of 2.04 work RVUs, as the visits would no longer be bundled in the global period. CPT code 46030 is currently bundled with half of a post-operative follow up office visit, CPT code 99212. In CY 2022, when the currently bundled visits in the global period are furnished, practitioners could bill for a total of 0.35 work RVUs, as the visit would no longer be bundled in the

global period. We continue to believe that the RUC did not adequately account for the removal of these E/M visits as a result of the global period changes in their recommended work RVUs for CPT codes 46020 and 46030.

We agree with commenters that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been underestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Some commenters stated that they were concerned about CMS' lack of consideration for compelling evidence that services have changed. Commenters stated that CMS appeared to dismiss the fact that services may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services. Commenters requested that CMS address the compelling evidence submitted with the RUC recommendations when the agency does not accept the RUC's recommended work RVUs.

Response: The concept of compelling evidence was developed by the RUC as part of its work RVU review process for individual codes. The RUC determines whether there is compelling evidence to justify an increase in valuation. The RUC's compelling evidence criteria include documented changes in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the service. While we appreciate the submission of this additional information for review, we emphasize that the RUC developed the concept of compelling evidence for its own review process; an evaluation of ''compelling evidence,'' at least as conceptualized by the RUC, is not part of our review process, as our focus is on the time and intensity of services, in accordance with the statute. With that said, we do consider changes in technology, patient population, and other compelling evidence criteria, as such evidence may affect the time and intensity of a service under review. For example, new technology may cause a service to become easier or more difficult to perform, with corresponding effects on the time and intensity of the service. However, we are under no obligation to adopt the same review process or compelling evidence criteria as the RUC. We instead focus on evaluating and addressing the time and intensity of services when reviewing potentially misvalued codes because section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service.

Based on the aforementioned references and consideration of the comments, we are finalizing the work RVUs as proposed for CPT codes 46020 and 46030 based on the reverse building block methodology. We continue to believe the proposed work RVU for CPT code 46020 adequately accounts for the 5-minute decrease in intraservice time, 26-minute decrease in total time, 51-minute decreased in postservice time, and a change to a 000-day global period which will allow for separately billable E/M visits as medically necessary. We continue to believe that the 1.48 work RVUs for CPT code 46030 adequately accounts for the 3-minute decrease in intraservice time, 8-minute decrease in post-service time, and a change to a 000-day global period which will allow for separately billable E/M visits as medically necessary.

Comment: Some commenters stated that CMS is proposing to refine the preservice clinical labor times for major procedures to conform to the 000-day global period standards despite the RUC recommendation of standard 090-day preservice clinical labor times. Commenters stated that CPT codes 46020 and 46030 are major procedures performed under general anesthesia when performed the facility setting. Commenters stated that the change to a 000-day global period was requested to account for variable post-operative care and does not change the need for clinical staff time typical of 90-day global procedures performed in the facility setting. Commenters stated that reassignment of global periods for select codes does not negate the fact that a major procedure is a major procedure and the pre-service facility clinical staff time for a major procedure is independent of the global period assignment. Commenters stated that each procedure should be evaluated on a case-by-case basis.

Response: We agree with the commenters that the direct PE inputs for each service should be evaluated on a case-by-case basis based on our criteria of what would be reasonable and medically necessary in the typical case. We reviewed the individual codes in question and concluded that the use of 000-day global period standards for ''Extensive use of clinical staff'' for CPT code 46020 and 000-day global period standards for ''Minimal use of clinical staff'' for CPT code 46030 in the facility would be most typical in these cases. As we noted under the Standardization of Clinical Labor Tasks section (section II.B) of this final rule, we continue to believe that setting and maintaining clinical labor standards provides greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes.

We refer readers to section II.B of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

After consideration of the comments, we are finalizing the work RVUs as proposed for CPT codes 46020 and 46030. We are also finalizing our

clinical labor inputs as proposed for CPT codes 46020 and 46030.

(14) Periurethral Balloon Continence Device Procedures (CPT Codes 53451, 53452, 53453, and 53454)

In October 2020, the CPT Editorial Panel replaced four CPT Category III codes with four new CPT Category I codes to report periurethral adjustable balloon continence devices. Given the low utilization and the low survey response rate for the four new codes, the RUC recommended that CMS assign contractor pricing to these procedures. We agree with the RUC and we proposed contractor pricing for all four codes in the family, CPT codes 53451 *(Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance),* 53452 *(Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance),* 53453 *(Periurethral transperineal adjustable balloon continence device; removal, each balloon)* and 53454 *(Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume).*

Comment: Several commenters supported the proposal to assign contractor pricing for CPT Codes 53451–53454.

Response: We appreciate the support for our proposal from the commenters.

After consideration of the comments, we are finalizing our proposal of contractor pricing for all four codes in the family.

(15) Intracranial Laser Interstitial Thermal Therapy (LITT) (CPT Codes 61736 and 61737)

In October 2020, the CPT Editorial Panel approved the addition of two codes to report laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance (MR) imaging guidance for a single trajectory for 1 simple lesion and multiple trajectories for multiple or complex lesion(s). LITT is a novel procedure that involves multiple steps and movements of the patient through the hospital for different stages of the procedure. The typical facility does not have an interoperative MRI suite (a small minority of academic medical centers may), so patient transport is necessary.

The RUC recommended a work RVU of 20.00 for CPT code 61736 *(Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion)* based on the survey median response. CPT code 61736 was surveyed with having one subsequent hospital visit, CPT code 99232 *(sbsq hospital care/day 25 minutes)* and 40 minutes of immediate postservice time. The RUC noted that although the survey median immediate postservice time was 40 minutes, for 61736, the CMS 23-Hour Stay Outpatient Surgical Services with Subsequent Hospital Visits Policy was applied which resulted in the 99232 visit being removed and its 20 minutes of intraservice time being applied to the 40 minutes of immediate postservice time resulting in 60 minutes of immediate postservice time. See the 2011 PFS final rule (75 FR 73226) for an in-depth explanation of the 23-hour policy. We believe the RUC partially applied the 23-hr policy when it applied the policy to the immediate post service time but not to the work RVU. We believe the 23-hour policy in its entirety should be applied to CPT code 6173661736 which includes the work RVUs along with the immediate postservice time.

Following the valuation methodology we established for 23-hour stay services in the CY 2011 PFS final rule, CPT code 61736 will have a work RVU of 19.06.

The steps are as follows:

- Step (1): CPT code 61736 does not have a hospital discharge day management service; therefore, we will skip this step.
- Step (2): 20 − 1.39 ** = 18.61.
- Step (3): 18.61 + (20 minutes × 0.0224)*** = 19.06 RVUs.

* Value associated with 1/2 hospital discharge day management service.

** Value associated with an inpatient hospital visit, CPT code 99232.

*** Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

Therefore, for CY 2022 we proposed a work RVU of 19.06 for CPT code 61736.

In reviewing the RUC-recommended direct PE inputs for 61736 we noticed the RUC proposed the standard 090-day preservice times for the following clinical labor activities:

- Complete preservice diagnostic and referral forms (CA001) 5 minutes.
- Coordinate pre-surgery services (including test results) (CA002) 20 minutes.
- Schedule space and equipment in facility (CA003) 8 minutes.
- Provide preservice education/ obtain consent (CA004) 20 minutes.

Complete pre-procedure phone calls and prescription (CA005) 7 minutes.

We note that the RUC recommended 090-day preservice times despite surveying the service as a 000-day service. We disagree with the RUC-recommended 090-day times as we believe this is a 000-day service and should have times consistent with 000-day services. However, we recognize there is time needed to coordinate this service. Therefore, for CY 2022 we proposed the following standard clinical labor times for a 000-day extensive:

- Complete preservice diagnostic and referral forms (CA001) 5 minutes.
- Coordinate pre-surgery services (including test results) (CA002) 10 minutes.
- Schedule space and equipment in facility (CA003) 5 minutes.
- Provide preservice education/ obtain consent (CA004) 7 minutes.
- Complete pre-procedure phone calls and prescription (CA005) 3 minutes.

For CPT code 61737 *(Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)),* the RUC recommended a work RVU of 24.00 which is the survey median. The RUC's recommendation also included 40 minutes of immediate postservice time and one hospital visit, CPT code 99233 *(sbsq hospital care/day visit 35 minutes).* We believe it will be appropriate to apply the 23-hr policy to CPT code 61737 as well.

The steps are as follows:

- Step (1): CPT code 61737 does not have a hospital discharge day management service. Therefore, we will skip this step.
- Step (2): 24 − 2 ** = 22
- Step (3): 22 + (30 minutes × 0.0224) *** = 22.67 RVUs

* Value associated with hospital discharge day management service.

** Value associated with an inpatient hospital visit, CPT code 99233.

*** Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

This results in a work RVU of 22.67, and an immediate post service time of 70 minutes. Therefore, for CY 2022 we proposed a work RVU of 22.67 and 70 minutes of immediate postservice time for CPT code 61737.

For the direct PE, the RUC proposed identical preservice times for CPT codes 61736 and 61737. For the reasons stated above concerning the direct PE inputs for CPT code 61736, we proposed the standard clinical labor times associated with a 000-day extensive for CPT code 61737 for CY 2022.

Comment: A commenter stated that CMS proposed to apply a formulaic

reduction to the work RVU attributed to the CMS 23-Hour Stay Outpatient Surgical Services with Subsequent Hospital Visits Policy when it proposed its work valuation for CPT code 61736. The commenter also noted that the LITT codes have 000-day global periods, which typically do not allow for an E/M visit on the same day as the procedure. However, in its recommendation the RUC applied the CMS 23-hour policy related to the post-service time for the base code. Although the median survey post-service time for CPT code 61736 was 40 minutes, the CMS 23-hour stay policy was applied resulting in 60 minutes of immediate post-service time. The intra-service time was reallocated from the same-day E/M code 99232 to the immediate post-service time of the outpatient service (adding 20 minutes of intra-service time from 99232). Lastly, the commenters stated that mathematically reducing work RVUs, despite a valid RUC survey, was not warranted and was not previously implemented by CMS when other services eligible for the 23-hour stay policy were reviewed.

Response: As we have stated earlier in this rule and in the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), CMS uses a variety of methodologies and approaches to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. In the CY 2011 PFS final rule, we also discussed the 23-hour policy and provided the formula for applying the policy to the work RVUs and the times of the outpatient service and the same-day E/M code. The commenter's statement reaffirms our belief that the RUC partially applied the 23-hour policy in its calculation of the recommended RVUs. When the policy is applied correctly, a work RVU of 19.06 is the appropriate valuation for CPT code 61736.

We also note, had we used the 25th percentile in the RUC's survey, which the RUC frequently recommends for valuing services, CPT code 61736 would have an RVU of 17.78, which is more than one RVU lower that CMS' proposed value. We also note that the RUC-recommended work RVU of 20.00 for CPT code 61736 is significantly higher than similarly timed codes which could imply that the service is overvalued. The commenter noted that the LITT codes have 000-day global periods, which typically do not allow for an E/M visit on the same day as the procedure. However, CPT code 61736 was surveyed as having one same-day E/M visit of CPT code 99232. We do not believe it is appropriate to apply select portions of the 23-hour policy. As we stated in the proposed rule, the 23-hour policy, when applied, should be applied in its entirety and applying the 23-hour policy in this context resulted in the work RVU of 19.06 for CPT code 61736. Lastly, we believe we have consistently applied the CMS 23-hour stay policy where applicable, in accordance with the policy that we finalized in the 2011 PFS final rule (75 FR 73226).

Comment: A commenter stated their objection to any proposed valuation that uses reverse building block methodology, or any other purely formulaic approach, to systematically reduce work RVUs for services. In the case of CPT code 61737, the commenter noted that, although these codes have 000-day global periods which typically do not allow for an E/M visit on the same day as the procedure, code 61737 typically involves a full 2-midnight admission which justifies the same-day E/M visit.

The commenter also stated when compared to patients undergoing LITT for a single lesion, the complexity of code 61737 and the level of patient medical instability and risk is greater. The typical number of ''multiple'' trajectories is two, thus in many aspects the physician work is doubled.

Response: In the CY 2011 PFS final rule we stated we believed that the 23-hour stay issue encompasses several scenarios. The typical patient under the 23-hour policy is commonly in the hospital for less than 24 hours, which often means the patient may indeed stay overnight in the hospital. On occasion, the patient may stay longer than a single night in the hospital; however, in both cases (one night or more than one night), the patient is considered for Medicare purposes to be a hospital outpatient, not an inpatient, and our claims data support that the typical 23-hour stay service is billed as an outpatient service. Accordingly, we believe that the valuation of the codes that fall into the 23-hour stay category should not reflect work that is typically associated with an inpatient service.

The RUC surveyed and recommended CPT code 61737 with a CPT code 99233 subsequent hospital visit. In the CY 2010 PFS proposed rule and final rule with comment period (74 FR 33556 and 74 FR 61777, respectively), we stated that we believed the use of inpatient E/M visit codes for services rendered in the post-service period for outpatient 23-hour stay procedures would result in overpayment for pre- and post-service work that would not be furnished. In CY 2011, we modified our proposed CY 2010 approach and suggested that in the future, when the AMA RUC reviews new and potentially misvalued codes that are identified as 23-hour stay services, the AMA RUC would apply the 23-Hour Stay Outpatient Surgical Services with Subsequent Hospital Visits Policy. Therefore, we believe it would be inappropriate to not apply the policy we established for services in this scenario.

With regards to the commenter's statement on the physician's work being doubled for CPT code 61737, we note the RUC-recommended a difference of four RVUs between CPT codes 61736 and 61737. We proposed a work RVU of 19.06 for CPT code 61736 and a work RVU of 22.67 for CPT code 61737, which would maintain a 3.61 RVU difference between these codes. We believe that a difference of 3.61 RVUs is fairly consistent with the RUC's recommendation and values the physician's work appropriately.

Comment: One commenter noted that CMS proposed the standard clinical labor times associated with the pre-service time package for 000-day global ''Extensive use of Clinical Staff'' facility inputs for CPT codes 61736 and 61737 while the RUC had recommended time associated with 090-day global periods. The commenter stated that it is most appropriate for the specialties to be able to advocate for the appropriate pre-service time for any given service. The commenters also suggested that with evidence some subset of codes may require extensive use of clinical staff and has allocated time when appropriate despite the assigned global period.

Response: We agree with the commenter that the direct PE inputs for each service should be evaluated on a case-by-case basis based on our criteria of what would be reasonable and medically necessary in the typical case. We reviewed the individual codes in question and concluded that the use of 000-day or 010-day global period standards for ''Extensive use of clinical staff'' would be most typical in these cases. As we noted under the Standardization of Clinical Labor Tasks (section II.B) part of this final rule, we continue to believe that setting and maintaining clinical labor standards provides greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For additional discussion, we direct readers to the individual code families affected by our proposed preservice clinical labor times (CPT codes 46020 and 46030 and CPT codes 61736 and 61737).

After consideration of the public comments, we are finalizing our

proposals for CPT codes 61736 and 61737 as proposed.

(16) Arthrodesis Decompression (CPT Codes 63052 and 63053)

For CPT codes 63052 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess* stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)) and 63053 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)*), we disagree with the RUC-recommended work RVUs of 5.55 and 4.44, respectively, because these values are anomalously high in comparison to other similar add-on codes that have longer intraservice times, and we proposed a work RVU of 3.08 for CPT code 63052 and a work RVU of 2.31 for CPT code 63053.

CPT codes 63052 and 63053 are new add-on codes to report decompression when performed in conjunction with posterior interbody arthrodesis at the same interspace. The proposed work RVU for CPT code 63052 is based on an intraservice time ratio between the proposed 40 minutes of intraservice time for CPT code 63052 and the 45 minutes of intraservice time for CPT code 63048 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)*). We believed that CPT code 63048 was a stronger reference code for CPT code 63052 than the RUC-recommended reference CPT codes 33924 (*Ligation and takedown of a systemic-to-pulmonary artery shunt, performed in conjunction with a congenital heart procedure (List separately in addition to code for primary procedure)*) and 22614 (*Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)*) because of the similarities in the long descriptors, physician time, and intensity of intraservice work for CPT codes 63052 and 63048. The intraservice time ratio between CPT codes 63048 and 63052 equals a work RVU of 3.08 for CPT code 63052 ((40 minutes/45 minutes) * 3.47 = 3.08). Therefore, we proposed a work RVU of 3.08 for CPT code 63052. The intraservice time ratio between CPT codes 63048 and 63052 was selected to value CPT code 63052 because of the similarities in the descriptions of intraservice work provided in the RUC's summary of recommendations for CPT code 63052 and the RUC Database for CPT code 63048. We proposed a work RVU of 2.31 for CPT code 63053 based on an intraservice time ratio between the proposed 30 minutes of intraservice time for CPT code 63053 and the proposed 40 minutes of intraservice time for CPT code 63052 ((30 minutes/40 minutes) * 3.08 = 2.31), given that the RUC contends that there are some efficiencies in providing an additional level of decompression, evidenced by the 10 minutes less of intraservice time for CPT code 63053 compared to CPT code 63052. These work RVU proposals are further supported by brackets of other 30 and 40 minute ZZZ codes.

We note that the proposed work RVU for CPT code 63052 falls between CPT code 19294 (*Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy (List separately in addition to code for primary procedure)*), which has a work RVU of 3.00, and CPT code 37185 (*Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)*), which has a work RVU of 3.28. Both of these bracketing reference codes have identical intraservice times as CPT code 63052. The proposed work RVU for CPT code 63053 falls between CPT code 43273 (*Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) (List separately in addition to code(s) for primary procedure)*), which has a work RVU of 2.24, and CPT code 22870 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)*), which has a work RVU of 2.34. Both of these bracketing reference codes have identical intraservice times as CPT code 63053. When we compared the RUC-recommended work RVU of 5.55 for CPT code 63052 and 4.44 for CPT code 63053 to other spinal add-on codes in the 63000 CPT code series in the RUC database, we found that CPT code 63052 would have the highest work RVU and the second shortest intraservice time (with CPT code 63053 having the shortest intraservice time), and CPT code 63053 would have the third highest work RVU and shortest intraservice time compared to the 10 other nationally-priced spinal add-on codes in the 63000 CPT code series. We do not agree that decompression when performed in conjunction with posterior interbody arthrodesis at the same interspace should have an anomalously high work value in comparison to other similar add-on codes in the 63000 CPT code series that have longer intraservice times. 6305263053We note that the specialty societies did not survey the two new add-on codes with the base codes for the January 2021 RUC, which is a standard to provide assurance that the respondents followed instruction to only consider the work of the add-on codes. CPT codes 63052 and 63053 were reviewed again with their base codes at the April 2021 RUC meeting. There were also revisions to the base codes' definitions, guidelines, and parenthetical instructions, which were approved by the CPT Editorial Panel for CY 2022.

The RUC did not recommend any direct PE inputs for these codes and we did not propose any direct PE inputs.

Comment: Several commenters requested that CMS use the interim RUC recommendations from the April 2021 meeting for these add-on codes which had previously been reviewed at the January 2021 RUC meeting. Commenters stated that the earlier RUC recommendations were made on an interim basis and requested an expedited review of the recommendations from the April 2021 RUC meeting; the RUC resubmitted its recommendations for these code families as part of its comment submission.

Response: We finalized a policy in the CY 2015 PFS final rule to make all changes in the work and MP RVUs and the direct PE inputs for new, revised, and potentially misvalued services under the PFS by proposing and then finalizing such changes through notice and comment rulemaking, as opposed to initially finalizing changes on an interim final basis (79 FR 67602–67609). As we stated when promulgating the CY 2015 PFS final rule, this approach has the significant advantage that the RVUs

for all services under the PFS are established using a full notice and comment procedure, including consideration of the RUC recommendations, before they take effect, providing the public the opportunity to comment on a specific proposal prior to it being implemented. We continue to believe that this is a far more transparent process which assures that we have the full benefit of stakeholder comments before establishing values. Since we did not make proposals on the code families in question using the RUC's recommendations from the April 2021 meeting, we would be forced to finalize valuation for these codes on an interim final basis, without the opportunity for public comment. This would contradict the policy that we finalized in the CY 2015 PFS final rule and we do not believe that it would serve the interests of transparency. Although we will consider any information submitted by stakeholders for valuation during the comment period, as we do for all codes which are subject to notice and comment rulemaking, we will formally review the recommendations from the April 2021 RUC meeting next year as part of the CY 2023 rule cycle.

Comment: Commenters unanimously disagreed with the intraservice time ratio between CPT codes 63048 and 63052, stating that CPT code 63048 is an inappropriate comparator because of differences in procedure and patient elements. Commenters stated that part of the work and time involved in CPT code 63048 is that of exposure of bony and soft tissue elements of the adjacent level. Commenters stated that CPT code 63052 does not require additional work of exposure because it is completed as part of the base interbody fusion code, and therefore, CPT code 63052 describes only the high intensity, dangerous aspects of neural element and spinal cord decompression. Commenters agreed that the procedures are similar, but differ in intensity.

Response: We appreciate the additional information provided by the commenters and are compelled to utilize a different methodology than the proposed intraservice time ratio between CPT codes 63048 and 63052, to value CPT code 63052 because the commenters provided sufficient information about how CPT codes 63048 and 63052 differ in intensity.

After consideration of the public comments regarding CPT code 63052, we are finalizing a work RVU of 4.25 for CPT code 63052 based on a crosswalk to CPT code 22853 (*Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)*), which has a work RVU of 4.25 and an intraservice time of 45 minutes. CPT code 22853 has only 5 more minutes of intraservice time than CPT code 63052, is a spinal procedure, and is an add-on code to the same base codes as CPT code 63052. We note that the finalized work RVU of 4.25 is supported by the commenters. Commenters supported the bracket of key reference service CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)*) and MPC CPT code 34812 (*Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral (List separately in addition to code for primary procedure)*). CPT code 22552 has a work RVU of 6.50 and an intraservice time of 45 minutes, and commenters noted that CPT code 22552 has a higher intensity as anticipated for a surgical procedure and in comparison, with a lumbar procedure. CPT code 34812 has a work RVU of 4.13 and 40 minutes of intraservice time, and commenters noted that this code involves open femoral artery exposure by groin incision and closure of the wound, typically for separately reported delivery of an endovascular prosthesis for an asymptomatic infrarenal abdominal aortic aneurysm. In comparison, exposure and closure for CPT code 63052 are performed as part of the primary arthrodesis code and the intraservice time includes higher intensity bony and soft tissue resection, therefore, although both codes require the same time, the physician work and intensity of CPT code 63052 is greater than CPT code 34812.

After consideration of the public comments regarding CPT code 63053, we are finalizing a work RVU of 3.19 for CPT code 63053 based on an intraservice time ratio between CPT codes 63052 and 63053 ((30 minutes/40 minutes) * 4.25 = 3.19). As we stated above, we are also finalizing a work RVU of 4.25 for CPT code 63052 based on a crosswalk to CPT code 22853. The RUC did not recommend any direct PE inputs for these codes and we are not finalizing any direct PE inputs.

(17) Hypoglossal Nerve Stimulator Services (CPT Codes 64582, 64583, and 64584)

In October 2020, the CPT Editorial Panel added three new CPT Category I codes to report open implantation, revision or replacement, and removal of hypoglossal nerve stimulator array. These new CPT codes replaced three CPT Category III codes which were reported with CPT codes 64568 (*Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator*), 64569 *(Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator)* and 64570 *(Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator).*

CPT code 64582 (*Open implantation of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array*) was previously reported using the now deleted Category III CPT code 0466T (*Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)*) along with CPT code 64568. We did not propose the RUC-recommendation to use the survey median work RVU of 16.00 for CPT code 64582. We proposed a work RVU of 14.00 based on the intraservice time ratio of CPT code 64568 compared to the RUC-recommended intraservice time for CPT code 64582. CPT code 64568 has a work RVU of 9.00, intraservice time of 90 minutes and total time of 275 minutes. CPT code 64582 has a RUC-recommended work RVU of 16.00, intraservice time of 140 minutes and total time of 294 minutes. Additionally, when we reviewed CPT code 64582, we found that the RUC-recommended work RVU was higher than other global 90-day codes with similar time values. We did not agree that it would be typical to value this code so much higher than services with similar work time values. Additionally, we note that the proposed work RVU of 14.00 is also the survey 25th percentile. Therefore, as previously stated, we believe 14.00 is a more appropriate value overall than 16.00 when compared to the range of codes with similar work times.

We did not propose the RUC-recommended work value of 16.50 for CPT code 64583 (*Revision or replacement of hypoglossal nerve neruostimulator array and distal respiratory sensor electrode or electrode*

array, including connection to an existing pulse generator), rather we proposed a work RVU of 14.50. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 64582 and 64583 is equivalent to the recommended increment of 0.50 RVUs. Therefore, we proposed a work RVU of 14.50 for CPT code 64583 based on the recommended increment of 0.50 additional RVUs above our proposed work RVU of 14.00 for CPT code 64582. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Additionally, we note that the proposed work RVU of 14.50 is also nearly identical to the 25th percentile survey value for CPT code 64583 of 14.63. Therefore, as previously stated, we believe 14.50 is a more appropriate value than 16.50 to maintain an appropriate intra-family relativity.

We did not propose the RUC-recommended work value of 14.00 for CPT code 64584 (*Removal of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array*), rather we proposed a work RVU of 12.00. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 64582 and 64584 is equivalent to the recommended increment of −2.0 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we proposed a work RVU of 12.00 for CPT code 64584 based on the recommended increment of 2.0 RVUs below our proposed work RVU of 14.00 for CPT code 64582. Additionally, we note that the proposed work RVU of 12.00 is also the RUC 25th percentile survey value for CPT code 64584.

We proposed the RUC-recommended direct PE inputs without refinements for CPT codes 64582, 64583 and 64584.

Comment: A few commenters including the RUC urged CMS to finalize a work RVU of 16.00 for CPT code 64582, 16.50 for CPT code 64583 and 14.00 for CPT code 64584 based on the survey median. The commenters disagreed with CMS calculating intra-service time ratios for valuing 64582, and also disagreed with CMS utilizing the incremental difference for valuing 64583 and 64584. The commenters also indicated that the survey median is more appropriate, given the physician work, intensity and complexity of the service.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. Therefore, when our review of recommended values reveals that changes in time are not accounted for in a recommended work RVU, we believe we have an obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Again, we clarify that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. We have responded to concerns about our methodology earlier in this section. We disagree with the commenters and continue to believe that finalizing a work RVU of 14.00 is more appropriate than a work RVU of 16.00 for CPT code 64582 based on the intraservice time ratio of CPT code 64568 compared to the RUC-recommended intraservice time for CPT code 64582. As stated in the proposed rule, the AMA RUC surveyed 25th percentile work RVU for CPT code 64582 was 14.00. Additionally, we also note that the RUC has also used the surveyed 25th percentile work value as a basis to recommend the work RVU for a code.

We believe the use of an incremental difference between the work RVUs of codes is a valid methodology for setting values, especially in valuing services within a family. Historically, we have frequently utilized an incremental methodology in which we value a code based upon the incremental work RVU difference between the code and another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between the work RVUs of codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not believe it is necessary for codes to share the same site of service, patient population, or utilization level to in order to serve as an appropriate crosswalk. Therefore, we are finalizing a work RVU of 14.50 for CPT code 64583 based on the recommended increment of 0.50 additional RVUs above the finalized work RVU of 14.00 for CPT code 64582, and we are finalizing a work RVU of 12.00 for CPT code 64584 based on the recommended increment of 2.0 RVUs below the finalized work RVU of 14.00 for CPT code 64582.

Comment: A commenter supported CMS' proposal to accept the RUC-recommended direct PE inputs without refinements for CPT codes 64582, 64583 and 64584.

Response: We appreciate the support for our proposed direct PE inputs.

After consideration of public comments, we are finalizing work RVUs of 14.00 for CPT code 64582, 14.50 for CPT code 64583 and 12.00 for CPT code 64584. We are finalizing the RUC-recommended direct PE inputs without refinement for CPT codes 64582, 64583 and 64584.

(18) Destruction by Neurolytic Agent (CPT Codes 64633, 64634, 64635, and 64636)

In September 2014, the Relativity Assessment Workgroup identified a work neutrality issue for CPT codes 64633 (*Destruction by neurolytic agent, paravertebral facet* joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint), 64634 (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)), 64635 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with*

imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint), and 64636 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)) related to incorrect coding relative to how the services were originally valued. In May 2015, the CPT Editorial Panel revised the parenthetical instructions for the five codes describing paravertebral facet joint nerve destruction to clarify that these codes are reported per joint, not nerve. Due to the extensive growth and original incorrect assumptions about distribution of reporting, the RUC recommended that CPT codes 64633–64636 be surveyed. We proposed the RUC-recommended work RVU of 1.32 for CPT code 64634 and the RUC-recommended work RVU of 1.16 for CPT code 64636.

For CPT codes 64633 and 64635, we did not propose the RUC-recommended work RVU of 3.42 for both codes, as we believe this value understates the decrease in physician work time for these codes. An analysis of all 010-day global period codes indicates that these proposed values will place these codes among the highest valued for codes with similar time values. We are instead using a total-time ratio methodology to propose work RVUs of 3.31 for CPT code 64633 and 3.32 for CPT code 64635. We support these values by noting that they fall between CPT codes 54164 (*Frenulotomy of penis*), with a work RVU of 2.82, and CPT code 68371 (*Harvesting conjunctival allograft, living donor*), with a work RVU of 5.09; these reference codes have total time values that are similar to, and intraservice time values that are identical to those recommended for CPT codes 64633 and 64635.

We proposed the RUC-recommended direct PE inputs without refinement.

Comment: Commenters supported the proposal of the RUC-recommended work RVUs for the add-on codes, CPT codes 64634 and 64636, and the RUC-recommended direct PE inputs for all codes. However, many commenters opposed the proposed work RVUs for CPT codes 64633 and 64635 and urged CMS to finalize the RUC-recommended work RVUs for these codes. According to commenters, the proposed values for these codes placed these services out of rank order with similar services such as the top key reference code, CPT code 64625 (*Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography*) (work RVU = 3.39, 30 minutes intra-service time and 98 minutes total time)). Commenters stated that CPT codes 64633 and 64635 are slightly more intense and complex than CPT code 64625 due to the anatomical differences in anatomic locations; while CPT code 64625 requires more injections, CPT codes 64633 and 64635 are in a much more clinically complex location, requiring greater clinical expertise. CPT codes 64633 and 64635 also require more total time than 64625 and the RUC-recommended median work RVU of 3.42 maintains the proper rank order between these services. Commenters stated that CMS' time ratio calculation ignored magnitude estimates as indicated by physicians who perform these services and compromises the correct relativity of these services. Commenters also stated that CMS' calculation also ignored the intensity of these services and discounted it by arriving at a value by calculation. The RUC requested that CMS provide clinical rationale on why CPT codes 64633 and 64635 require less physician work or intensity than other similar services. The RUC recommended that the work RVU for CPT codes 64633 and 64635 be the same. According to commenters, the CMS references to CPT codes 54164 and CPT code 68371 are inappropriate as they describe procedures that are too clinically different.

Response: We disagree that our time ratio calculation is inaccurate and we continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys which suggests that the amount of time involved in furnishing the service has changed significantly. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this final rule (section II.E.2.), as well as a detailed discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). We do not agree that the proposed work RVU for CPT code 64633 would create a rank order anomaly with CPT code 64625, as the proposed value for CPT code 64633 recognizes that this is a higher intensity procedure than CPT code 64625. We understand that the RUC asserts that CPT code 64633 and 64635 describe services of similar intensity, and therefore, we are finalizing work RVUs of 3.32 for both codes, rather than 3.31 for CPT code 64633 and 3.32 for CPT code 64635 as proposed. Given the identical intensity of these two services, we used total time ratios to estimate a value that we believe more accurately captures the time as proposed, then we used the relative relationship between the two codes to further refine the value for 64633 from 3.31 to 3.32. With regard to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that they are necessarily more appropriate crosswalks. We disagree that our proposed RVUs undervalued these codes in reference to other similar procedures, and we note that even considering our proposed work RVUs reductions, these codes would still be among the highest valued of all 010-day global period codes.

After consideration of the comments, we are finalizing the proposed work RVUs for CPT codes 64634, 64635, and 64636, as proposed. For CPT code 64633, we are instead finalizing a work RVU of 3.32 to match the work RVU of CPT code 64635. We are also finalizing the RUC-recommended direct PE inputs for these codes as proposed without refinement.

(19) Destruction of Intraosseous Basivertebral Nerve (CPT Codes 64628 and 64629)

In October 2020, the CPT Editorial Panel added two Category I codes to report thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance for the first two vertebral bodies (lumbar or sacral) and for each additional vertebral body (lumbar or sacral).

We did not propose the RUC-recommended work value of 8.25 for CPT code 64628 (*Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; first two vertebral bodies, lumbar or sacral*). When we reviewed CPT code 64628, we found that the RUC-recommended work RVU was higher than codes with the same 10-day global period, same intraservice time and similar total times. The RUC-recommended work RVU of 8.25 would value CPT code 64628 at the 90th percentile of comparable 10-day global and we do not agree that it will

be typical to value this code so much higher than services with similar work time values. We believed it would be more accurate to propose a work RVU of 7.15 based on a crosswalk to CPT code 63650 (*Percutaneous implantation of neurostimulator electrode array, epidural*) with a work RVU of 7.15, identical intraservice time of 60, and similar total time of 170. We believe the crosswalk to CPT code 63650 serves as a more accurate valuation for CPT code 64628.

We also did not propose the RUC-recommended work value of 4.87 for CPT code 64629 (*Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 64628 and 64629 is equivalent to the recommended increment of −3.38 RVUs. However, since the recommended work RVU of code 64628 was higher than other codes with the same 10-day global period, same intraservice time, and similar total times, we refined the work RVU for code 64629 to preserve the incremental difference between the two codes. We believe that these refinements maintain the relationship between the two codes in the family while better preserving relativity with other similar 10-day global codes on the wider PFS. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we proposed a work RVU of 3.77 for CPT code 64629 based on the recommended increment of 3.38 RVUs below our proposed work RVU of 7.15 for CPT code 64628.

We proposed the RUC-recommended direct PE inputs without refinements for CPT code 64628. CPT code 64629 is an add-on code and does not have any direct PE inputs.

Comment: Several commenters including the RUC urged CMS to finalize the RUC-recommended work RVU of 8.25 for CPT code 64628 and 4.87 for CPT code 64629 which are both based on the survey 25th percentile. The commenters disagreed that the proposed crosswalk to CPT code 63650 serves as a more accurate valuation for CPT code 64628 and supports the RUC's recommendation for code 64628 with comparisons to the reference CPT code 22514 (*Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar*) with a work RVU of 7.99, and CPT code 22513 (*Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic*) with a work RVU of 8.65. The commenters suggested that CMS proposals and methodology consider survey data, review by specialty societies and cross-specialty comparison. A commenter urged CMS to finalize a work RVU of 9.75 for CPT code 64628 and 4.87 for 64629. Another commenter urged CMS to finalize a work RVU of 10.40 for the base CPT code 64628, and agreed that the additional level code, CPT code 64629, should have a work RVU of approximately 50 percent of the base code, and be assigned a work RVU of 5.20. A few commenters noted that CMS' proposal does not accurately reimburse physicians for their work and that the proposed values will negatively impact access to care. For CPT code 64629, commenters including the RUC urged CMS to finalize a work RVU of 4.87 based on the survey 25th percentile for this add-on code. A few commenters disagreed with CMS utilizing incremental differences for valuing services.

Response: We appreciate the feedback from commenters, and we are sensitive to the need for appropriate payment under the PFS to ensure that beneficiaries maintain access to care. However, we disagree with the commenters that the RUC's recommended 25th percentile bracketed to CPT codes 22514 and 22513 is a more accurate choice than our proposed reference code CPT code 63650. We continue to believe that CPT code 63650 is a more accurate reference code for 64628, and note that the CPT Editorial Panel assigned the Destruction of Intraosseous Basivertebral Nerve family to the 60000 series.

We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate code comparison or an appropriate crosswalk.

Additionally, we believe the use of an incremental difference between the work RVUs of codes is a valid methodology for setting values, especially in valuing services within a family. Historically, we have frequently utilized an incremental methodology in which we value a code based upon the incremental work RVU difference between the code and another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between the work RVUs of codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not believe that it is necessary for codes to share the same site of service, patient population, or utilization level in order to serve as an appropriate crosswalk.

Comment: Some commenters supported CMS proposing the RUC-recommended direct PE inputs without refinements for CPT code 64628.

Response: We appreciate the support for our proposed direct PE inputs.

After consideration of the comments, we are finalizing a work RVU of 7.15 for CPT code 64628 and 3.77 for CPT code 64629, as proposed. We are also finalizing the RUC-recommended direct PE inputs as proposed without refinement for CPT code 64628.

(20) Dilation of Aqueous Outflow Canal (CPT Codes 66174 and 66175)

These services were identified through the New Technology/New Services List. In January 2020, the specialty societies submitted an action plan and the RUC recommended referral to the CPT Editorial Panel in 2020 to possibly revise the descriptor and add exclusionary parentheticals for CPT code 66174 (*Transluminal dilation of aqueous outflow canal; without retention of device or stent*). In October 2020, the CPT Editorial Panel revised this code to add a parenthetical to restrict reporting this code in conjunction with CPT code 65820 (*Goniotomy*).

We did not propose the RUC-recommended work RVUs of 8.53 for CPT code 66174 and 10.25 for CPT code 66175 (*Transluminal dilation of*

aqueous outflow canal; with retention of device or stent), as we believe these values do not adequately reflect the surveyed reductions in physician time. These RVUs will rank these codes among the highest valued 090-day global period codes of similar time values. We proposed a work RVU of 9.34 for CPT code 66175 using a reverse building block methodology. We then subtract the incremental difference between the two RUC-recommended work RVUs, an increment of 1.72, from our proposed work RVU of 9.34 for CPT code 66175 to propose a work RVU of 7.62 for CPT code 66174. We believe this approach is consistent with the RUC's assumption that the intensity and complexity of CPT code 66174 is the same as that of CPT code 66175, the only difference between the two procedures being the additional intraservice time associated with placement of the stent. As further support for these values, we note that they fall between CPT code 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*), with 7.35 work RVUs, and CPT code 15150 (*Tissue cultured skin autograft, trunk, arms, legs; first 25 sq cm or less*), with 9.39 work RVUs.

We proposed the RUC-recommended PE inputs without refinement.

Comment: The RUC urged CMS to accept a work RVU of 8.53 for CPT code 66174 and 10.25 for CPT code 66175. The RUC disagreed with CMS utilizing reverse building block methodology for valuing services and stated that both CMS recommended work values are below the survey 25th percentile and well below the current values. The RUC stated that the reverse building block methodology, or any other purely formulaic approach, should not be used as the primary methodology to value services. Commenters stated that this was inappropriate as magnitude estimation has been used to establish work RVUs for services since the publication of the first Medicare PFS in 1992.

Response: We disagree with the commenter regarding the validity of the building block methodology. We note that our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). We believe an alternative valuation methodology, in this case the building block methodology, more accurately reflects the reductions in physician time values.

We continue to believe that our proposed values more accurately reflect both the surveyed physician time, as well as the relative relationship among these codes and other services of similar time values as compared to the RUC-recommended values, which would overvalue these codes relative to other 090-day global period codes. The proposed work RVUs for CPT codes 66174 and 66175 are among the highest of 90-day global period codes with these time values. Therefore, we are finalizing work RVUs of 7.62 for CPT code 66174 and 9.34 for CPT code 66175, as proposed. We are finalizing the RUC-recommended direct PE inputs without refinement.

(21) Cataract Removal With Drainage Device Insertion (CPT Codes 66989, 66991, 66982, 66984, 66987, 66988, and 0671T)

The RUC identified CPT code 0191T (*Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion*) via the Category III codes with High Utilization screen (2018 estimated Medicare utilization over 1,000). In January 2020, the RUC recommended that the specialty societies develop a coding application for Category I status for CPT code 0191T and CPT code 0376T (*each additional device insertion (List separately in addition to code for primary procedure*). In October 2020, the CPT Editorial Panel replaced two Category III codes (CPT codes 0191T and 0376T) with two new codes, CPT codes 66989 and 66991, to report extracapsular cataract removal with insertion of intraocular lens prosthesis and one Category III code to report insertion of anterior segment aqueous drainage device without concomitant cataract removal.

The RUC recommended a work RVU of 12.13 for CPT code 66989 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more*) based on the survey 25th percentile.

In its recommendation, the RUC noted that the recommended intraservice time of 28 minutes for CPT code 66989 is 2 minutes less than the intraservice time of 30 minutes associated with CPT code 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation*). The RUC further noted this should not be the case, as the insertion of the intraocular lens prosthesis should take the same amount of time and be represented by the same relative work for both procedures and that it is counterintuitive that the intraservice time for CPT code 66989 will be lower than the intraservice time for CPT code 66982, as CPT code 66989 includes both complex cataract surgery and the insertion of the intraocular anterior segment aqueous drainage device. The specialty society that surveyed the codes explained that this is likely because the early adopters of this new technology service are highly skilled surgeons who will likely perform these procedures quickly. They stated that as this procedure diffuses into the wider population of ophthalmologic surgeons over the next few years, the intraservice time will likely rise above the intraservice time associated with CPT codes 66982 and 66984 and will come

in line for both CPT codes 66989 and 66991.

CPT code 69982 has a work RVU of 10.25, 125 minutes of total time and 30 minutes of intraservice time. CPT code 66989 has a RUC-recommended work RVU of 12.13, 176 minutes of total time and 28 minutes of intraservice time. We agree with the RUC assessment that both procedures, CPT code 66982 and CPT code 66989, are almost identical in time and intensity. However, we disagree with the RUC-recommended work RVU of 12.13 for CPT code 66989 noting that CPT code 66982 has a work RUV of 10.25. We proposed a work RVU of 10.31 based on the current total time ratio of CPT code 66982 compared to the RUC-recommended total time for CPT code 66989.

For CPT code 66991, the RUC recommended a work RVU of 9.23. The RUC determined that it would be appropriate to use the increment between the 25th percentile work RVU value for CPT code 66989 and the current RUC-reviewed work RVU value for CPT code 66982 to build a work RVU recommendation for CPT code 66991. The RUC determined that the increment between the 25th percentile work RVU value for CPT code 66989 (work RVU = 12.13) and the current RUC-reviewed work RVU value for CPT code 66982 (work RVU = 10.25) will yield an increment between those two codes of 1.88. The RUC added the 1.88 increment to 7.35, the current work RVU for 66984, which yields a RUC-recommended work RVU value of 9.23. This comparison results in a work RVU recommendation of 9.23 for CPT code 66991. We proposed a work RVU of 7.41, which is the increment between the current RUC-reviewed work RVU value for CPT code 66982 and CPT code 66984. The increment between CPT code 66982 (work RVU = 10.25) and CPT code 66984 (work RVU = 7.35) yields a work RUV of 2.90. We subtracted this 2.90 increment from 10.31, to determine our proposed work RVU of 7.41 for CPT code 66989.

We proposed the RUC-recommended indirect PE values for CPT codes 66989 and 66991.

We did not propose any new valuations but reaffirmed the work RVUs and direct PE inputs that we previously finalized for CPT codes 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation*) and 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*). For CPT codes 66987 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation*) and 66988 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation*) we continue to believe these services should be contractor priced.

Comment: One commenter urged CMS to finalize its proposed valuation for CPT codes 66989 and 66991, stating that these new services are overpriced and underperformed.

Response: We appreciate the commenter's feedback.

Comment: Commenters requested that CMS finalize the RUC-recommended work RVU of 12.13 for CPT code 66989 and the RUC-recommended work RVU of 9.23 for CPT code 66991. The commenters urged CMS to consider the intensity of CPT code 66989 and to also provide clinical rationale on why CPT code 66989 should only be valued 0.06 more work RVUs than CPT code 66982. Commenters stated that CMS is only focusing on time and not the clinical work and intensity required to perform CPT code 66989. Furthermore, this code is more intense than CPT code 66982 because it includes both complex cataract surgery and the insertion of the intraocular anterior segment aqueous drainage device. The commenters stated that CMS' proposed value for CPT code 66991 assumes that the CMS proposed value for CPT code 66989 is appropriate and commenters disagreed that the proposed value for CPT code 66989 is correct as indicated above.

Response: We appreciate the additional information supplied by commenters regarding the clinical work and intensity required to perform CPT codes 66989 and 66991, particularly their relationship in terms of intensity with CPT code 66982. After consideration of these comments, we are not finalizing our proposed work RVUs and will instead finalize the RUC-recommended work RVU for both codes.

Comment: Commenters requested that CMS finalize the RUC-recommended work RVU of 13.15 for CPT code 66987 and 10.25 for CPT code 66988. They note that these services will be reported more than 7,000 times per year and contractor pricing, as proposed, is burdensome.

Response: We appreciate commenters' feedback. However, we continue to believe that CPT codes 66987 and 66988 should be contractor priced. We previously finalized the use of contractor pricing in the CY 2020 PFS final rule due to a lack of survey data and crosswalks to support the RUC-recommended work RVUs (84 FR 62751–62753). Since the RUC and commenters merely reaffirmed the same work RVUs from CY 2020 without providing new information, we continue to believe that contractor pricing is the most appropriate choice for these codes.

Comment: Many commenters expressed concern that the proposed change to bundle minimally invasive glaucoma surgery (MIGS) procedures with cataract surgery would make the reimbursement rate too low for providers to offer the procedure which could impact beneficiary access to the service.

Response: We agree with commenters concerns regarding the payment rate of these services. We are concerned that the recommended values of these new services might not fit within the family of services as currently valued given concerns raised by stakeholders. In consideration of stakeholder concerns, including early feedback on how the instraservice time for these services may not be reflective of what will be considered typical in how these services may be furnished, we encourage the RUC and other stakeholders to reconsider the valuation of the cataract procedure family as a whole, including the new codes, in the near term.

After consideration of comments we are finalizing the RUC-recommended work RVUs of 12.13 and 9.23 for CPT codes 66989 and 66991; respectively. We are finalizing the proposal to maintain contractor pricing for CPT codes 66987 and 66988. We are also finalizing the RUC-recommended direct PE inputs as proposed for this code family.

(22) Retinal Detachment Prophylaxis (CPT Codes 67141 and 67145)

CPT code 67145 (*Prophylaxis of retinal detachment (e.g., retinal break, lattice degeneration) without drainage, 1 or more sessions; photocoagulation (laser or xenon arc)*) was identified in October 2019 as a Harvard Valued service with utilization over 30,000. In January 2020, the RUC agreed with the specialty societies that surveyed the service and recommended that CPT code 67145, as well as its parent CPT code 67141 (*Prophylaxis of retinal detachment (e.g., retinal break, lattice degeneration) without drainage, 1 or more sessions; cryotherapy, diathermy*), be referred to the CPT Editorial Panel for a descriptor and global period change. The codes were edited to remove the reference to ''1 or more sessions'' so that the services may be valued as a 010-day procedure versus the current 090-day global. At the May 2020 CPT Editorial Panel meeting, the Panel approved revision of the two codes to remove ''1 or more sessions'' from the descriptors and deletion of the Eye and Ocular Adnexa Prophylaxis guidelines.

For CY 2022, we proposed the RUC-recommended work RVU of 2.53 for CPT codes 67141 and 67145. We also proposed the RUC-recommended direct PE inputs without refinements.

Comment: One commenter urged CMS to adopt the 25th percentile survey work values reviewed by the RUC and recommended to CMS.

Response: We appreciate the commenters feedback. For CPT codes 67141 and 67145, we are finalizing the RUC-recommended work RVU of 2.53 for CPT codes 67141 and 67145 and the RUC-recommended direct PE inputs without refinements, as proposed.

(23) Strabismus Surgery (CPT Codes 67311, 67312, 67314, 67316, 67318, 67320, 67331, 67332, 67334, 67335, and 67340)

In April 2020, The RUC recommend that add-on CPT codes 67320, 67331, 67332, 67334, 67335, and 67340 be surveyed along with the base codes in which these services are typically reported (CPT codes 67311, 67312, 67314, 67316 and 67318). When AMA staff compiled a list of 010-day and 090-day services for increases in physician work and time during the surgical global period, they noticed that several low volume codes that were converted to ZZZ global periods in 1999 still included office visits (specifically CPT codes 67320, 67331, 67332, 67334, 67340). It appeared that these office visits may not be appropriate for these services. This issue was deferred until October 2020.

We proposed the RUC-recommended work RVUs for all base codes within this family. This includes a work RVU of 5.93 for CPT code 67311 (*Strabismus surgery, recession or resection procedure; 1 horizontal muscle*), 9.50 for CPT code 67312 (*Strabismus surgery, recession or resection procedure; 2 horizontal muscles*), 5.93 for CPT code 67314 (*Strabismus surgery, recession or resection procedure; 1 vertical muscle (excluding superior oblique)*), 10.31 for CPT code 67316 (*Strabismus surgery, recession or resection procedure; 2 or more vertical muscles (excluding superior oblique)*), and 9.80 for CPT code 67318 (*Strabismus surgery, any procedure, superior oblique muscle*).

We also proposed the RUC-recommend work RVUs for all of the add-on codes within this family. This includes a work RVU of 3.00 for CPT code 67320 (*Transposition procedure (e.g., for paretic extraocular muscle), any extraocular muscle (specify)(List separately in addition to code)*), 2.00 for CPT code 67331 (*Strabismus surgery on patient with previous eye surgery or injury that did not involve the extraocular muscles (List separately in addition to code for primary procedure)*), 3.50 for CPT code 67332 (*Strabismus surgery on patient with scarring of extraocular muscles (e.g., prior ocular injury, strabismus or retinal detachment surgery) or restrictive myopathy (e.g., dysthyroid opthalmopathy) (List separately in addition to code for primary procedure)*), 2.06 for CPT code 67334 (*Strabismus surgery by posterior fixation suture technique, with or without muscle recession (List separately in addition to code for primary procedure)*), 3.23 for CPT code 67335 (*Strabismus surgery by posterior fixation suture technique, with or without muscle recession (List separately in addition to code for primary procedure)*), and 5.00 for CPT code 67340 (*Strabismus surgery by posterior fixation suture technique, with or without muscle recession (List separately in addition to code for primary procedure)*).

We proposed the RUC-recommended direct PE inputs for this code family without refinements.

Comment: Commenters unanimously opposed the RUC-recommended RVUs for every code in this family. Commenters did not agree with the reference codes used by the RUC to support their recommended values. They stated that they believe it is inappropriate to use reference codes to support a valuation that is lower than the 25th percentile survey result for CPT code 67311, CPT code 67314, and CPT code 67320, while valuing all other CPT codes within the family at the 25th percentile. Commenters asked that CMS raise the RVUs for these CPT codes to also be the 25th percentile survey result, which would make the family consistently valued. Commenters also asked that the reduction in RVUs be phased in over a 3 to 5-year timeframe instead of the statutory 2 years.

Response: We generally agree that there should be consistency within code families. The recommendations presented to us by the RUC for this CPT code family, however, include a review of surveys for time changes, intensity, clinical aspects, and a thoughtful review of survey results with the intent for the revaluation to minimize rank order anomalies and have valuations consistent with and accounting for the reductions in intraservice and total times for each CPT code. In regards to the possibility of an extended phase-in, section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. CPT codes 67311, 67314, 67320, 67331, 67332, and 67334 were subject to the phase-in transition and it was applied in calculating their proposed RVUs; we direct readers to the Codes Subject to Phase-In public use file for the CY 2022 PFS proposed rule for additional details. The statute defines the phase-in transition as taking place over 2 years. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929).

Comment: Commenters stated that CMS should revise the policy finalized in the 2021 PFS final rule (85 FR 84472) that revalued E/M office visits but excluded the valuations from 90 and 10-day postoperative global surgery packages. Commenters requested the revised values be applied to the postoperative visits in global surgery CPT code families as well, and they noted this is particularly relevant to this and other CPT code families.

Response: We did not address the exclusion of postoperative office visits within global surgery packages from the E/M revaluation for this service, or other services, in the proposed rule. Therefore, this policy is out of scope for the CY 2022 PFS proposed and final

rules. We refer readers to our discussion on this topic in the CY 2021 PFS final rule (84 FR 84472).

Comment: Commenters raised several concerns about potential impacts on clinicians, as well as beneficiaries due to the large reduction in work RVUs for each code. Commenters were also concerned about a further reduction in the surgical ophthalmology workforce which they say suffers an existing shortage. The commenters stated that the further reduction could be caused by the proposed reimbursement cuts, low reimbursement compared to other ophthalmology services, and lingering financial impacts from the PHE. Commenters also stated that a reduction will disproportionately impact pediatric beneficiaries, minorities, and rural areas. They also stated that it could increase health disparities, generally, because the patient population for this service is primarily comprised of children insured by Medicaid. Commenters were concerned that Medicaid and private insurance payers will follow Medicare reimbursement and reduce payment for these services as well.

Response: We remain committed to minimizing health disparities and increasing health equity across all patient populations and demographics. We also are committed to minimizing impacts on clinicians as they relate to burden and workforce shortage. We acknowledge that impacts could potentially occur to special populations outside of Medicare as a result of reimbursement cuts to certain covered services. We appreciate that stakeholders have raised concerns about these CPT codes and we believe that it would be worthwhile for stakeholders, including the RUC to review these services in light of the concerns that stakeholders presented. We are also interested in engaging with stakeholders in light of concerns about beneficiary access to these services.

After consideration of these public comments, we are finalizing the work RVUs and direct PE inputs for the Strabismus Surgery CPT code family as proposed.

(24) Lacrimal Canaliculus Drug Eluding Implant Insertion (CPT Codes 68841)

CPT code 68841 (*Insertion of drug-eluting implant, including punctal dilation, when performed, into lacrimal canaliculus, each*) was recommended for RUC review in October 2020 since the CPT Editorial Panel replaced CPT Category III (temporary) code 0356T with a new CPT Category I code to report the insertion of a drug eluting implant into the lacrimal canaliculus. We proposed the RUC-recommended work RVU of 0.49 for CPT code 68841.

For the direct PE inputs, we proposed to refine the equipment time for the ''lane, screening (oph)'' (EL006) from the RUC-recommended 9 minutes of equipment time to the 5-minute equipment standard for CPT code 68841. Five minutes is the standard equipment time associated with EL006 for this procedure. The recommended materials for this code family from the RUC state that the screening lane is used for the duration of setup, procedure, cleaning, and counselling post procedure and that the standard formulas are applied. We believe that the RUC inadvertently failed to update the equipment time associated with this procedure when CPT code 68841 was reviewed. The recommended materials for CPT code 68841 state the standard equipment time formula will be typical for this service, which will be 5 minutes in this case (the CA013 and CA024 equipment times are included but not the CA035 equipment time). We proposed to refine the equipment time for the equipment item lane, screening (oph) (EL006) from 9 minutes to 5 minutes to match this change in equipment time and solicited additional comments from stakeholders regarding the RUC-recommended non-standard equipment time of 9 minutes. We do not agree that it would be typical for CPT code 68841 to require an additional 4 minutes of equipment time totaling 9 minutes.

Comment: Several commenters opposed the proposed work RVU of 0.49 for CPT code 68841, stating that the payment is too low and much lower than what they were paid under the temporary CPT category III code 0356T, when carrier-priced. Commenters suggested that CMS return to using the temporary CPT category III code 0356T and its same payments for CY 2022.

Response: Since CPT has established a category I code—CPT code 68841—to replace the temporary CPT category III code 0356T, this temporary code will be replaced by the new category I CPT code 68841, so maintaining payment for CPT category III code 0356T is not possible.

Comment: Commenters urged CMS to withdraw the proposed RUC-recommended value of 0.49 work RVUs for CPT code 68841 and offered a series of other possible CPT codes with higher work RVU values as crosswalks for CPT code 68841. Some commenters also asked that the 4 minutes of equipment time for the ''lane, screening (oph)'' (EL006) be restored to the total of 9 minutes. Another commenter thanked CMS for correcting the equipment time to 5 minutes.

Response: After reviewing the procedure itself, its intra-service time and the RUC-recommended work RVUs for this service, we believe that this work is appropriate and maintains a proper relativity to similar codes within the PFS. After considering all the suggestions from commenters and reviewing the RUC-recommended work RVUs with the RUC-recommended physician times for this CPT code, and re-examining the surveyed work RVU of 0.74 at the 25th percentile with 3 minutes of intraservice physician time and 11 minutes of total time, we are finalizing the work and PE inputs for CPT code 68841 as proposed.

(25) Transcutaneous Passive Implant-Temporal Bone (CPT Codes 69714, 69717, 69716, 69719, 69726, and 69727)

In October 2020, the CPT Editorial Panel deleted two codes used for mastoidectomy and replaced them with four new codes for magnetic transcutaneous attachment to external speech processor. The CPT Editorial Panel made additional revisions to differentiate implantation, removal, and replacement of the implants.

We proposed the RUC-recommended work RVU for all six of the codes in this family. We proposed a work RVU of 8.69 for CPT code 69714 (*Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor*), a work RVU of 9.77 for CPT code 69716 (*Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor*), a work RVU of 8.80 for CPT code 69717 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor*), a work RVU of 9.77 for CPT code 69719 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor*), a work RVU of 5.93 for CPT code 69726 (*Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor*), and a work RVU of 7.13 for CPT code 69727 (*Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor*).

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Post-operative visits (total time)'' (CA039) activity from the RUC-recommended 108 minutes to 99 minutes for CPT codes 69714 and 69717. 99 minutes is the clinical labor time associated with one Level 2 postoperative office visit and two Level

3 postoperative office visits; we believe that the RUC inadvertently failed to update the clinical labor time associated with these postoperative office visits when CPT codes 69714 and 69717 were reviewed. We also proposed to refine the equipment time for all equipment items other than the basic instrument pack (EQ137) from 108 minutes to 99 minutes to match this change in clinical labor time.

Comment: Several commenters stated that they supported the proposed work RVUs for all six codes in the family. Commenters noted that the work RVUs recommended by the RUC were interim and updated work RVUs will be submitted following an upcoming RUC meeting.

Response: We appreciate the support for our proposed work RVUs; we will consider any future RUC recommendations when they are submitted.

Comment: Several commenters stated that they agreed with the direct PE refinements.

Response: We appreciate the support for our proposed direct PE refinements.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs as proposed for all six of the codes in the family.

(26) X-Rays at Surgery Add-On (CPT Code 74301)

The RUC recommended that CPT code 74301 (*Cholangiography and/or pancreatography; additional set intraoperative, radiological supervision and interpretation (List separately in addition to code for primary procedure)*) be deleted for October 2020. The specialty societies that typically bill for this service submitted a code change application to delete CPT code 74301 at the February 2020 CPT meeting. However, the specialty societies withdrew the deletion request after receiving feedback from the dominant provider of CPT code 74301 (general surgery), indicating the code is still necessary and should not be deleted. The RUC recommended to maintain the work RVU of 0.21 for CPT code 74301. The specialty societies did not resurvey CPT code 74301 due to its low utilization (2019 Medicare utilization = 63) and the difficulty of obtaining 30 survey responses from service providers with experience in the past 12 months. Since there was no survey done, there is no new information and the RUC recommended to maintain the current value. The work RVU suggested by the RUC is a reaffirmation of the current value.

We proposed the RUC-recommended work RVU of 0.21 for CPT code 74301. This is an add-on code with no direct PE inputs.

Comment: The commenters appreciated that CMS proposed the RUC-recommended work RVU for CPT code 74301.

Response: We thank the commenters for their support.

We are finalizing the proposed work RVU of 0.21 for CPT code 74301. We did not propose and we are not finalizing any direct PE inputs.

(27) Trabecular Bone Score (TBS) (CPT Codes 77089, 77090, 77091, and 77092)

We proposed the RUC-recommended work RVUs of 0.20 for CPT codes 77089 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk) and 77092 (Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk interpretation and report on fracture risk only, by other qualified health care professional*). CPT codes 77090 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere) and 77091 (Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only*) are PE only codes; the RUC did not recommend and we did not propose a work RVU for these codes.

The RUC PE recommendations for CPT codes 77089 and 77091 include a new ''TBS iNsight Software'' supply input. The submitted invoice for this supply indicates that it is a licensing fee associated with the use of the software, which is not typically considered to be a form of direct PE under our methodology. Historically, we have considered most computer software and associated licensing fees to be indirect costs tied to associated costs for hardware considered to be medical equipment. However, as we noted in II.B of this final rule, stakeholders have routinely expressed concerns with this policy, especially for evolving technologies that rely primarily on software and licensing fees with minimal costs in equipment or hardware. Most of the recommended resource costs for CPT codes 77089 and 77091 are for this analysis fee and these costs are not well accommodated by the PE methodology since these sorts of technological applications did not exist when the data that underlie the PE allocation was last collected in 2007 through 2008.

Therefore, we proposed to value the PE for CPT codes 77089 and 77091 through the use of a crosswalk to a comparable service, CPT code 71101 (*Radiologic examination, ribs, unilateral; including posteroanterior chest, minimum of 3 views*), which, for CY 2021, had a PE RVU of 0.94. We proposed that the PE RVU for CPT code 77091 equals the PE RVU from code 77089 minus the PE RVU from codes 77090 and 77092 so that the three codes sum to the valuation of code 77089. (CPT code 77089 is the global code in this family and CPT codes 77090, 77091, and 77092 must sum together to equal the value of 77089.) CPT code 71101 is another type of bone imaging procedure that we believe reflects codes 77089 and 77091 similar direct PE resource costs as CPT codes 77089 and 77091. We recognize that the services being performed in this crosswalk code are not the same as the services in CPT codes 77089 and 77091, however; we believe that the direct resource costs will typically be analogous across these codes. We believe that this is the most accurate way to incorporate the costs of the software employed in CPT codes 77089 and 77091 which will not typically be considered direct PE under our current methodology. We solicited comments, both on the specific proposal for the Trabecular Bone Score codes, as well as our broader discussion of this topic in section B of this final rule.

Comment: Some commenters supported our proposed methodology of calculating PE RVU values for CPT codes 77089 and 77091 through the use of a crosswalk to CPT code 71101, stating that this is a reasonable interim solution until CMS' PE methodology is updated to better account for these technologies. Other commenters did not support our proposed approach, urging CMS to accept the RUC-recommended direct PE inputs for CPT codes 77089 and 77091, which include the TBS iNsight Software supply input. These commenters stated that the TBS iNsight Software is currently sold ''per click'' or per scan. The invoice submitted by the RUC depicts a TBS iNsight 1-year License and covers a total of 100 scans. The total unit price for the license is $2,500; therefore, the cost is estimated to be $25 per patient (or scan). As this is a single-use item used per patient encounter, the RUC included it as a direct expense supply item, not an equipment item, which is typically accounted for by minutes used. One commenter disagreed with our assertion that software costs would not typically

be considered direct PE, as there are many codes including ''software'' direct inputs, and noted that CMS would therefore not be setting a precedent by potentially including software as a direct input in the work RVUs for CPT codes 77089 and 77091.

Response: We are finalizing as proposed the RUC-recommended work RVUs of 0.20 for CPT code 77089 and 77092, as well as direct PE inputs for CPT codes 77089 and 77091 based on a crosswalk approach to CPT code 71101. As we stated in the CY 2019 PFS final rule (83 FR 59557), we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment, and we continue to consider that to be the case for these CPT codes 77089 and 77091. We refer readers to section II.B of this final rule (the PE section) for a comprehensive discussion of our policy for accounting for computer software and associated licensing fees in the PE methodology.

(28) Pathology Clinical Consult (CPT Codes 80503, 80504, 80505, and 80506)

The Relativity Assessment Workgroup identified CPT code 80500 (*Clinical pathology consultation; limited, without review of patient's history and medical records*) via the CMS/Other source codes with the Medicare utilization over 20,000 screen. In October 2019, the RUC referred this issue to the CPT Editorial Panel to define this service more specifically as the current descriptor is vague. In October 2020, the CPT Editorial Panel replaced CPT codes 80500 and 80502 (*Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records*) with four new codes, CPT codes 80503 (*Pathology clinical consultation; for a clinical problem with limited review of patient's history and medical records and straightforward medical decision making. When using time for code selection, 5–20 minutes of total time is spent on the date of the consultation. (For consultations involving the examination and evaluation of the patient, see 99241, 99242, 99243, 99244, 99245, 99251, 99252, 99253, 99254, 99255)), 80504 (for a moderately complex clinical problem, with review of patient's history and medical records and moderate level of medical decision making. When using time for code selection, 21–40 minutes of total time is spent on the date of the consultation), 80505 (for a highly complex clinical problem, with comprehensive review of patient's history and medical records and high level of medical decision making. When using time for code selection, 41–60 minutes of total time is spent on the date of the consultation), and 80506 (prolonged service, each additional 30 minutes (List separately in addition to code for primary procedure)(Use 80506 in conjunction with 80505)(Do not report 80503, 80504, 80505, 80506 in conjunction with 88321, 88323, 88325) (Prolonged pathology clinical consultation service of less than 15 additional minutes is not reported separately) (For consultations involving the examination and evaluation of the patient, see 99241–99255)*) to report pathology clinical consultation and creation of guidelines to select and document the appropriate level of service.

The RUC recommended a work RVU of 0.50 for CPT code 80503 based on the 25th percentile of the survey. The RUC-recommended 15 minutes of intraservice and total times for CPT code 80503 are 2 minutes above the current instraservice and total times for CPT code 80500. This represents a 15 percent increase in the respective times. However, the RUC-recommended work RVU of 0.50 is 35 percent higher than the current work RVU of 0.37 for CPT code 80500. We believe that the increase or decrease in times should be commensurate with the increase or decrease in the work RVU. Therefore, we proposed a work RVU of 0.43. This represents the ratio of total time between the current total time of CPT code 80500 and the proposed total time of CPT code 80503 (0.15) applied to the current value of CPT code 80500 (0.37 $\times$ 0.15 = 0.43).

We proposed the RUC-recommended work RVU of 0.91 without refinements for CPT code 80504.

The RUC recommended a work RVU of 1.80 for CPT code 80505 based on the 25th percentile of the survey. The current intraservice and total times for CPT code 80502 are 42 minutes. The RUC-recommended times for CPT code 80505 are 54 minutes. Similar to the scenario described above for CPT code 80503, the intraservice and total times for CPT code 80505 increased 28.6 percent while the work RVU increased 35 percent. As stated above, we believe the increase or decrease in time should be commensurate with the increase or decrease in the work RVU. Therefore, for CPT code 80505 we proposed a work RVU of 1.71, which is the current total time ratio of CPT code 80502 compared to the RUC-recommended total time for CPT code 80505.

We proposed the RUC-recommended work RVU of 0.80 for CPT code 80506 without refinement.

For the direct PE inputs of CPT codes 80503, 80504, and 80505, we proposed to refine the time associated with the clinical labor activity PA001 (Accession and enter information) from the RUC-recommended time of 4 minutes to 0 minutes as we believe the time is duplicative with clinical labor activity PA008 (File specimen, supplies, and other materials).

The RUC recommended 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80503, 80504, 80505, and 80506, respectively. We note that there is no indication from the code descriptors that the pathologist is reviewing physical slides. The code descriptor and description of work indicate that the pathologist is reviewing paper records and/or electronic health record (EHR), and therefore, we proposed to remove the equipment time associated with EP024 (microscope, compound) from CPT codes 80503, 80504, 80505, and 80506.

Additionally, the proposed Levels of Decision Making for Table for Pathology Clinical Consult codes includes ''Assessment requiring an independent historian(s)'' as an element of ''Amount and/or Complexity of Data to be Reviewed and Analyzed *—Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.'' Neither the code descriptors nor the descriptions of work indicate that this type of assessment is typical in a pathology clinical consult as was discussed for the office visit Levels of Decision Making table. For these reasons, CMS proposes that this element not be included as an element that we will recognize as an element of medical decision making. We note that CMS will monitor the use of these replacement codes per our usual practice to ensure appropriate billing and inform future rulemaking as needed. We also solicited comments on how these replacement codes will most typically be billed relative to use of existing pathology coding. Such information will also inform future rulemaking as needed.

Comment: A commenter urged CMS to accept the RUC-recommended work RVU of 0.50 for 80503 and 1.80 for 80505. The commenter stated CMS' use of a total time ratios to value 80503 and 80505 was flawed as the predecessor code 80500 was deleted and split out into three base codes and one add-on code with different reporting requirements. The commenter stated CMS should not compare the time of 80503 to the deleted code 80500 because the code descriptor for 80503, in contrast to 80500, includes the

review of patient's history and medical records. The commenter also noted that the descriptor for 80502 described a clinical pathology consultation for a ''complex diagnostic problem'', whereas new code 80505 describes a ''highly complex clinical problem''.

Response: In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. As we have previously stated, section 1848(c)(1)(A) of the Act requires CMS to consider time and intensity when developing work RVUs. Therefore, we believe it is appropriate to compare CPT code 80503 to CPT code 80500 and CPT code 80505 to code 80502, which CPT code 80505 replaced, as the PFS is a relative value system. We continue to believe that the increases or decreases in work times should be commensurate with the increase or decrease in the work RVU, which is why we proposed a work RVU of 0.43 for CPT code 80503 and a work RVU of 1.71 for CPT code 80505 based on the time methodology detailed above.

Comment: Several commenters disagreed with the proposal to remove the equipment time associated with EP024 (microscope, compound) from CPT codes 80503, 80504, 80505, and 80506. Commenters noted that the RUC's Summary of Recommendation (SOR) states that a patient's medical record is reviewed focusing on recent and relevant remote clinical and diagnostic findings and all applicable diagnostic material, slides, primary analytical data are retrieved/unarchived for the pathologist's examination and review. Commenters stated it is typical for a consulting pathologist performing CPT codes 80503–80506 to review all relevant information about the patient that is available, and a physical component of the patient material within the case review is the patient's specimen slides. Commenters stated that these slides are typically reviewed on a high grade professional microscope at the pathologist's workstation and during the service, the microscope itself is not available for other personnel to use on other patients, as the pathologist may review the slides multiple times during the service. Commenters stated that the RUC understood that pathologists require a microscope to perform this and numerous other pathology related professional services which is why the RUC included equipment time for the EP024 compound microscope in its recommendations. Therefore, commenters urged CMS to accept and implement the RUC-recommended times of 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80503, 80504, 80505, and 80506.

Response: We appreciate the additional information provided by commenters. We found the affirmation from commenters that pathologists typically review the patient's specimen slides compelling, and we agree that the use of the EP024 microscope would be typical for these codes based on this additional information. Therefore, we are finalizing a policy to restore the RUC-recommended times of 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80503, 80504, 80505, and 80506.

Comment: Commenters urged CMS to accept and implement the RUC-recommended time of 4 minutes for clinical labor activity PA001 for CPT codes 80503, 80504, and 80505. Commenters stated for these services, accessioning and entering information on the patient case is a preservice clinical labor task that is not duplicative with the post service work of filing specimen slides, filing reports and all relevant patient information retrieved for the pathologist to review. The preservice clinical labor work here involves the careful documentation of the connection between the requesting physician and the pathologist onto a worksheet or accession form. The form is used to transcribe the request for consult, the primary complaint, patient encounter, and other related information so that it becomes part of the patient's EHR. This is one of the first steps of the complete service.

Response: We thank commenters for the additional information. However, we believe the majority of the accessioning tasks performed in the PA001 activity constitute forms of indirect PE. Although we agree that the unique nature of pathology and laboratory services can make comparisons across codes more difficult than for other services, we believe the comparison of similar clinical labor activities across different services is important to maintaining the relativity of the direct PE inputs. As we stated in the CY 2017 PFS final rule (81 FR 80324), we agree with the commenters that patient documentation and entering patient data into information systems is an important task, and we agree that these would take more than zero minutes to perform. However, we continue to believe that these activities are correctly categorized as indirect PE as administrative functions, and therefore, we do not recognize the entry of patient data as direct PE inputs, and we do not consider this task as typically performed by clinical labor on a per-service basis. While we do not agree that the data entry tasks described in this activity would constitute direct PE, we note that the recommended materials for these codes state that multiple existing forms of data will need to be identified and incorporated into this accession. We believe that these interpretive tasks do constitute a form of direct PE as they are individually allocable to a particular patient for a particular service. Therefore, we are finalizing 1 minute of clinical labor activity associated with PA001 for CPT codes 80503, 80504, and 80505 to capture the labor performed in these interpretive tasks. We note that we have also previously finalized 1 minute for the PA001 clinical labor activity in other pathology services such as CPT codes 88360 and 88361.

For CY 2022, we are finalizing the work RVUs of 0.43, 0.91, 1.71, and 0.80 for 80503, 80504, 80505, and 80506 as proposed. For the direct PE, we are finalizing a policy to restore the RUC-recommended times of 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80503, 80504, 80505, and 80506 and 1 minute of clinical labor activity associated with PA001 for CPT codes 80503, 80504, and 80505 to capture the labor performed in these interpretive tasks.

We reiterate that CMS will monitor the use of these replacement codes per our usual practice to ensure appropriate billing and inform future rulemaking as needed. We continue to look for stakeholder input on how these replacement codes will most typically be billed relative to use of existing pathology coding. Such information will also inform future rulemaking as needed.

(29) Revaluing End-Stage Renal Disease (ESRD) Monthly Capitation Payment Services (MCP) (CPT Code 90954)

In the CY 2021 PFS final rule (85 FR 84551 through 84554), we revalued most, but not all, of the ESRD MCP services. We finalized an increase in valuations for those ESRD MCP codes with values tied to the values of Outpatient/Office Evaluation and Management (O/O E/M) codes. We did not revalue CPT code 90954 (*End-stage renal disease (ESRD) related services monthly, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care*

professional per month) because it was originally valued by a crosswalk.

Stakeholders stated that CPT code 90954 was different from the other ESRD MCP codes. Rather than using an O/O E/M code building block methodology as had been used originally to value the other ESRD MCP codes, CPT code 90954 was valued based upon a crosswalk to CPT code 99293 (*Inpatient pediatric critical care provided for children age 29 days through 24 months old, per day*). When CPT code 99293 was deleted, the value of CPT code 90954 was crosswalked to a replacement code, CPT code 99471 (*Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age*). By crosswalking CPT code 90954 to CPT code 99471, the rank order across the ESRD MCP code family at that time was preserved.

Since we finalized the revalued ESRD MCP values for CY 2021, stakeholders have requested that we revalue CPT code 90954 because by not updating it, we created a rank order anomaly for work RVUs and time within the ESRD MCP code family. A stakeholder suggested that we address the rank order anomaly by revaluing CPT code 90954 based upon a new crosswalk to CPT code 33977 (*Removal of a ventricular assist device; extracorporeal, single ventricle*). The stakeholder stated that CPT code 33977 more appropriately represented the time and effort of the service provided over one month than the existing crosswalk to CPT code 99471 relative to the revalued services within the MCP code family.

In response to stakeholder requests to update the value of CPT code 90954, we proposed to increase the value of CPT code 90954, a global code with a current work RVU of 15.98, by crosswalking it to CPT code 33977, a 090 day procedural code with a work RVU of 20.86 to preserve relativity within the ESRD MCP family. We also solicited comments on our proposal to increase the value of CPT code 90954.

Comment: A few commenters supported our proposal to increase the value of the ESRD MCP CPT code 90954.

Response: We appreciate the support of the commenters.

Comment: One commenter stated that it was unfair and inconsistent to increase the value of CPT code 90954 in order to eliminate a rank order anomaly that resulted from our having revalued the other ESRD MCP codes in the CY 2021 PFS final rule. The commenter noted that as a global code, CPT code 90954 was initially valued based upon magnitude estimation with additional negotiations at the RUC. The commenter concluded that all the global codes should thus be revalued using the same methodology.

Response: We understand that some commenters disagree with our revaluation of CPT code 90954. We maintain that revaluing CPT code 90954 was important to maintaining rank order within the ESRD MCP family. The code identifies ESRD services for our youngest beneficiaries, infants and toddlers diagnosed with ESRD. We note that CPT code 90954 is not a global code. Nevertheless, we concur with the commenter that the group of global codes demands further review and possibly revaluation in the future as we come to better understand the nature of the services furnished during global periods.

In response to the majority of commenters and because of our desire to eliminate a rank order anomaly, we are finalizing our proposal to increase the value of CPT code 90954 to a work RVU of 20.86 in order to preserve relativity within the ESRD MCP family. In future rules, we will likely revisit the valuing of global codes.

(30) Colon Capsule Endoscopy (CPT Codes 91110, 91111, and 91113)

In October 2020, the CPT Editorial Panel replaced Category III code 0355T (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report) with a new Category I code 91113 (Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report*) to report gastrointestinal tract imaging. CPT codes 91110 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report*) and 91111 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report*) were added as part of the family and surveyed for the January 2021 RUC meeting.

We proposed the RUC-recommended work RVU for two of the codes in this family. We proposed a work RVU of 2.24 for CPT code 91110 and a work RVU of 2.41 for CPT code 91113 as recommended by the RUC in both cases. For CPT code 91111, we disagree with the RUC-recommended work RVU of 1.00 and we proposed a work RVU of 0.90 based on a crosswalk to CPT code 95923 (*Testing of autonomic nervous system function; sudomotor, including 1 or more of the following: quantitative sudomotor axon reflex test (QSART), silastic sweat imprint, thermoregulatory sweat test, and changes in sympathetic skin potential*). CPT code 95923 is an autonomic nervous system testing procedure that shares the identical intraservice work time of 15 minutes with CPT code 91111 and has 5 additional minutes of immediate postservice work time. When we reviewed CPT code 91111, we noted that the surveyed intraservice work time had decreased by 3 minutes, from 18 minutes to 15 minutes, while the RUC recommended maintaining the current work RVU of 1.00. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, decreases in time should typically be reflected in decreases to work RVUs. In the case of CPT code 91111, we believe that it will be more accurate to propose a work RVU of 0.90 based on a crosswalk to CPT code 95923 to account for these decreases in the surveyed work time.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from the RUC-recommended 9 minutes to 6 minutes for CPT code 91111. The recommended materials for this code family state that the 6 minutes for the CA016 activity are used to connect the equipment, fit belt to patient, put data recorder on patient, and sync capsule to each sensor on belt. This description of this clinical labor activity is identical for CPT codes 91110 and 91113 and each code has the same recommended time of 6 minutes. However, the recommended materials for CPT code 91111 state that 6 minutes are used to connect the equipment, fit belt, put data recorder on patient, sync capsule to each sensor and then an additional 3 minutes are used to position the patient (assist patient onto table lying down on right side and then into a sitting position after the capsule is swallowed). We do not agree that it will be typical for CPT code 91111 to require an additional 3 minutes for positioning as compared with the other codes in the family, particularly in light of the clinical similarities between these services. We are refining the clinical labor time to 6 minutes for CPT code 91111 to maintain relativity within the family.

We also proposed to refine the equipment time for the capsule endoscopy recorder kit (EQ146) from 64 minutes to 61 minutes and the exam table (EF023) from 44 minutes to 41 minutes to match this change in clinical labor time for CPT code 91111.

Comment: A commenter disagreed that the work time had decreased for CPT code 91111. The commenter stated that although there was a minor reduction in intra-service time, the total time reported by the survey takers was 7 minutes greater than the current total time even though this time was ultimately not added to pre- and post-service time. Therefore, the commenter stated that in practice CPT code 91111 does not take less total time than in the past.

Response: We disagree with the commenter that the work time for CPT code 91111 has not decreased. The survey showed a decrease of 3 minutes in the intra-service work time from 18 minutes to 15 minutes and the RUC recommended maintaining the same pre-service and post-service work time of 5 minutes. The RUC routinely makes adjustments to pre-service and post-service surveyed work times in its recommendations as it did here for CPT code 91111. We agree with the RUC that the typical pre-service and post-service work time has not increased for CPT code 91111 which results in an overall decrease for the code.

Comment: Several commenters disagreed with the CMS proposed work RVU of 0.90 for CPT code 91111 and stated that CMS should instead finalize the RUC-recommended work RVU of 1.00. Commenters disagreed with the CMS crosswalk to CPT code 95923 and stated that although there was a decrease in surveyed work time for CPT code 91111, the intensity level required to perform the service has stayed the same. Commenters stated that the decrease of 3 minutes of work time for CPT code 91111 may be due to efficiencies in the healthcare setting, not with the overall complexity of delivering the service. Commenters stated that the intra-service time, intensity level, and RUC-recommended RVU of 1.00 properly fell within a relative range compared to similar codes. Commenters compared the work of CPT code 91111 to CPT codes 70470 (*Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections*) and 76391 (*Magnetic resonance (e.g., vibration) elastography) and 95819 (Electroencephalogram (EEG); including recording awake and asleep*) to support their belief that the intensity relativity is appropriate and that the recommended current work value of 1.00 placed the survey code well within the relativity of the family.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 0.90 is a more accurate choice for CPT code 91111. As we stated in the proposed rule, since the two components of work are time and intensity, decreases in time should typically be reflected in decreases to work RVUs. The survey for CPT code 91111 found that the typical intraservice time required to perform the procedure had decreased by 3 minutes and we believe that this decrease in work time should be reflected in the work RVU. Even if the decrease in work time was due to greater efficiencies in delivering the service, this decrease in work time should be reflected in the work RVU for the service in question.

We do not agree with commenters that there has been a corresponding increase in intensity for CPT code 91111 which would justify maintaining the work RVU at 1.00 despite this surveyed decrease in work time. The CPT Editorial Panel did not revise the code descriptor for CPT code 91111 and both the survey vignette and the clinical description of work remain unchanged for CY 2022. Our proposed work RVU of 0.90 maintains the current intensity of the procedure, and we also note that the intensity of this procedure would be noticeably higher than the rest of the code family at the recommended work RVU of 1.00 which we do not believe would serve the interests of relativity. We also note that our proposed work RVU of 0.90 does reflect a small increase in the intensity of this service as compared to its previous intensity.

We also disagree that the work RVU of CPT codes 70470, 76391, or 95819 would be more appropriate comparisons for CPT code 91111. All of these procedures have similar work times but employ more complex forms of imaging such as CT imaging or magnetic resonance imaging. For example, CPT code 76391 makes use of an MR room (EL008) equipment item with a cost over $1.5 million in comparison to the capsule endoscopy video system (ES029) used in CPT code 91111 which costs approximately $10,000. While we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, we believe that CPT code 95923 is a more accurate crosswalk for CPT code 91111.

Comment: Several commenters disagreed with the CMS proposal to refine the clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from the RUC-recommended 9 minutes to 6 minutes for CPT code 91111. Commenters stated that there had been a detailed accounting of time for clinical labor activities included with the recommended materials for the code family. Commenters stated that for capsule endoscopy of the esophagus (CPT code 91111), clinical staff position the patient on the bed with a pillow (6 cm or 2.5 inches high) under the head to facilitate drinking and ingestion. The patient is typically assisted from supine to the left side to delay capsule transit across the gastroesophageal junction and then into a sitting position after the capsule is swallowed. Commenters stated that capsule endoscopy of the gastrointestinal tract (CPT code 91110) and colon (CPT code 91113) do not require these additional steps for positioning, as noted in the recommended materials.

Response: We appreciate the additional information provided by the commenters clarifying the clinical labor tasks taking place during the CA016 activity for CPT code 91111. The commenters explained that for CPT code 91111 the patient is typically assisted from supine to the left side to delay capsule transit across the gastroesophageal junction and then into a sitting position after the capsule is swallowed, which justifies the additional 3 minutes of clinical labor time recommended by the RUC. We are therefore not finalizing our proposed refinement to the clinical labor time and will instead finalize the RUC-recommended time of 9 minutes for this activity. We are correspondingly also not finalizing our proposed refinements the equipment time for the capsule endoscopy recorder kit (EQ146) and the exam table (EF023) for CPT code 91111; we are finalizing the RUC-recommended equipment time of 64 minutes and 44 minutes respectively.

After consideration of the comments, we are finalizing our proposed work RVUs for all three codes in the family. We are not finalizing our proposed direct PE refinements and are instead finalizing the RUC-recommended direct PE inputs for all three codes.

(31) External Cardiovascular Device Monitoring (CPT Codes 93228 and 93229)

For CPT code 93228 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*), we disagreed with the RUC-recommended work RVU of 0.52, and we proposed a

work RVU of 0.43. The proposed work RVU is based on an intraservice time ratio between the current and RUC-recommended intraservice times for CPT code 93228 ((10 minutes/12 minutes)*0.52), yielding a work RVU of 0.43. This proposed work RVU reflects the decrease in total time and is a direct work RVU crosswalk to CPT code 93290 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors*). CPT code 93290 has the same pre-, intra-, and postservice times as the survey times for CPT code 93228 and was reviewed in October 2016. While we recognize that the number of ECG tracings and daily reports have increased because of the increase in average wear time from 14 days to 20 days, the specialty societies and the RUC contend that this is offset by technology advancements, integrations with EHRs, and online portals that make it easier to manage and review the data in a chronological and efficient manner. Therefore, we proposed a work RVU that accounts for decrease in total time to provide this service, given that the increased tracings and daily reports are offset by the efficiencies gained by technological advancements.

The RUC recommended 10 minutes for ''Provide education/obtain consent'' (CA011) for CPT code 93228, based on a direct crosswalk and duplication of CPT code 93229 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*). We disagree with the RUC-recommended duplication of clinical labor to provide education that the patient will hear for a second time from the IDTF technician. While we understand that the duplication is by design, we do not agree with a direct crosswalk from CPT code 93229, because the provider of CPT code 93229 will likely have more in-depth education, specific to the patient, including materials and instructions for the patient to review. Therefore, we proposed the standard 2 minutes for CA011 in the non-facility for CPT code 93228.

The RUC recommended the addition of 24 minutes for quality assurance ''overread'' done by a second, senior technician, Clinical Activity Code CA021, Line 67 on the RUC-recommended PE Spreadsheet, for CPT code 93229. This is a new clinical activity for CPT code 93228, and we solicited public comments about the typicality of a second senior technician. We requested additional information about the IDTF's current quality assurance measures and parameters within the ECG recording program that should act as some degree of quality assurance. We also solicited additional information from IDTFs about the current error rate for improperly transmitted tracings to the physician that would indicate that it is typical for a second, senior technician to perform ''overread.'' We proposed 0 minutes for Clinical Activity Code CA021, Line 67 on the RUC-recommended PE Spreadsheet, unless commenters could provide compelling information that a second, senior technician typically performs quality assurance measures. Otherwise, we agree with the RUC-recommended direct PE inputs and proposed the refinements as recommended.

In addition to the proposed work RVU and direct PE input refinements, we requested additional information about the acquisition costs for equipment item EQ340 Patient Worn Telemetry System. Due to the proprietary nature of this equipment, invoices were unattainable to update this equipment item. Substantial technological improvements have been made to these devices since the last update in 2008, but they are proprietary devices, owned and manufactured for each IDTF. We solicited public comments on the manufacturing costs and other information to help update the equipment item for CY 2022. Second, we requested additional information about the useful lifetime of EQ340. We currently assign 3 years of useful life to EQ340, but the RUC notes that this is the only equipment item and CPT code 93228 is the only CPT code with an equipment item that has more than 500 minutes of equipment time and a useful life of 3 years or less. We solicited public comments to help update the useful life of EQ340, as it has not been updated since 2008, and the device has experienced significant technological changes.

Comment: Commenters disagreed with our use of the intraservice time ratio to value CPT code 93228, claiming it disproportionately decreased the work RVU by 17 percent, whereas the total time only decreased by 8 percent. Commenters also disagreed with the choice of reference CPT code 93920, stating that CPT code 93920 is often performed parallel to a separately reported pacemaker interrogation and wearable defibrillator interrogation service, thus making it less intense than CPT code 93229, which is usually performed without any separately reported services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the intensity has not changed or the amount of time involved in furnishing the service has changed. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. Given the well-established assertion in the RUC recommendations that the increased tracings and daily reports from the increased average wear time (from 14 to 20 days) is offset by the fact that the technology has advanced to make it easier to manage and review the data, resulting in a net zero change in intensity, we are obligated to account

for the change in time. We also clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regard to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Some commenters stated that the proposed work RVU for CPT code 93228 would result in an intensity that is dramatically lower than the intensity assigned to a level 1 established patient office visit, CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal.), which does not require the presence of a physician or other qualified healthcare professional.

Response: The RUC-recommended work RVU of 0.52 also assigns CPT code 93228 a lower intensity than code CPT code 99211; therefore, we do not agree that the proposed work RVU for CPT code 93228 would create a rank order anomaly. We agree with the RUC that CPT code 93228 is more accurately valued at a lower intensity than CPT code 99211. We also agree with the RUC that CPT code 93228 should have a lower intensity than key reference CPT codes 93298 (Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional) and 93015 (Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report) from the survey.

Comment: One commenter stated that while technology has advanced to negate some low intensity work, making review and management of data more efficient, the RUC-recommended RVU for CPT code 93228 accurately reflects the average wear time increasing from 14 to 20 days, the number of ECG tracings, and the increased daily reports.

Response: We agree with the initial statements in the RUC recommendations, such as that increased tracings and daily reports from the increased average wear time from 14 to 20 days are offset by the fact that the technology has advanced to make it easier to manage and review the data. The RUC and specialty societies stated that technology has advanced to make it easier to manage and review the data, which accounts for the reduced intra-service time. The interface for physician interaction with the reports has moved from primarily a fax and paper-based system, which resulted in large amounts of paper reports, to more streamlined digital reports with better organized and more easily accessible data. The number of episodes that the physician reviews and adjudicates have increased due to the increased wear time but the RUC agreed that the increased amount of data and the efficiency gained in reviewing that data directly offset each other. This supports the assertion that intensity of the service has not changed, given the offset discussed in the RUC recommendations. We believe the offset yields a net zero change in intensity, which is supported by the RUC and specialty societies' statements in the recommendations.

After consideration of public comments, we are finalizing a work RVU of 0.48 for CPT code 93228 based on a total time ratio between the current and RUC-recommended total times for CPT code 93228 ((23 minutes/25 minutes)*0.52). The finalized work RVU addresses commenters' concerns that the proposed work RVU was disproportionately decreased compared to the decrease in total time. The finalized work RVU also maintains the same intensity, which is supported by the statements in the RUC's recommendations that the increased amount of data and the efficiency gained in reviewing that data offset each other, yielding a net zero change in intensity. Based on this well-established assertion in the RUC recommendations, we believe it is appropriate to maintain the same intensity.

Comment: One commenter expressed concern with the proposed standard 2 minutes for ''Provide education/obtain consent'' (CA011) in the non-facility for CPT code 93228, and recommended a crosswalk of 5 minutes for this activity, similar to extended external ECG recording codes 93225, 93242, and 93246. The commenter stated that they believe the standard 2 minutes would be inadequate for clinical staff to explain next steps with the IDTF, to obtain the monitor, explain the goals and use of the device, and answer technology questions asked by this elderly population.

Response: The RUC recommended 10 minutes for ''Provide education/obtain consent'' (CA011) for CPT code 93228 based on a direct crosswalk and duplication of CPT code 93229. We continue to disagree with the RUC-recommended duplication of clinical labor because the patient will hear the same information from the IDTF technician and the provider of CPT code 93229 will likely have more in-depth education, specific to the patient, including materials and instructions for the patient to review. We are compelled by the additional information provided by the commenter and the provision of 5 minutes of clinal staff time to provide education and obtain consent (CA011) in some external extended ECG codes, particularly for CPT code 93224 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional*), as this is a code for review and interpretation by a physician or qualified healthcare professional similar to CPT code 93228.

After consideration of public comments, we are finalizing 5 minutes for CA011 in the non-facility for CPT code 93228 based on a crosswalk to the extended external ECG recording codes.

Comment: Commenters reiterated that the recommendation of the addition of 24 minutes for quality assurance ''overread'' done by a second, senior technician, Clinical Activity Code CA021, Line 67 on the RUC-recommended PE Spreadsheet, for CPT

code 93229 was based on two separate training/process documents that specifically discuss the role of a ''Senior Monitoring Technician'' and the typicality of this clinical labor activity. Commenters also corroborated the assertion in the Moran materials that a senior technician is contacted when the initial read of the transmitted data is unable to confirm the accuracy of the arrhythmias detected by the software algorithms. One commenter stated that an ''overread'' by a senior technician occurs for well over 50 percent of the services provided and that on average, the second ''read'' takes approximately 25 minutes of clinical staff time. The commenter gave the following two examples of when a second ''read'' is necessary: (1) There is enough motion artifact to interfere with the algorithm's ability to definitively identify arrhythmias; and (2) the occurrence of a complex arrhythmia that was not properly identified by the algorithm or the initial reviewer is high.

Response: We appreciate the additional information provided by the commenters. After consideration of the public comments, we agree with the commenters and are finalizing the RUC-recommended 24 minutes for CA021 for CPT code 93229.

Comment: In response to the request for additional information about the acquisition costs and useful life of equipment item EQ340 Patient Worn Telemetry System, commenters reiterated the uniqueness of mobile cardiac telemetry (MCT) and agreed that invoices were unattainable because the companies that furnish MCT manufacture their own devices and systems, so the equipment is not bought or sold in the marketplace. Commenters disagreed with the RUC's assertion that EQ340 has not been evaluated since 2008 and reiterated that the price was adjusted in the 2019 PFS final rule (83 FR 59478). Commenters opined that EQ340 has a relatively short life-span because it is worn continuously for several weeks, resulting in a high degree of wear, tear, damage, and loss. Commenters urged CMS to retain its current pricing and useful life for EQ340. One commenter urged consideration of the granularity of equipment input in comparison to other patient worn cardiac device monitoring systems. Other comments disagreed with the recommendation to consider granularity given the uniqueness of CPT code 93228.

Response: We believe that the additional information supplied by commenters reinforces that the current pricing and useful life of the EQ340 equipment item are accurate. We are maintaining the current price of $23,494 and useful life of 3 years for the EQ340 equipment item.

After consideration of the public comments, we are finalizing a work RVU of 0.48 for CPT code 93228, which is an increase from our proposed work RVU of 0.43. We are finalizing a clinical labor time of 5 minutes for the CA011 activity for CPT code 93228, an increase from our proposed clinical labor time of 2 minutes for this activity. We are finalizing the RUC-recommended direct PE inputs for CPT code 93229 without refinement.

(32) Electrophysiologic Evaluation (CPT Code 93621)

In October 2019, the RUC identified CPT code 93621 (*Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure*) as a high-growth service. It is an add-on code that can be used with several different procedures—base codes or other add-on codes, diagnostic, as well as therapeutic. CPT code 93621 is furnished in the facility only and thus has no direct PE inputs.

We disagree with the RUC-recommended work RVU of 1.75 based on a crosswalk to CPT code 36483 (*Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure*). We proposed a work RVU of 1.50 based on a crosswalk to CPT code 16036 (*Escharotomy; each additional incision*). CPT code 16036 is also an add-on code for a surgical incision that shares both an identical intraservice work time and a total time of 20 minutes with CPT code 93621. While the RUC's recommended crosswalk code also has 20 minutes of intraservice and total time, CPT code 36483 is more intense than CPT code 93621, whereas CPT code 16036 has a similar level of intensity as CPT code 93621.

The RUC did not recommend and we did not propose any direct PE inputs for CPT code 93621.

Comment: Several commenters disagreed with the CMS proposed work RVU of 1.50 for CPT code 93621 and stated that CMS should instead finalize the RUC-recommended work RVU of 1.75. Commenters stated that the crosswalk to CPT code 36483 that the RUC recommended was based on discussions among the RUC reviewers and accounted for similarities between services that both rely upon catheters to execute complex maneuvers inside the cardiovascular system. Commenters stated that the proposed crosswalk was problematic because CPT code 16036 is completely different from cardiac procedures and can be billed multiple times. Commenters stated that the RUC-recommended crosswalk code (CPT code 36483) is a cardiovascular procedure and carries similar intensity of work to CPT code 93621.

Response: We disagree with the commenters that the RUC's recommended crosswalk to CPT code 36483 is a more accurate choice than our proposed crosswalk to CPT code 16036. We note that all three of the codes in question share the identical intraservice and total work time of 20 minutes, and therefore, differ only in their work RVUs and intensities. Commenters largely objected to the use of CPT code 16036 as a crosswalk code because it is an escharotomy procedure instead of a cardiovascular procedure. However, we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, utilization level, or (in this case) number of times billable per day to serve as an appropriate crosswalk.

We disagree that CPT code 36483 at a work RVU of 1.75 was the most accurate choice to use as a crosswalk for CPT code 93621; though this was the RUC's recommended work RVU, using it would have resulted in a substantial increase in intensity for CPT code 93621. We note that the CPT Editorial Panel did not revise the code descriptor for CPT code 93621 and the two surveys conducted on this code (at the 2020 April and October RUC meetings) both indicated that the work time had decreased from 30 minutes to 20 minutes. While we recognize that there have been several changes in technique since CPT code 93621 was last surveyed in 2001, we do not agree that these changes have resulted in a substantial increase in the intensity of the service, especially given that the work time typically required to perform the service has fallen by a third. We were also concerned that the intensity for add-on CPT code 93621 would potentially be

higher than the base codes that it is reported with. Although we agree that this can occur in some rare cases, we continue to believe that it is more accurate to value CPT code 93621 at a work RVU of 1.50. Our proposed valuation represents a modest increase in intensity rather than the large increase in intensity resulting from the recommended work RVU of 1.75, which we believe more accurately captures the typical case for this service.

After consideration of the comments, we are finalizing the proposed work RVU of 1.50 for CPT code 93621. The RUC did not recommend and we are not finalizing any direct PE inputs for CPT code 93621.

(33) Cardiac Ablation Services Bundling (CPT Codes 93653, 93654, 93655, 93656, and 93657)

The technologies and clinical practices associated with Cardiac Ablation Services have changed enough over the past decade (since 2011 when they were first developed) that the specialty societies recommended referring theses codes to CPT Editorial Panel to have the code descriptors for Cardiac Ablation Services updated to create new and more complete descriptors reflecting the fact that many of these services are commonly performed together and should be incorporated and bundled. In October 2020, the CPT Editorial Panel revised the three existing cardiac ablation codes to be bundled with 3D mapping and to include ''induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus,'' and ''left atrial pacing and recording from coronary sinus or left atrium'' and ''intracardiac echocardiography including imaging supervision and interpretation'' into their descriptors.

A survey of the Cardiac Ablation Services was sent out using the newly revised CPT code descriptors asking cardiac electrophysiologists about the revised language in the existing CPT codes. From the survey results, the RUC advisory committee believes that many of the survey respondents may not have realized that the code descriptors had been substantially revised and that they may not have read the updated code descriptors thoroughly enough to understand that services that are separately billed, were now combined into the existing codes (since CPT did not issue new codes for the revised descriptors). The RUC recommended that these services be valued as interim to allow for re-survey and subsequent review at the April 2021 RUC meeting.

CPT code 93653 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry*) (previous work RVU of 14.75 with 000-day global) is now bundled with the add-on CPT codes 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)*) (work RVU of 5.23 with 90 minutes of intraservice time) and the add-on CPT code 93621 (*Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)*) (work RVU of 2.10 with 30 minutes of intraservice time). The RUC-recommended work RVU for CPT code 93653 is 18.49, with 40 minutes of preservice evaluation, 3 minutes of preservice positioning, 15 minutes of preservice scrub/dress/wait time, 125 minutes of intraservice time and 30 minutes of immediate postservice time.

Since the two add-on codes are combined with the primary CPT code 93653, one would expect the intraservice time to have increased or remained similar to the current 180 minutes. Instead, the RUC-recommended intraservice time has decreased to 125 minutes. Accounting for changes in technologies and clinical practices from over 10 years since this code family's last review, we will expect better efficiencies and reductions in work times, but with the addition of two add-on codes whose work is mostly, if not all, added to the intraservice time, one would not expect a net decrease in minutes. This is not what the collected responses from this survey show and it is a concern. Some of CPT code 93653 add-on service times may have shifted over to the increases in preservice times, but there does appear to be a collective misunderstanding in the survey's work RVUs and physician work time responses.

In light of the RUC's intention to resurvey and re-review CPT code 93653 (and this family of codes) at the April 2021 RUC meeting, and to resolve any flaws from the initial survey, such as survey respondents probably not realizing that a new descriptor describing the inclusion of services is now bundled to the existing CPT code (and not a newly issued CPT code), we proposed to maintain the current physician times and current work RVU of 14.75, until the AMA RUC returns with a more definitive and accurate valuation.

For CPT code 93654 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed*) (work RVU of 19.75), the RUC recommends 40 minutes of preservice evaluation, 3 minutes of preservice positioning, 20 minutes of preservice scrub/dress/wait time, 240 minutes of intraservice time and 33 minutes of immediate postservice time for a total of 336 minutes, an increase to the code's current 309 total minutes. Unlike CPT codes 93653 and 93656, CPT code 93654 already accounts for the work RVUs and physician times for 3-dimensional mapping of add-on CPT code 93613. The RUC recommended maintaining the current work RVU value of 19.75. We proposed the RUC-recommended updates to the physician times (net increase in total minutes) and to maintain the same work RVUs for CPT code 93654 for CY 2022.

CPT code 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)*) has a current work RVU of 7.50 with a physician intraservice time of 90 minutes. The RUC recommended a revised intraservice time of 60 minutes and 6.50 work RVUs. The primary change to CPT code 93655 is the reduction of the intraservice time of

about 67 percent, which we use as a guide to determine a work RVU. We compare add-on CPT code 22854 (*Insertion of intervertebral biomechanical device(s)* (*e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring* (*e.g., screws, flanges*), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)) also with 60 minutes of intraservice and total time and a work RVU of 5.50 to CPT code 93655 and we believe that this is a more accurate valuation than the RUC's work RVU crosswalk to CPT code 34709 (*Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed, per vessel treated (List separately in addition to code for primary procedure)*) with a work RVU of 6.50 and an intraservice and total time of 60 minutes because the proportional reduction in physician time should also reflect a similar proportional reduction in work RVUs. We proposed the RUC-recommended 60 minutes of intraservice and total time, but instead proposed a work RVU of 5.50 for CPT code 93655.

CPT code 93656 (*Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed*) is now bundled with the add-on CPT codes 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)*) (work RVU of 5.23 with 90 minutes of intraservice time) and the add-on CPT code 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure*) (work RVU currently carrier-priced with 25 minutes of intraservice time) which previously were separately reported add-on services, similar to above CPT code 93653 and its add-on codes.

The RUC-recommended work RVU for CPT code 93656 is 20.00, with 40 minutes of preservice evaluation, 3 minutes of preservice positioning, 20 minutes of preservice scrub/dress/wait time, 210 minutes of intraservice time and 33 minutes of immediate postservice time, for a total of 306 minutes. The current physician times for CPT code 93656 are 23 minutes of preservice evaluation, 1 minutes of preservice positioning, 5 minutes of preservice scrub/dress/wait time, 240 minutes of intraservice time, and 40 minutes of immediate postservice time, for a total of 309 minutes, which is a net difference of 3 minutes less in the total proposed minutes, and the RUC is recommending a work RVU of 20.00, which is 0.23 more work RVUs than the current work RVU of 19.77.

In light of the RUC's intention to resurvey and review CPT code 93653 (and this family of codes) with its new bundling at their April 2021 RUC meeting to resolve any flaws from the initial survey, where many of the survey respondents may not have realized that the code descriptors had been substantially revised and that they may not have read the updated code descriptors thoroughly enough to respond correctly, we believe CPT code 93656 is in the same situation with its new bundling thus, we proposed the RUC-recommended updates to the physician times (a net decrease of 3 minutes in total time) and to maintain the current work RVU of 19.77.

From the survey of CPT code 93657 (*Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)*), a value of 8.00 work RVUs was obtained at the 25th percentile for this add-on code. The RUC recommended a work RVU of 6.50, for the 60 minutes of intraservice and total physician time. The current work RVU is 7.50, for 90 minutes of intraservice and total physician time.

We compare add-on CPT code 22854 (*Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)*) with 60 minutes of intraservice and total time and 5.50 work RVUs to CPT code 93657 and we believe that this is a more accurate valuation, since the primary change to CPT code 93657 is the reduction of the intraservice time of about 67 percent, which we use as a guide to determining a work RVU. The RUC-recommended work RVU is crosswalked from CPT code 34709 (*Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed, per vessel treated (List separately in addition to code for primary procedure)*) with a work RVU of 6.50 and an intraservice and total time of 60 minutes, does not reflect the proportional reductions to the intraservice time and work. For CPT code 93657, we proposed the RUC-recommended 60 minutes of intraservice and total time, and a work RVU of 5.50, crosswalked from CPT code 22854.

There are no direct PE inputs for these facility-only CPT codes.

Comment: In light of the proposed CY 2022 reductions in payment for the Cardiac Ablation codes, commenters were concerned that there will be fewer providers of these services, which could cause beneficiaries to encounter longer waits for atrial fibrillation treatments as there will be fewer Cardiac Electrophysiologists to treat them. Longer waits to schedule for the earliest treatments possible are the exact opposite scenario to be the most effective in prevent strokes, heart failures, acute myocardial infarctions, trachycardia, etc. Some commenters requested that CMS and the AMA RUC withdraw their restructuring of these codes in their bundling. Commenters explained that in the typical progression of Cardiac Ablation treatment services, procedures are employed in a series, that services are additive in nature, and that subsequent services selected by practitioners are dependent on the outcomes of the previous procedures. Different individual patients do not necessarily receive the same group of services in every session of treatment,

which is what the bundling of services describes.

Response: We note that the restructuring of these procedures resulted from the AMA CPT deliberative process that CMS does not control. This restructuring was developed because of claims evidence showing that two or more procedures are observed occurring together on the same day, with the same practitioner, for the same beneficiary, frequently enough to justify a bundling of services under one new procedure code; the CPT panel decided to retain the old procedure code and only adjust its descriptor to include the new appended service. This appears to have created the misunderstanding with the survey respondents that yielded the flawed results and why the AMA RUC presented CMS with ''interim'' work RVUs rather than surveyed values. At this stage in the development of these codes, unbundling these services does not appear possible, so we have decided to maintain the current values where we can for another year, until we have new AMA RUC recommendations for next year, where stakeholders can comment further.

Comment: Some commenters stated that since these Cardiac Ablation services were going to be reviewed, their work RVUs should be increased to reflect more physician time and increases in physician work and work intensities. Instead, code bundling has reduced total payments.

Response: In consideration of concerns about a flaw in the original survey for these codes, CMS proposed to maintain the current work RVUs for some of the Cardiac Ablation services for CY 2022. We will re-review the new and revised AMA RUC recommendations for these codes when they become available and will consider for future rulemaking.

Comment: Commenters noted that the AMA RUC was aware of issues with the survey for these codes, but submitted work RVUs to CMS as recommended ''interim values''. Commenters noted that the AMA RUC informed CMS that they also intended to resurvey members of the American College of Cardiology & the Heart Rhythm Society, and to re-review those new survey results in their April 2021 meeting. The new results were discussed at that meeting and the updated work RVUs were proposed for recommendation to CMS at the conclusion of that meeting. The AMA RUC has included those recommendations in comment, and urges CMS to implement those corrected work RVUs for CY 2022, replacing the ''interim values'' first presented in January 2021.

Response: Stakeholders are aware that in recent years CMS revised its review process to align with our rulemaking timelines and to allow for consistency and transparency throughout the process. We thank the commenters for providing us with information from the April 2021 AMA RUC meeting, but note that these values along with recommendations from the subsequent October 2021 and January 2022 AMA RUC meetings will be considered as part of our CY 2023 PFS rulemaking cycle.

After consideration of comments on these Cardiac Ablation codes, we are finalizing all of the work RVUs as proposed. We did not propose and we are not finalizing any direct PE inputs for these facility-only codes.

(34) 3D Imaging of Cardiac Structures (CPT Code 93319)

In May 2020, the CPT Editorial Panel created one new add-on code to describe the 3D echocardiographic imaging and postprocessing during transesophageal or transthoracic echocardiography for congenital cardiac anomalies for the assessment of cardiac structure(s). The 3D imaging could be performed as a follow-up to a 2D transthoracic echocardiogram.

We proposed the RUC-recommended work RVU of 0.50 for CPT code 93319 (*3D echocardiographic imaging and postprocessing during transesophageal echocardiography, or during transthoracic echocardiography for congenital cardiac anomalies, for the assessment of cardiac structure(s) (e.g., cardiac chambers and valves, left atrial appendage, interatrial septum, interventricular septum) and function, when performed (List separately in addition to code for echocardiographic imaging*).

While we proposed no refinements to the direct PE inputs, we requested additional information about the 3D echocardiography probe equipment item. The RUC recommended that a 3D probe was required in addition to the base echocardiography machine. We received an invoice for $31,754.30 for this equipment item. It was unclear if the invoice reflected both the 3D probe and the base echocardiography machine or only the probe itself. We solicited additional information to know if this equipment item reflected both the 3D probe and the base echocardiography machine or only the probe.

Comment: Several commenters stated that they supported the proposal of the RUC-recommended work RVU of 0.50 for CPT code 93319.

Response: We appreciate the support for our proposed work RVU from the commenters.

Comment: A commenter stated that they had reviewed the submitted invoice and was able to confirm that the proposed price of $31,754.30 is for the 3D echocardiography probe (ER121) itself, not any other equipment. Another commenter agreed that the $31,754.30 cost on the submitted invoice was for the probe itself and stated that they were including additional invoices which reflected a range of costs between $34,678.00 to $36,556.44 for 3D probes to support this pricing.

Response: We appreciate the clarification of the pricing on the submitted invoice from the commenters. Unfortunately, we were unable to find the additional invoices mentioned by the commenter in their submission, and therefore, we were unable to review them for the stated range of costs between $34,678.00 to $36,556.44. Commenters are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

After consideration of the comments, we are finalizing the proposed work RVU of 0.50 and the proposed direct PE inputs for CPT code 93319. We are also finalizing the proposed price of $31,754.30 for the 3D echocardiography probe (ER121) equipment.

(35) Cardiac Catheterization for Congenital Defects (CPT Codes 93593, 93594, 93595, 93596, 93597, and 93598)

In May 2020, the CPT Editorial Panel replaced a family of four cardiac catheterization codes with five new codes (CPT codes 93593–93597) to describe cardiac catheterization for congenital cardiac defect(s). The CPT Editorial Panel also replaced two cardiac output measurement codes with one new add-on code (CPT code 93598) to report cardiac output measurement(s), performed during cardiac catheterization for congenital cardiac defects.

We proposed the RUC-recommended work RVU for two of the codes in this family. We proposed a work RVU of 3.99 for CPT code 93593 (*Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections*) and a work RVU of 6.10 for CPT code 93594 (*Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections*) as recommended by the RUC in both cases.

For CPT code 93595 (*Left heart catheterization for congenital heart*

defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections), we disagree with the RUC-recommended work RVU of 6.00 and we instead proposed a work RVU of 5.50 based on a crosswalk to CPT code 32607 (*Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (e.g., wedge, incisional), unilateral*). CPT code 32607 is a thorascopy procedure with three fewer minutes of intraservice work time (45 minutes) than CPT code 93595 but a higher total work time of 178 minutes. CPT code 93595 has similar surveyed work time to CPT code 93593 but the RUC recommended a work RVU of 3.99 for the first code in the family as compared to 6.00 for CPT code 93595. While we agree that CPT code 93595 is a more intensive procedure, we do not agree that it should be valued more than two full RVUs higher as compared to the first code in the family. We believe that it will be more accurate to propose a work RVU of 5.50 based on the aforementioned crosswalk to CPT code 32607. We note that the intensity of CPT code 93595 remains higher than the first two codes in the family at the proposed work RVU of 5.50.

For CPT code 93596 (*Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections*), we disagree with the RUC-recommended work RVU of 7.91 and we instead proposed a work RVU of 6.84 based on a crosswalk to CPT code 32608 (*Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (e.g., wedge, incisional), unilateral*). CPT code 32608 is another thorascopy procedure from the same family as CPT code 32607, with the same 60 minutes of intraservice work time as CPT code 93596 and a higher total work time of 195 minutes. In the same fashion as the previous code, CPT code 93596 has similar surveyed work time to CPT code 93594 but the RUC recommended a work RVU of 6.10 for the second code in the family as compared to 7.91 for CPT code 93596. While we agree that CPT code 93596 is a more intensive procedure, we do not agree that it should be valued almost two full RVUs higher as compared to the second code in the family. We believe that it will be more accurate to propose a work RVU of 6.84 based on the aforementioned crosswalk to CPT code 32608. We note that the intensity of CPT code 93596 remains the highest among the first four codes in the family at the proposed work RVU of 6.84. We believe that our proposed RVUs for CPT codes 93595 and 93596 better preserve relativity both within the family and also with other services on the PFS.

For CPT code 93597 (*Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections*), we disagree with the RUC-recommended work RVU of 9.99 and we instead proposed a work RVU of 8.88 based on the median work RVU from the survey. The RUC's recommendation of a work RVU of 9.99, based on maintaining the prior work RVU of deleted CPT code 93532 (*Combined right heart catheterization and transseptal left heart catheterization through intact septum with or without retrograde left heart catheterization, for congenital cardiac anomalies*), was nearly equal to the 75th percentile work RVU from the survey at 10.00. Since the RUC recommended the survey median work RVU for the other four non-measurement codes in the family, we do not understand the recommendation of a value for CPT code 93597 that sits within 0.01 RVUs of the survey 75th percentile. The survey for CPT code 93597 also revealed that it typically requires far less work time to perform as compared with predecessor code 93532 (83 minutes of intraservice work time as compared to 175 minutes for the predecessor code). Although we agree that CPT code 93597 is a more intensive procedure than its predecessor code, we do not believe that the work RVU should remain unchanged given the greatly reduced work time in the new procedure. Since the two components of work are time and intensity, we believe that decreases in time should typically be reflected in decreases to work RVUs. Therefore, we proposed a work RVU of 8.88 for CPT code 93597 based on the survey median outcome. We believe that our proposed RVU more accurately accounts for these changes in surveyed work time and better preserves relativity with the rest of the family.

For CPT code 93598 (*Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects*), we disagree with the RUC-recommended work RVU of 1.75 and we instead proposed a work RVU of 1.44 based on a crosswalk to CPT code 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel*). CPT code 37253 is an intravascular ultrasound procedure that shares the same intraservice work time of 20 minutes as CPT code 93598 and has 1 additional minute of immediate postservice time. We note that the intensity of CPT code 93598 as recommended by the RUC at a work RVU of 1.75 will be the second-highest in the family, higher than CPT code 93597 for example. We do not agree that this cardiac output measurement code will typically be more intensive to perform than the two types of heart catheterization taking place in CPT code 93597.

We also note that the recommended work RVU for CPT code 93598 was higher than the sum of its two predecessor codes. Former CPT codes 93561 (*Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement*) and 93562 (*Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output*) had CY 2021 work RVUs of 0.95 and 0.77 respectively. These two codes sum together to a work RVU of 1.72 which will be lower than the RUC's recommendation of 1.75 for CPT code 93598. The RUC's recommendation suggests that there will be no efficiencies gained or savings created in the process of creating CPT code 93598; we believe that the survey for the new code indicates otherwise, as the predecessor codes had work times of 15 minutes and 12 minutes respectively (27 minutes total) as compared to 20 minutes of surveyed work time for the new code. This lower work time suggests that the creation of CPT code 93598 has led to greater efficiencies in the service which, under the resource-based nature of the RVU system, lends further support for a reduction in the work RVU as compared to a sum of the predecessor codes. Therefore, we believe that it will be more accurate to a work RVU of 1.44 based on the aforementioned crosswalk to CPT code 37253.

The RUC did not recommend any direct PE inputs for these six codes and we did not propose any direct PE inputs.

Comment: Several commenters disagreed with the proposed valuation for the codes in the Cardiac Catheterization for Congenital Defects family. Commenters stated that CMS did not address compelling evidence for these services. Commenters stated that CMS dismisses the fact that services may change due to technological

advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services, and CMS only proposes blanket reductions instead of considering how a service may have changed or increased. Commenters requested that CMS address the compelling evidence that was submitted with the RUC recommendations when the agency does not propose the RUC's recommended values.

Response: As we stated under Methodology for Establishing Work RVUs near the beginning of this Valuation of Specific Codes section, compelling evidence is a concept developed by the RUC for its review process. Compelling evidence is not part of our statutory framework which requires that the valuation of codes be based on time and intensity. We do consider changes in technology, patient population, etc. insofar as they affect the time and intensity of the service under review. The RUC's criteria for compelling evidence may overlap with our statutory requirement to value services based on time and intensity; for example, new technology may cause a service to become easier or more difficult to perform, with corresponding effects on the time and intensity of the service. However, we are under no obligation to specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation process stipulated by statute. In the context of the codes in the Cardiac Catheterization for Congenital Defects family, we discussed the intensity of the new services at length in the proposed rule, which includes changes that may have been due to technological advances, patient population, etc.

Comment: Several commenters disagreed with the CMS proposed work RVU of 5.50 for CPT code 93595 and stated that CMS should instead finalize the RUC-recommended work RVU of 6.00. Commenters stated that it was unclear what criteria CMS used to reject the RUC recommendation or to select CPT code 32607 as a direct crosswalk. Commenters stated that CMS did not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale, and made no acknowledgement that this service is typically for pediatric patients with congenital cardiac defects.

Response: As we stated in the proposed rule, CPT code 32607 is a thoracopy procedure with three fewer minutes of intraservice work time (45 minutes) than CPT code 93595 but a higher total work time of 178 minutes. We believe that the close match in work times between CPT codes 93595 and 32607 makes our proposed crosswalk the most accurate choice for valuing CPT code 93595, and also better preserves relativity within this family of codes as compared to the RUC's recommendation of the survey median work RVU. In more general terms, we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. We are aware that the codes in this family are typically performed on pediatric patients with congenital cardiac defects but this in no way exempts them from comparisons to other services on the PFS, each of which has patient populations with their own associated risks. We also note that the crosswalk codes recommended by the RUC for valuation do not always describe clinically similar services, including within this very code family. The RUC recommended using a crosswalk to CPT code 36483 to value CPT code 93598 at a work RVU of 1.75, even though the former code describes endovenous ablation therapy of an incompetent vein while the latter code describes cardiac output measurement(s) performed during cardiac catheterization.

Comment: Several commenters stated that the CMS proposed value for CPT code 93595 would produce a rank order anomaly between CPT codes 93595 and 93594 as the difference in intensities between these two services would not be appropriately reflected. Commenters stated that risk of arterial catheterization is always high due to risks of stroke, bleeding into the brain for infants on heparin, and femoral artery injury for infants. Commenters stated that for an abnormal connection patient, the procedure is more complex, as doctors are now facing crossing arterial shunts or the patent ductus arteriosus (PDA) to evaluate the pulmonary arteries, or evaluating other vascular structures like major aortopulmonary collateral arteries (MAPCAs), which can be multiple. Commenters stated that these procedures require a significantly greater level of diagnostic evaluation, catheter and wire manipulation, and angiography to identify each and every vessel for surgical planning than previously afforded with the non-congenital diagnostic codes, and that due to this the physician work intensity is very high.

Response: We agree with the commenters that the catheterization services described by CPT code 93595 represent an intensive procedure, which is why we proposed a work RVU of 5.50. We agree with the commenters that this code should be valued at a higher intensity than CPT code 93594, which is why we proposed CPT code 93595 at a higher intensity. We do not agree that our proposed valuation creates a rank order anomaly, however; as we stated in the proposed rule, we do not agree that CPT code 93595 should be valued more than two full RVUs higher as compared to the first code in the family. We believe that the RUC's recommended work RVU of 6.00 would do more to create rank order anomalies within the family, as CPT code 93595 would be valued almost identically to CPT code 93594 (6.00 as compared to 6.10) despite having 12 minutes fewer of intraservice work time (48 minutes as compared to 60 minutes). At the RUC's recommended work RVU of 6.00, CPT code 93595 would also be valued 2.01 RVUs higher than the work RVU of 3.99 for CPT code 93593 despite having only 3 additional minutes of intraservice work time (48 minutes as compared to 45 minutes). While we agree that CPT code 93595 is a more intensive code than the first two codes in the family, and we therefore proposed a higher intensity for the code, we do not agree that this intensity is so high as to merit the RUC-recommended work RVU of 6.00.

Comment: Several commenters disagreed with the CMS proposed work RVU of 6.84 for CPT code 93596 and stated that CMS should instead finalize the RUC-recommended work RVU of 7.91. Commenters again stated that CMS does not provide any clinical foundation for their proposed crosswalk to CPT code 32608, did not seem to consider the compelling evidence provided in the RUC rationale, and made no acknowledgement that this service is typically for pediatric patients with congenital defects. Commenters stated that the proposed work RVU would assign CPT code 93596 an intensity that is substantially lower than the top two key reference codes from the survey, even though 3/4ths of the survey respondents that selected those top reference codes indicated that the survey code was a more intense service than either reference code.

Response: As we stated above in the case of CPT code 93595, we believe that the close match in work times between

CPT codes 93596 and 32608 makes our proposed crosswalk the most accurate choice for valuing CPT code 93596, and also better preserves relativity within this family of codes than the RUC's recommendation of the survey median work RVU. We direct readers to our previous discussion of compelling evidence and clinical similarity between crosswalk codes addressed above. With regards to the two reference codes from the survey (CPT codes 93460 and 93461), commenters stated that the proposed work RVU of 6.84 would assign CPT code 93596 a lower intensity than both reference codes. However, the RUC's recommended work RVU of 7.91 for CPT code 93596 also assigns a lower intensity than the two reference codes, which indicates that the RUC also believed that CPT code 93596 was appropriately valued at a lower intensity despite what the survey respondents may have indicated. As we stated in the proposed rule, while we agree that CPT code 93596 is a more intensive procedure, we do not agree that it should be valued almost two full RVUs higher as compared to the second code in the family. Commenters did not provide a rationale in their submissions as to why CPT code 93596 should be valued so much higher than CPT code 93594. We again note that the intensity of CPT code 93596 remains the highest among the first four codes in the family at the proposed work RVU of 6.84 and we continue to believe that our proposed RVUs for CPT codes 93595 and 93596 better preserve relativity both within the family and also with other services on the PFS.

Comment: Several commenters disagreed with the CMS proposed work RVU of 8.88 for CPT code 93597 and stated that CMS should instead finalize the RUC-recommended work RVU of 9.99. Commenters stated that CMS did not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale, and made no acknowledgement that this service is typically for pediatric patients with congenital defects. Commenters stated that the proposed work RVU would assign this service a similar intensity to CPT code 93596, even though CPT code 93597 is for a more complex patient with an abnormal native connection.

Response: We did not provide a clinical foundation for the proposed work RVU of 8.88 because it was taken from the survey median value; we believe that the commenters may have confused our proposed valuation of CPT code 93597 with the other codes in this family where we employed a crosswalk methodology. We direct readers again to our previous discussion of compelling evidence and clinical similarity between crosswalk codes addressed above. We agree with the commenters that our proposed work RVU of 8.88 would assign CPT code 93597 a similar intensity to CPT code 93596. However, we believe that this is appropriate because the RUC also recommended a similar intensity between the two codes in its own recommendations. The RUC recommended a difference in intensity of 0.003 between the two codes while we proposed a difference in intensity of 0.002; we believe that this provides strong evidence that we are maintaining the relationship between these two codes as recommended by the RUC.

We stated in the proposed rule that the RUC's recommendation of a work RVU of 9.99, based on maintaining the prior work RVU of deleted CPT code 93532, was nearly equal to the 75th percentile work RVU from the survey at 10.00. Since the RUC recommended the survey median work RVU for the other four non-measurement codes in the family, we did not understand the recommendation of a value for CPT code 93597 that sits within 0.01 RVUs of the survey 75th percentile. We noted that the survey for CPT code 93597 also revealed that it typically requires far less work time to perform as compared with predecessor code 93532 (83 minutes of intraservice work time as compared to 175 minutes for the predecessor code), and although we agreed that CPT code 93597 is a more intensive procedure than its predecessor code, we did not believe that the work RVU should remain unchanged given the greatly reduced work time in the new procedure. Commenters did not address these topics that we raised in the proposed rule and did not explain why CPT code 93597 should be valued within 0.01 RVUs of the survey 75th percentile and should maintain the valuation of its predecessor code despite requiring substantially less work time to perform. We continue to believe that our proposed RVU of 8.88 more accurately accounts for these changes in surveyed work time and better preserves relativity with the rest of the family.

Comment: Several commenters disagreed with the CMS proposed work RVU of 1.44 for CPT code 93598 and stated that CMS should instead finalize the RUC-recommended work RVU of 1.75. Commenters stated that CMS did not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale, and made no acknowledgement that this service is typically for pediatric patients with congenital defects. Commenters stated that the crosswalk code used for valuing CPT code 93598 (CPT code 37253) is a relatively less intense and less risky service typically performed in the lower extremity of an adult patient, making it an inappropriate crosswalk. Commenters stated that CPT code 93598 is a more intense service typically performed on a more complex pediatric patient, where a Swan Ganz catheter is introduced from the venous sheath, advanced through the right heart, and placed into the pulmonary artery for purpose of assessing cardiac output by thermodilution.

Response: As we stated above in the case of CPT codes 93595 and 93596, we believe that the close match in work times between CPT codes 93598 and 37253 makes our proposed crosswalk the most accurate choice for valuing CPT code 93598, and also better preserves relativity within this family of codes than the RUC's recommendation of a crosswalk to CPT code 36483. All three of these codes in question (93598 and the two crosswalks to 37253 and 36483) share the identical intraservice work time of 20 minutes, however we believe that our proposed crosswalk to CPT code 37253 is a more accurate choice for valuation. As we stated in the proposed rule, the intensity of CPT code 93598 as recommended by the RUC at a work RVU of 1.75 would be the second highest in the family, higher than CPT code 93597 for example. We do not agree that this cardiac output measurement code would typically be more intensive to perform than the two types of heart catheterization taking place in CPT code 93597. We also noted in the proposed rule that the recommended work RVU for CPT code 93598 was higher than the sum of its two predecessor codes (CPT codes 93561 and 93562) which had CY 2021 work RVUs of 0.95 and 0.77 respectively. These two codes sum together to a work RVU of 1.72 which would be lower than the RUC's recommendation of 1.75 for CPT code 93598. We noted in the proposed rule that the RUC's recommendation suggested that there would be no efficiencies gained or savings created in the process of creating CPT code 93598, which the surveyed work times for the new code indicated otherwise. Commenters did not address these topics that we raised in the proposed rule and did not explain why CPT code 93598 should have the second-highest intensity in the family or why CPT code 93598 should be valued higher than the sum of its two predecessor codes. We therefore continue to believe a work

RVU of 1.44 for CPT code 93598 would be more accurate, based on the aforementioned crosswalk to CPT code 37253.

After consideration of the comments, we are finalizing our proposed work RVUs for all six codes in the Cardiac Catheterization for Congenital Defects family. The RUC did not recommend any direct PE inputs for these six codes and we are not finalizing any direct PE inputs.

(36) Outpatient Pulmonary Rehabilitation Services (CPT Codes 94625 and 94626)

CPT code 94625 (*Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)*) and CPT code 94626 (*Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session) (Do not report 94625, 94626 in conjunction with 94760, 94761)*) are two new codes created by the CPT Editorial Panel to replace HCPCS G code G0424 (*Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day*), which was created by CMS in 2010. The RUC-recommended work RVUs for CPT codes 94625 and 946226 were 0.55 and 0.69, respectively.

We disagreed with the RUC-recommended work RVUs for both CPT code 94625 and 94626. Although the pulmonary rehabilitation services as described did not change, the RUC recommended an increase in intraservice work time for the services.

Based upon a comparison of intraservice time for the current HCPCS code G0424 relative to the RUC-recommended values, we proposed a work RVU of 0.36 for CPT code 94625 and a work RVU of 0.56 for CPT code 94626, both of which represent an increase to the work RVUs from the current HCPCS code G0424, the code that these two new codes are replacing. Our proposed RVU values reflect a commensurate increase in work relative to the increase in intraservice time.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Provide education/obtain consent'' (CA011) activity from the RUC-recommended 15 minutes to 2 minutes for both CPT codes 94625 and 94626. The recommended activities for the two codes include 15 minutes for the CA011 activity used for education. Education is provided at each session and according to RUC documents follows a curriculum outlined in the pulmonary rehabilitation guidelines.

We disagreed that it would be typical for CPT codes 94625 and 94626 to require an additional 13 minutes for education and consent given that the patient is seen two or three times a week for pulmonary rehabilitation and the educational activities are covered during those sessions. We stated that the educational activities would be done during the ''Perform procedure/service—NOT directly related to physician work time'' (CA021). Thus, we refined the clinical labor time to 2 minutes for both CPT codes 94625 and 94626 to maintain relativity, particularly in light of the clinical similarities between the services.

We also proposed to refine the equipment time by lowering the pulse oximeter w-printer (EQ211) and exercise equipment (treadmill, bike, stepper, UBE, pulleys, balance board) (EQ118) equipment times from 93 minutes to 80 minutes to match the change in clinical labor time for CPT codes 94625 and 94626.

Finally, we proposed to revise the utilization that is used to set rates for CPT code 94626 to reflect our understanding that pulmonary rehabilitation is always done with pulse oximetry. Thus, we proposed to update our analytic crosswalk to reflect our belief that 100 percent of the utilization for the pulmonary rehabilitation services currently billed using HCPCS code G0424 will now be billed using CPT code 94626. We stated that it is unlikely that the outpatient pulmonary rehabilitation services would be billed using CPT code 94625 because it is our understanding that pulmonary rehabilitation is typically provided with pulse oximetry, and therefore, we expected little or no utilization for CPT code 94625. We sought comment from stakeholders on our proposal to revise the utilization as stated.

The following is a summary of the comments we received and our responses.

Comment: Commenters expressed concern about the values we proposed for the two new outpatient pulmonary rehabilitation codes. They stated HCPCS G0424 is not the same service as the two new codes, therefore, the intraservice work should not be compared to HCPCS G0424. Commenters noted that the more recently developed clinical guidelines for pulmonary rehabilitation were not captured or valued in HCPCS code G0424. Additionally, the commenters stated that the valuation of HCPCS G0424 was based upon incorrect assumptions/flawed methodology of the CMS/Other valuation because the code was not surveyed by pulmonary medicine physicians.

Response: We appreciate the concerns of commenters. We understand from stakeholders that the services of the two new CPT codes are not described exactly the same as the service of HCPCS code G0424. We also understand that commenters found our approach to valuing the new codes, by using the current value of HCPCS G0424, flawed. We continue to believe, however, that the services of all the codes remain fundamentally the same, and as such, our use of time ratios is an appropriate method for identifying potential work RVUs for particular PFS services, especially when alternative recommended values do not provide a rationale for the need for additional time. Our review of the recommended work RVUs and time inputs included, but was not limited to, a review of information provided by the RUC, other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and the rationale for the recommendations.

Comment: A couple of commenters stated that pulse oximetry may be assessed intermittently, as needed, or continuously.

Response: We thank the commenters for their insights into the utilization of the two codes and will consider this information going forward.

After consideration of the comments, we are finalizing the proposed values for CPT codes 94625 and 94626 and will delete HCPCS code G0424. We are also finalizing the proposed refinements to the direct PE inputs and our proposal to update our analytic crosswalk to reflect our belief that 100 percent of the utilization for the pulmonary rehabilitation services currently billed using HCPCS code G0424 will now be billed using CPT code 94626.

(37) Remote Therapeutic Monitoring/Treatment Management (CPT Codes 98975, 98976, 98977, 98980, and 98981)

Remote Therapeutic Monitoring (RTM) is a family of five codes created by the CPT Editorial Panel in October 2020 and valued by the RUC at its January 2021 meeting. The RTM family includes three PE-only codes and two codes that include professional work.

In recent years, we have finalized seven codes in the Remote Physiological Monitoring (RPM) family that include

services similar to the new RTM codes. (See the CY 2021 PFS final rule at 85 FR 84542 through 84546 for more information.) Based upon our analysis, the services and code structure of RTM resemble those of RPM. For example, the RTM codes reflect similar staff and physician work, although the specific equipment used is different because the data being monitored are non-physiologic rather than physiologic as they are with RPM.

While there are notable similarities between the two sets of code descriptors, there are two primary differences. One difference, based upon our review of the RUC-recommended valuation materials for these codes, is that the primary billers of RTM codes are projected to be physiatrists, NPs, and physical therapists. Stakeholders have suggested that the new RTM coding was created to allow practitioners who cannot bill RPM codes, to furnish and bill for services that are similar to those described by the RPM codes. RPM services are considered to be E/M services and physical therapists, for example, are not permitted to furnish E/M services. In the CY 2020 PFS final rule, we designated the two RPM treatment codes (that is, CPT codes 99457 and 99458) as care management services (84 FR 62697 through 62698). We designated the incident to services in the RPM treatment management codes as care management services. As care management services, the clinical labor in the PE of the two RPM treatment management codes, CPT codes 99457 and 99458, can be provided under general supervision rather than direct supervision, as required for incident to services.

In our review of the new RTM codes for the proposed rule, we stated that we had identified an issue that we believed would disallow therapists and other qualified healthcare professionals from billing the RTM codes. Specifically, we were concerned that by modeling the new RTM codes on the RPM codes, the clinical labor that is part of the direct PE of the PE only code CPT code 98975, as well as the two professional work codes, CPT codes 98980 and 98981, could be viewed as clinical labor incident to the professional services of the billing practitioner. It has been our understanding that there is no incident to benefit for therapists (that is, physical therapists, occupational therapists, and speech-language pathologists). As a result, we sought public comment on how we might remedy the issues related to the RTM code construction in order to permit practitioners who are not physicians or NPPs to bill and be paid for furnishing RTM services.

The second primary difference between the RTM and RPM codes is the nature of the data to be collected and how the data are collected. According to the code descriptors, RTM codes monitor health conditions, including musculoskeletal system status, respiratory system status, therapy (for example, medication) adherence, and therapy (for example, medication) response, and as such, allow non-physiologic data to be collected. Reportedly, RTM data can be patient reported, as well as digitally uploaded while RPM requires that data be physiologic and be digitally uploaded. We note that, for both sets of codes, the device used must meet the FDA definition of a device as described in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA). We sought public comment on the typical type of device(s) and associated costs of the device(s) that might be used to collect the various kinds of data included in the code descriptors (that is, what devices would be used to collect data to monitor respiratory system status, musculoskeletal status, medication adherence, pain) for the RTM services.

Based upon our review of the RUC recommendations for these codes, we proposed the RUC-recommended work RVU of 0.62 for CPT code 98980 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/ caregiver during the calendar month; first 20 minutes*) and the RUC-recommended work RVU of 0.61 for its add-on code, CPT code 98981 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*) as a means of maintaining parity with the two RPM treatment management codes (CPT codes 99457 and 99458) upon which the two RTM codes are based. We proposed the RUC-recommended direct PE inputs for the two treatment management codes, CPT codes 98980 and 98981, without refinement.

We proposed to refine the direct PE inputs for the three PE-only RTM codes: CPT code 98975 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment*), CPT code 98976 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*), and CPT code 98977 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*). We proposed to value the PE for CPT code 98975 by crosswalking to the PE RVU for RPM code 99453 upon which the new RTM code was based. We also proposed to value the PE for CPT codes 98976 and 98977 by crosswalking to the PE RVU for comparable RPM code 99454, a code that includes payment for the medical device used to collect and transmit data. We noted that the only input to CPT code 98976 is a monthly fee of $25, which would not be paid as a direct cost under the PFS. Historically, we have considered most computer software and associated licensing fees to be indirect costs. However, as we noted in section II.B. of this final rule (the PE section), stakeholders have routinely expressed concern with this policy, especially for evolving technologies that rely primarily on software and licensing fees with minimal costs in equipment or hardware. As noted in that section of this rule, CMS continues to consider how best to reflect such costs under our current PE methodology.

We received many comments from interested stakeholders regarding our requests and proposal related to the new Remote Therapeutic Monitoring/ Treatment Management codes.

Comment: The majority of commenters disagreed with our determination that physical therapists are not permitted to bill remote therapeutic monitoring codes. They stated that although the services may be performed incident to the services of a billing physician or practitioner, they would not represent ''incident to'' services when billed by physical therapists. Commenters encouraged us to reevaluate our interpretation of the codes to permit physical therapists to bill and be paid for these services.

Response: We appreciate the insights of the commenters and understand their concerns. We agree that the new RTM codes are general medicine codes. However, we continue to be concerned about the construction of the codes.

We questioned in the proposed rule whether the RTM codes as constructed could be used by therapists because the Medicare benefit does not include services provided incident to the services of a therapist. We viewed the clinical labor described in the RTM codes as being services incident to the billing practitioner's professional services. In the proposed rule, we focused on therapists as providers of RTM services because we heard from stakeholders that the codes were developed in response to the needs of physical therapists. We note here, however, that speech-language pathologists, clinical social workers, registered dietitians, nutrition professionals, and CRNAs also have Medicare benefits that do not include incident to services.

Despite our concerns about the construction of the codes, we believe the services described by the codes are important to beneficiaries. Thus, we are finalizing a policy that permits therapists and other qualified healthcare professionals to bill the RTM codes as described. However, where the practitioner's Medicare benefit does not include services furnished incident to their professional services, the items and services described by these codes must be furnished directly by the billing practitioner or, in the case of a PT or OT, by a therapy assistant under the PT's or OT's supervision.

Comment: Some commenters recommended that we implement the new RTM codes as constructed so that non-physicians who cannot bill E/M services can bill for RTM services.

Response: We thank commenters for their recommendation.

Comment: Commenters identified various issues with the proposed RTM codes and offered solutions. For example, commenters described a problem with supervision of clinical staff activities. Stakeholders noted that the clinical labor in the direct PE of the two RTM treatment management codes (that is, CPT codes 98980 and 98981) would have to be directly supervised unlike the similar RPM codes (that is CPT code 99457 and 99458), which as care management codes allow general supervision by physicians and NPPs. Commenters expressed concerns that physicians and NPPs would be unlikely to use the new RTM codes if they had to directly supervise the clinical staff activities associated with the codes. To remedy the situation, commenters suggested that CMS designate the two RTM treatment management codes as care management services. By designating the clinical services of the two codes as care management services, physicians and NPPs would be able to supervise clinical staff activities under general supervision. Stakeholders offered alternatively that CMS develop HCPCS G codes with designated care management services to allow general, rather than direct, supervision.

We received other suggestions for developing G codes. Several commenters suggested that CMS create new codes that would allow a greater array of practitioners to offer RTM services as intended. They proposed that HCPCS G codes mirroring CPT codes 98980 and 98981 be created just as CMS did with HCPCS codes G2061, G2062, and G2063 for e-visits. The three e-visit HCPCS G codes mirror the original CPT codes for e-visit codes that can be billed only by physicians and NPPs.

Some commenters suggested that we consider developing HCPCS G codes that mirror CPT codes 99457 and 99458 for RPM but construct them specifically to allow qualified healthcare professionals such as physical therapists to offer RPM treatment management services.

Response: We thank commenters for their investment in identifying issues and solutions related to the construction of the RTM codes. We look forward to further discussions about the coding and structure of these services. We believe this topic is worthy of ongoing collaboration among stakeholders.

Comment: Several commenters wrote in support of our decision to crosswalk the values of CPT codes 98976 and 98977 to the RPM device-supply code, CPT code 99454. Other commenters urged us to consider creating a single temporary HCPCS code similar to CPT code 99454, but in addition to CPT codes 98976 and 98977, to serve as a PE-only code to facilitate the use of RTM. Commenters offered a list of the types of data (for example, motion, gait, balance, breathing regulation, sleep patterns, daily symptom reporting) that could be collected if there were a general device code available for use.

Response: We appreciate the support of commenters, as well as the descriptions about the value of having a generic code for devices. We also thank commenters for the information provided regarding the kinds of data that could be collected remotely if a generic code were available.

Comment: Commenters expressed enthusiasm for the new coding and our willingness to establish values and pay for the RTM services. The commenters requested that we finalize the codes so healthcare professionals would be able to provide and bill for RTM services.

Response: We thank stakeholders for the comments. We note that we received comments on topics that were outside the scope for this rule and, as a result, we did not address them here. Instead, we may consider the comments in future rulemaking.

After considering the comments, we are finalizing our proposed adoption of the RTM codes and our proposed valuations for the services. We heard commenters express concern about billing the new RTM codes. Comments covered the range of possible outcomes—from accepting the CPT codes to revising or developing new codes. Our decision to finalize the proposed RTM codes and our proposed valuations for the services strikes a balance between supporting beneficiary access to care that these services describe and allowing for non-E/M billing practitioners to furnish and bill for these services. We acknowledge the major themes that emerged in the comments from stakeholders about broadening the base of practitioners that could furnish the RTM and RPM services, as well as maximizing the efficiency with which these services could be furnished.

In the interest of coding efficiency for these services, we hope to continue to engage in dialogue with stakeholders, including the AMA CPT, in the immediate future on how best to refine the coding for the RTM services to address some of the specific concerns raised by stakeholders. We note that as general medicine codes, these codes can be billed by physicians and other qualified health care professionals. We also note that the five RTM codes will be designated as ''sometimes therapy'' codes, which means that the services can be billed outside a therapy plan of care by a physician and certain NPPs, but only when appropriate. While therapists' services must always be provided under therapy plans of care, RTM services that relate to devices specific to therapy services, such as the ARIA Physical Therapy device (CPT code 98977), should always be furnished under a therapy plan of care. We are also clarifying that the two device codes, CPT codes 98976 and 98977, are not subject to the *de minimis* standard that establishes the threshold for the statutorily required payment adjustment that applies to therapy services provided in whole or in part by therapy assistants. However, the initial set-up and patient education services represented by CPT code 98975 is subject to the *de minimis* policy. For more information about how the *de minimis* policy is applied for services provided in whole or in part by therapy

assistants, see the Therapy pages at section II.H.1. of this final rule.

We thank the many stakeholders for their thoughtful comments regarding the new RTM coding. We will continue to consider the issues raised about this set of codes in the context of potential future rulemaking.

(38) Principal Care Management and Chronic Care Management (CPT Codes 99490, 99439, 99491, 99437, 99487, 99489, 99424, 99425, 99426, and 99427)

In recent years, we have engaged in efforts to update and improve the relative value of care management and coordination services within the PFS by identifying gaps in payment and coding. One of those PFS services is Chronic Care Management (CCM). CCM services, which include management and support services provided by clinical staff under the supervision of a physician or NPP or services provided personally by a physician or NPP, have received ongoing refinements related to payment and coding since CY 2013.

Beginning in the CY 2014 PFS final rule (78 FR 74414 through 74427), we noted that physicians and NPPs who furnish care to patients with multiple chronic conditions require greater resources than are required to support patient care in a typical E/M service. In response, we finalized a separately payable HCPCS code, GXXX1 (*Chronic Care Management (CCM) services furnished to patients with multiple (2 or more) chronic condition expected to last at least 12 months, or until the death of the patient; 20 minutes or more per in 30 days of chronic care management services provided by clinical staff and directed by a physician or other qualified health care practitioner*). For CY 2015 (79 FR 67715 through 67730), we refined aspects of the existing CCM policies and adopted separate payment for CCM services under CPT code 99490 (*Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; Comprehensive care plan established, implemented, revised, or monitored*). For CY 2017 (81 FR 80244), we adopted CPT codes 99487 (*Complex chronic care management (CCCM) services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) and 99489 (*CCCM services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*). Then, in the CY 2019 PFS final rule (83 FR 59577), we adopted a new CPT code, 99491 (*CCM services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*), to describe at least 30 minutes of CCM services performed personally by a physician or NPP. In the CY 2020 PFS final rule (84 FR 62690), we established payment for an add-on code to CPT code 99490 by creating HCPCS code G2058 (*CCM services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month*). We also created two new HCPCS G codes, G2064 and G2065 (84 FR 62692 through 62694), representing comprehensive services for a single high-risk disease (that is, principal care management). In the CY 2021 PFS final rule (85 FR 84639), we finalized a RUC-recommended replacement code for HCPCS code G2058, CPT code 99439, which was given the same valuation and the identical descriptor as G2058.

For CY 2022, the RUC resurveyed the CCM code family, including CCCM and Principal Care Management (PCM), and added five new CPT codes: 99437 (*CCM services each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), 99424 (*PCM services for a single high-risk disease first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*), 99425 (*PCM services for a single high-risk disease each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure*), 99426 (*PCM, for a single high-risk disease first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*), and 99427 (*PCM services, for a single high-risk disease each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*).

The CCM/CCCM/PCM code family now includes five sets of codes, each set with a base code and an add-on code. The sets vary by the degree of complexity of care (that is, CCM, CCCM, or PCM), who furnishes the care (that is, clinical staff or the physician or NPP), and the time allocated for the services. The RUC-recommended values for work RVUs and direct PE inputs for CY 2022 derive from the recent RUC specialty society survey.

We reviewed the RUC-recommended values for the 10 codes in the CCM family and proposed the recommended work values for the codes. We proposed the RUC-recommended direct PE inputs without refinements. We stated that accepting the updated values was consistent with our goals of ensuring continued and consistent access to these crucial care management services and acknowledges our longstanding concern about undervaluation of care management under the PFS. We solicited comments, however, on whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of billing PCM when appropriate.

In addition to the proposals on the values for CCM codes, we expressed interest in understanding the standard practice used by practitioners to obtain beneficiary consent for care management services. We stated that we had received questions from stakeholders regarding the consent requirements for CCM services. We stated in the proposed rule that we

believed the questions arose because of the many flexibilities allowed in response to the PHE for COVID–19. In particular, during the PHE for COVID–19, we allowed stakeholders to obtain beneficiary consent for certain services under general supervision (85 FR 19230, April 6, 2020). Before the PHE for COVID–19, we required that beneficiary consent be obtained either by or under the direct supervision of the primary care practitioner. This requirement is consistent with the conditions of payment for this service under the PFS. In considering the various policies implemented during the PHE for COVID–19, we wondered what policies should remain in effect beyond the PHE. We asked how billing practitioners furnishing CCM at different service sites (for example, physician office settings, RHCs, FQHCs) obtained beneficiary consent over the past year and how different levels of supervision impact this activity. We asked for public comment on the level of supervision that is necessary to obtain beneficiary consent when furnishing care management services and stated we would consider such comments in future rulemaking.

We also proposed to adopt CPT codes 99424 (*PCM First 30 minutes provided personally by a physician or other qualified health care professional, per calendar month) and 99426 (PCM First 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*) to replace HCPCS codes G2064 and G2065 in the calculation of the rate for HCPCS code G0511 for General Care Management services billed by RHCs and FQHCs. The payment rate for HCPCS code G0511 is calculated based on the average of the national non-facility PFS payment rate for care management and general behavioral health integration codes (CPT codes 99484, 99487, 99490, and 99491), as well as HCPCS codes G2064 and G2065 which describe PCM services billed under the PFS. The payment rate for HCPCS code G0511 is updated annually based on the PFS amounts for these codes.

TABLE 19: CY 2022 CCM/CCCM/PCM Values

CPT Code	Short Descriptor	Current Work RVU	RUC-recommended Work RVU	CMS Proposed Work RVU
99490	CCM clinical staff first 20 min	0.61	1.00	1.00
99439	CCM clinical staff each add 20 min	0.54	0.70	0.70
99491	CCM physician or NPP work first 30 min	1.45	1.50	1.50
99437	CCM physician or NPP work each add 30 min	new	1.00	1.00
99487	CCCM clinical staff first 60 min	1.00	1.81	1.81
99489	CCCM clinical staff each add 30 min	0.50	1.00	1.00
99424 (currently G2064)	PCM physician or NPP work first 30 min	new	1.45	1.45
99425	PCM physician or NPP work each add 30 min	new	1.00	1.00
99426 (currently G2065)	PCM clinical staff first 30 min	new	1.00	1.00
99427	PCM clinical staff each additional 30 min	new	0.71	0.71

We received many comments regarding our proposals and request for information related the CCM/CCCM/PCM code family. The following comments are a summary of the comments we received.

Comment: The majority of commenters supported our proposal to accept the RUC-recommended values for the CC/CCCM/PCM code family.

Response: We continue to believe that to accept these updated values is consistent with our goals of ensuring continued and consistent beneficiary access to these crucial care management services.

Comment: Many stakeholders responded to our request for more information about obtaining beneficiary consent when furnishing care management services. Commenters requested that they be able to continue to obtain beneficiary consent under the general supervision of the treating physician or NPP, as it has been during the PHE for COVID–19.

Response: We thank the stakeholders for their insights related to this request. We appreciate the comments and will consider them in future rulemaking.

Comment: One commenter stated that keeping professional PCM and CCM at the same value would not create an incentive to bill CCM instead of PCM. Specialty care practitioners often care for patients with a single high-risk disease and do not meet the criteria for reporting other types of care management services that require management of multiple conditions.

Response: We thank stakeholders for their comments regarding professional PCM and CCM billing.

Comment: We received several comments that we viewed as out-of-scope. Topics of the comments included eliminating copayments for care management services, reviewing ''30-day'' global codes including care management codes, giving CPT code 99072 an active status, and deleting HCPCS G0506.

Response: We may consider these topics in future rulemaking.

After consideration of the comments, we are finalizing the proposed values for the 10 CCM/CCCM/PCM codes, which includes finalizing the same values for professional PCM and CCM services.

We are also finalizing adoption of the CPT codes 99424 (*PCM First 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*) and 99426 (*PCM First 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*) to replace HCPCS codes G2064

and G2065 in the calculation of the rate for HCPCS code G0511 for General Care Management services billed by RHCs and FQHCs. The payment rate for HCPCS code G0511 is calculated based on the average of the national non-facility PFS payment rate for care management and general behavioral health integration codes (CPT codes 99484, 99487, 99490, and 99491) and will now include CPT codes 99424 and 99426 which describe PCM services billed under the PFS. The payment rate for HCPCS code G0511 is updated annually based on the PFS amounts for these codes.

(39) Moderate Sedation (HCPCS Code G0500)

Following the publication of the CY 2021 PFS final rule, a stakeholder contacted us regarding what they believed to be an error in the intraservice work time for HCPCS code G0500 (*Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older (additional time may be reported with 99153, as appropriate)*). We established HCPCS code G0500 in CY 2017 to more accurately capture the work of administering moderate sedation for gastrointestinal endoscopic procedures for patients 5 years of age or older. We based the physician work and time for HCPCS code G0500 on data from the 100 gastroenterologists who completed the survey of CPT code 99152 (*Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older*) presented at the October 2015 RUC meeting. The survey data for CPT code 99152 showed a significant bimodal distribution with data from gastroenterologists performing endoscopic procedures demonstrating a markedly different and lesser amount of physician work for moderate sedation compared to other specialties. The stakeholder stated that the finalization of 12 minutes of intraservice work time for HCPCS G0500 appeared to be an error and asked CMS to correct it to reflect the 5 minutes of intraservice work time indicated by survey data when gastroenterologists performed endoscopic procedures.

While we appreciate the feedback from the stakeholder, we disagreed in the proposed rule that the finalization of 12 minutes of intraservice work time for HCPCS code G0500 (matching CPT code 99152) was an error. The work time for HCPCS code G0500 was proposed and finalized at 12 minutes in CY 2017, with the intention that it would match the work time for CPT code 99152. This was the rationale behind the descriptor for HCPCS code G0500 listing that the code was intended for the initial 15 minutes of intraservice time. Furthermore, several commenters questioned the work time for HCPCS code G0500 in the CY 2017 PFS final rule (81 FR 80341) and we stated in response that we expected that practitioners would report the appropriate CPT or HCPCS code that most accurately described the services performed during a patient encounter, including those services performed concurrently and in support of a procedural service consistent with CPT guidance. We noted that the commenters referred to the time for moderate sedation in the survey data, while the time thresholds for the moderate sedation codes were intended to match the intraservice time of the procedure itself. For a full discussion of this topic, we refer readers to the CY 2017 PFS final rule (81 FR 80339 through 80349).

Although we did not propose a change in the work time for HCPCS code G0500, we solicited comments on this issue in the interest of gaining additional information about the typical use of this procedure. We did not receive any comments regarding the work time for HCPCS code G0500; we believe that this indicates that we were able to clarify this issue in the proposed rule.

(40) Payment for Synthetic Skin Substitutes (HCPCS Codes GXXAB, GXXAC, GXXAD, GXXAE, GXXAF, GXXAG, GXXAH, and GXXAI)

On July 1, 2020, Medicare implemented HCPCS code C1849 (*Skin substitute, synthetic, resorbable, per square centimeter*) and made it payable under the OPPS. In the CY 2021 OPPS final rule (85 FR 86064 through 86067) Medicare finalized payment for C1849—and the associated synthetic skin substitute products—allowing it to be billed with graft skin substitute procedure CPT codes 15271 through 15278. We note that under the OPPS, payment for C1849 is packaged into the payment for the graft skin substitute procedure, and its costs are reflected in the development of the payment rates for those services. The creation of the C-code and the CY 2021 OPPS rulemaking addressed the need for a mechanism to pay for graft skin substitute application services performed with synthetic graft substitute products in the outpatient hospital setting, which is comparable to how Medicare pays for graft skin substitute application services performed with graft skin substitutes that are regulated by the Food and Drug Administration (FDA) under its regulatory framework for human cells, tissues, and cellular and tissue-based products (HCT/Ps). We clarify that the availability of a HCPCS code for a particular HCT/P does not mean that the product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271 (85 FR 86058). We note that in a response to the CY 2021 OPPS proposal, a commenter noted that the use of a C-code meant that synthetic graft skin substitute products would only be payable under the OPPS, and would not be able to be reported for graft skin substitute services using a synthetic product in the physician office setting (85 FR 86066).

Currently, graft skin substitute application services are paid separately from the HCT/Ps skin substitutes under the PFS. Specifically, when a physician or NPP furnishes a surgical service to apply a (HCT/Ps) skin substitute in a non-facility setting, they may bill Medicare for the surgical service (as described by CPT codes 15271 through 15278), and separately bill for the (HCT/Ps) skin substitute. For CY 2022, in order to reconcile the gap in payment for synthetic products in the physician office setting, we proposed to create ten HCPCS codes (parallel to the aforementioned existing surgical codes) that would include the synthetic graft skin substitute product as a supply cost in determining the PFS rate. We indicated that we believe it would be appropriate to consider these products as incident to supplies in the office setting, and as such they should be built in as a supply cost in calculating the PFS rate. Therefore, we proposed to consider these products as incident to supplies in the office setting.

The codes and long descriptors for the proposed synthetic graft skin substitute services are:

- HCPCS Code GXXAB: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area.*
- HCPCS Code GXXAC: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure).*
- HCPCS Code GXXAD: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children.*
- HCPCS Code GXXAE: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure).*
- HCPCS Code GXXAF: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area.*
- HCPCS Code GXXAG: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure).*
- HCPCS Code GXXAH: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children.*
- HCPCS Code GXXAI: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure).*

We proposed contractor pricing for these codes for CY 2022; we note that there is limited data available on the cost of synthetic skin substitute products in physician offices, so we also solicited comments and documentation regarding the appropriate values for these services for consideration of national pricing in future rulemaking.

Though we proposed contractor pricing, we also considered an alternative approach that would use crosswalks to value these services in the physician office setting in a way that is commensurate with the rates paid under the OPPS. Though there is only limited data on the cost of graft synthetic skin substitute products in physician offices, hospitals began reporting costs associated with synthetic skin substitute products in CY 2020 after C1849 became effective and payable under the OPPS starting in July, 2020. We analyzed CY 2020 OPPS claims data and estimate HOPD costs for graft synthetic skin substitute products averaged $1500. We note that under the OPPS, outpatient departments are paid separately for the primary surgical application codes (CPT codes 15271, 15273, 15275, 15277), and the costs associated with the synthetic products, as well as the add-on services (described by CPT codes 15272, 15274, 15276, 15278) are packaged into the payment for the primary procedure.

Under this alternative, we considered following an approach similar to that use under the OPPS where the cost of the supply would be included in the primary codes (described by HCPCS GXXAB, GXXAD, GXXAF, and GXXAH) and not the add-on codes (described by HCPCS GXXAC, GXXAE, GXXAG, and GXXAI), though the add-on would continue to be reported and paid separately. Specifically, we would use direct crosswalks for the work RVUs, MP RVUs, and facility PE RVUs from the current surgical application codes (that is, CPT codes 15271 through 15278) as we believe that these payment components for the synthetic graft skin substitute services, described by the aforementioned HCPCS codes, would be similar.

However, with regard to the non-facility PE RVUs, we recognize that there are significant supply costs associated with synthetic skin substitute products. As described previously, we estimate that hospitals face average costs associated with synthetic skin substitute products of $1500. We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, may not be appropriate for these types of services because the specialists that typically furnish these types of services do not typically have significant supply costs within the methodology. As such, we used the hospital reported costs and we looked to other codes where specialists frequently have similarly high supply costs in order to crosswalk the non-facility PE RVUs. We considered services that have a significant proportion of supply costs and are furnished by specialists who typically have higher supply costs as potential crosswalks for the non-facility PE RVUs. For example, we considered a crosswalk to CPT code 21461 (*Open treatment of mandibular fracture; without interdental fixation*) for HCPCS codes GXXAB and GXXAF, and a crosswalk to CPT code 21462 (*Open treatment of mandibular fracture; with interdental fixation*) for HCPCS codes GXXAD and GXXAH. As an estimate of non-facility PE, we believe these would be appropriate codes for crosswalking non-facility PE RVUs.

As previously discussed in the proposed rule, for the purposes of the work RVUs, MP RVUs, and facility PE RVUs, we believed direct crosswalks to the current surgical application codes would be appropriate as those values would generally not be impacted by the addition of a synthetic skin substitute product. We realized this alternative considered would follow a similar coding and payment approach established under the OPPS, and that potential adoption of this alternative would mean that the cost of the products is included in the primary codes and not included in the add-on codes. We welcomed feedback on our proposal to treat synthetic skin substitute products as incident to supplies in the physician office, the proposal to have contractor pricing for these codes, and other ways we could obtain detailed and reliable cost information on synthetic skin substitutes that are furnished in the non-facility setting. We also solicited comment on the alternative approach that we considered (using crosswalks to value these services in the physician office setting). Additionally, we solicited comment on potential ways to reconcile these coding and payment differences across settings to yield a more consistent and rational payment approach for synthetic and HCT/P graft skin substitutes.

Comment: One commenter agreed with the proposal to create eight HCPCS codes for these services citing their previous position regarding high-cost disposable supplies, and that they had urged CMS to consider separately identifying and paying for services with disposable supplies over $500. The commenter disagreed with the proposed alternatives considered whereby instead of contractor pricing, we could alternatively utilize crosswalks to value these services in the physician office setting in a way commensurate with the rates paid under the OPPS. The commenter asserted that any use of the relativity of hospital charge data to determine the relativity of practice costs within the physician office setting is inconsistent with the statutory provisions articulated in Medicare statutory authority for the PFS. The commenter stated that the new procedure codes need to go through the CPT and RUC processes like all other services.

Response: With regard to the commenter's concerns regarding the proposed alternatives considered, we note that section 1848(c)(2)(N) of the Act authorizes us to use alternative approaches to establishing or adjusting PE RVUs using cost, charge, or other data from suppliers or providers of services in order to ensure accurate valuation of services under the PFS. Additionally, we reiterate that we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

Comment: One commenter requested clarification on how CMS intends to determine payment for proposed synthetic skin substitutes.

Response: We note that we discussed in the proposed rule that the eight new HCPCS codes would be contractor priced, and also discussed an alternative approach we considered whereby we would use direct crosswalks to the current surgical application codes for the work RVUs, MP RVUs, and facility PE RVUs as those generally would not be impacted by the addition of a synthetic skin substitute product; and with regard to the proposal to determine the non-facility PE RVUs for the eight new proposed HCPCS codes we would use crosswalks to other codes for which there are frequently similarly high supply costs.

Comment: Several commenters stated that they appreciate CMS' recognition of the need to develop appropriate payment mechanisms for synthetic skin substitute products in the physician office setting; however, the commenters urged CMS to not finalize the proposal to treat synthetic skin substitutes as incident to supplies in the physician office setting, and to instead adopt a uniform and consistent policy to treat all skin substitutes, including synthetic skin substitutes, in the same manner. Specifically, the commenters stated that CMS should pay separately for the procedure using the existing graft skin substitute application codes (CPT codes 15271–15278) and establish specific HCPCS codes for each distinct synthetic skin substitute product; some commenters noted that new synthetic skin substitutes will have variable costs and pricing and for that reason they believe unique HCPCS coding is necessary to provide identification to payers on claims, and track each product's cost. Some commenters also stated that synthetic skin substitutes are not supplies and mention that all other skin substitutes are not considered incident to supplies in any setting including the physician office setting. Therefore, they believe it is illogical that CMS would propose that synthetic skin substitutes be treated as incident to supplies in the physician office. The commenters stated that the proposal would create inconsistencies across treatment settings, and any policy differences between the OPPS and PFS will cause considerable confusion and unnecessary administrative burden. A few commenters stated that alternatively, CMS could mirror the methodology used in the outpatient department setting by assigning synthetic skin substitutes to a high or low-cost category and establish a single payment rate for each category, which would also require CMS to develop unique HCPCS coding for each synthetic skin substitute product.

Response: We thank commenters for their thoughtful comments and note that they highlighted several important factors that must be addressed as we consider payment for synthetic skin substitutes. We appreciate that there is a great deal of information and additional considerations we need to further examine in order to more comprehensively address our goal of establishing a consistent and rational payment approach for synthetic (as well as HCT/P) graft skin substitutes across settings. After consideration of the public comments, we acknowledge that the policy as proposed could contribute to continued differing treatment of synthetic skin substitutes in the physician office setting as compared to the hospital setting. However, we also recognize that currently there is no payment mechanism which makes use of synthetic skin substitute products payable under the PFS, and we acknowledge the need to reconcile the gap in payment for synthetic products in the physician office setting without delay. Therefore, in order to address this need, and to be responsive to the feedback we received from commenters, we are establishing a unique HCPCS Level II code for each of 10 products for which we have received a HCPCS Level II coding application and then, though this final rule, finalizing that these products will be payable in the physician office setting as contractor priced products that are billed separately from the procedure to apply them. The ten products are as follows: NovoSorb SynPath, Restrata Wound Matrix, Symphony, InnovaMatrix AC, Mirragen Advanced Wound Matrix, bio-ConneKt Wound Matrix, TheraGenesis, XCelliStem, Microlyte Matrix, and Apis. We note that we are taking a closer look at our approach to HCPCS Level II coding for a broad range of skin substitute products, also referred to as wound dressings, and that our decision on the ten applications for synthetic skin substitutes noted above is part of that ongoing work. These ten applications were received over the course of several quarterly and biannual coding cycles in 2020 and 2021. With the exception of the timing, the process we used to decide that we will establish a unique HCPCS Level II code for each the ten products that we are announcing in this final rule was the same process we currently use to decide other HCPCS Level II coding applications submitted during our quarterly and biannual coding cycles. Under that process, CMS staff review and make recommendations to agency leadership regarding whether to approve the applications. We post our coding decisions for drugs and biologicals on a quarterly basis. For our quarterly cycles for drugs and biologicals, we do not routinely review those applications at a HCPCS public meeting. For non-drugs and non-biologicals, we post our coding decisions on a biannual basis. For our biannual cycles for non-drugs and non-biologicals, we post preliminary coding decisions, then invite stakeholders to react to those preliminary coding decisions at a biannual HCPCS public meeting. After the HCPCS public meetings, we post the final coding decisions. We do not have a formal

process for consulting with an outside committee as part of our evaluation of HCPCS Level II coding applications. Around early November 2021, we will post information about these new HCPCS Level II codes on our website at *https://www.cms.gov/medicare/coding/medhcpcsgeninfo.* We are finalizing a policy to allow these HCPCS codes to be billed as add-on codes to the appropriate existing surgical application codes (CPT codes 15271–15278); this is consistent with the current treatment for other skin substitutes under the PFS. This approach differs from the original proposal in that the payment for the product is coded separately from the procedure to apply it, and it is consistent with the approach several of the commenters urged us to adopt instead. This approach will allow us to address the gap in payment for synthetic skin substitutes under the PFS, while also allowing us to take the necessary additional time to determine the most appropriate way to handle skin substitutes more comprehensively under the Medicare program. We anticipate addressing this matter more extensively in future rulemaking.

Comment: A few commenters stated that several refinements would be needed if the proposed G-codes are finalized. One commenter noted that the proposed alternative crosswalks for HCPCS codes GXXAB, GXXAD, GXXAF and GXXAH were inadequate, and provided alternate potential crosswalks for consideration. Additionally, a few commenters stated that CMS should not package payment for add-on codes, as proposed—whereby the cost of the supply would be included in the primary codes but not the add-on codes. The commenters also expressed that they believe this approach is also inappropriate under the OPPS where it was previously finalized, some stating that it overpays for treatment of smaller wounds and creates barriers to treating larger wounds in the HOPD. The commenters reference the August 23, 2021 Advisory Panel on Hospital Outpatient Payment stating that the panel unanimously approved recommendations to allow for payment for the existing skin substitute application add-on codes, and to assign similar APCs for skin substitute applications regardless of anatomical location on the body. The commenters stated that prior to adopting the proposed G-codes for payment in the physician office setting, these recommendations would need to be taken into consideration.

Response: As stated above, we are not finalizing the proposal to create G-codes that would treat the synthetic skin substitutes as incident to supplies, and instead are finalizing a modification to our proposal whereby we will establish product specific HCPCS codes that will be payable in the physician office setting. We appreciate the information regarding the recommendation to allow for payment of skin substitute application add-on codes under the OPPS, and will consider it in our ongoing review of all skin substitutes.

Comment: A few commenters urged CMS to re-evaluate the CY 2021 decision to issue HCPCS code C1849 for payment for synthetic skin substitute products under the OPPS and replace that generic code with unique product specific Q-codes similar to what occurs for all other skin substitutes.

Response: This comment regarding a policy finalized under the OPPS for CY 2021 is outside of the scope of this final rule.

Comment: One commenter stated that CMS had consistent policy for skin substitutes across the PFS and OPPS prior to CY 2014 when all products were paid separately as biologicals, and beginning in CY 2014 CMS began a policy of packaging skin substitutes under the OPPS while continuing to make separate payment under the PFS. The commenter stated that CMS could re-establish the old policy by reverting to separate payment for skin substitutes as CMS did prior to CY 2014.

Response: We appreciate the commenter's feedback, though the comment with regard to a policy established under the OPPS in CY 2014 is outside of the scope of this final rule; however, we would refer interested parties to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938) for the discussion regarding how the policy to package skin substitutes was part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure.

Comment: One commenter stated that they agree with the proposal to establish G-codes for synthetic skin substitutes in the office setting and if the proposed G-codes incorporate a high enough reimbursement level that considers the application of small to larger sizes and is also inclusive of existing in-office site preparation codes currently utilized today, then the proposed G-codes would be a positive step forward. The commenter stated that they do not agree with the industry commentary to consider utilization of Q-codes during the early adoption of such policy.

Response: We appreciate the commenters feedback regarding our proposal.

Comment: One commenter stated that the miscellaneous HCPCS code Q4100 could be used for the synthetic skin substitute product until specific HCPCS codes can be established through the usual HCPCS coding process that all other skin substitute products go through, and could be billed along with the existing application codes.

Response: We appreciate the commenter's feedback. As previously discussed, we are finalizing a policy to make synthetic skin substitute products payable under the PFS.

Comment: One commenter stated that there is no universal definition of what constitutes a synthetic product and that neither CMS nor the industry have clearly defined what a synthetic product is. The commenter noted that they believe a definition is a critical first step in determining the cost and other benefits to patients of new and advanced technology. Another commenter stated that synthetic skin substitute manufacturers should be given the opportunity to apply for a unique HCPCS codes as has been the process for all non-synthetic products rather than establish new HCPCS codes. The commenter stated that as the codes are evaluated by the HCPCS committee, the product should meet the significant therapeutic distinction criterion and demonstrate that the product heals wounds with statistical significance, and not simply act as a dressing or barrier for normal healing, and is only used when wounds become chronic. The commenter stated that the current proposal does not adequately account for variations in technology, stating that creating different coding and reimbursement methodologies does not account for the increasing intersection between biological, bioengineered, and synthetic components, as skin substitutes are a heterogenous group and that the materials used to produce skin substitutes are either natural, synthetic, or both. The commenter indicated that CMS previously assigned HCPCS code Q4117 to a product considered to be a synthetic skin substitute, which demonstrates that synthetic skin substitutes can function within the current coding under both the PFS and OPPS frameworks. The commenter stated that it would be better for CMS to judiciously assign HCPCS codes to synthetic products that meet the HCPCS coding application requirements of significant therapeutic distinction. The commenter also stated that the proposed introduction of eight new HCPCS codes would be confusing because if materials used to produce the skin substitute are either natural, synthetic, or both it would be difficult

for the provider to know which skin substitutes are synthetic and which are not, or if the product has both synthetic and natural components; and these uncertainties may cause potential delays or errors for providers and may have unintentional effect of increased patient responsibility if not coded correctly.

Response: We will take these comments into consideration for possible future rulemaking as we continue our work to address payment for all skin substitutes across settings, taking into account the intersection between biological, bioengineered, and synthetic components of these products. We also plan to further evaluate these components of products with an existing Q-code for future rulemaking to, in a similar manner, address payment policies for all skin substitutes across settings in a consistent manner along with products discussed in this rule. As indicated above we are finalizing a policy to create product specific HCPCS Level II codes that will be payable under the PFS. Additionally, we note that the definition of skin substitutes was clarified in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86058), but we certainly appreciate that the definitional issues raised in a comment on the CY 2022 PFS proposed rule are challenging, and we acknowledge that it will be important to develop the appropriate terminology for these products going forward. We expect this to be an evolving issue as we address this topic in future rulemaking.

Comment: One commenter stated that the proposed synthetic skin substitute HCPCS codes should include both resorbable, and non-resorbable synthetic skin substitutes, as well as resorbable and non-resorbable bio-synthetic skin substitutes. The commenter stated that the G-code descriptors should be modified to include ''bio-synthetic'' and clarify that the proposed G-codes can be reported for both synthetic and bio-synthetic skin substitute products that are either resorbable or non-resorbable. The commenter also stated that if CMS would like to distinguish between resorbable and non-resorbable, as well as bio-synthetic, that CMS should create several code sets that would make these distinctions.

Response: We appreciate the commenter's feedback and will take these comments into consideration for future rulemaking as we continue our work to address payment for all skin substitutes across settings.

Comment: A few commenters questioned the inclusion of the language which had previously been included in the CY 2021 OPPS/ASC final rule (85 FR 86058) stating that manufacturers of human cells, tissues, and cellular and tissue-based products should consult with the FDA Tissue Reference Group or obtain a determination through a Request for Designation on whether their HCT/Ps are appropriately regulated solely under section 361 of PHS Act and the regulations in 21 CFR part 1271. The commenters questioned why this information was included relating to synthetic resorbable skin substitutes since most of them have gone through the FDA's 510(k) process and received 510(k) clearance, and they are not considered HCT/Ps and thus should not be required to obtain another determination from the FDA TRG or RFD from FDA. The commenters stated that CMS should provide additional clarification and state which products must obtain a determination from the TRG or an RFD from FDA and remove any reference regarding consulting with the FDA TRG or obtaining a determination through an RFD from the discussion of synthetic skin substitutes since this information is not pertinent to these products.

Response: As indicated in the preamble to the CY 2022 PFS proposed rule (86 FR 39177), CMS established a policy with regard to payment for graft skin substitute application services performed with synthetic graft substitute products under the OPPS that is comparable to the way Medicare pays for graft skin substitute application services performed with HCT/P skin substitutes. We included the information about HCT/P skin substitutes in order to provide background and context for the policies we proposed when synthetic graft substitute products are furnished in the physician office setting. Similarly, our statement about consulting with the FDA TRG and the RFD process was intended to provide further background on CMS' overall approach to skin substitute products, and should not be interpreted as applying to products that received 510(k) clearance.

After consideration of the public comments, in order to address the need to establish a payment mechanism for synthetic skin substitutes in the physician office setting without further delay, and to be responsive to the feedback we received from commenters, we are creating the following unique HCPCS Level II codes for the following products: NovoSorb SynPath, Restrata Wound Matrix, Symphony, InnovaMatrix AC, Mirragen Advanced Wound Matrix, bio-ConneKt Wound Matrix, TheraGenesis, XCelliStem, Microlyte Matrix, and Apis; and are also finalizing that these synthetic skin substitutes will be payable with physician services in the office setting. Around early November 2021, CMS will post information about these new HCPCS Level II codes on its website at *https://www.cms.gov/medicare/coding/medhcpcsgeninfo.* These HCPCS Level II codes may be billed as add-on codes to the appropriate existing surgical application codes (CPT codes 15271–15278), and will be contractor priced.

(41) External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248)

In the CY 2021 PFS proposed rule (85 FR 50164), we proposed to adopt the RUC recommendations for CPT codes 93241 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93242 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), 93244 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation*), 93245 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93246 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93247 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*), and 93248 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation*).

We noted that the recommendations for this family of codes contain one new supply item, the ''extended external ECG patch, medical magnetic tape recorder'' (SD339). We did not receive a traditional invoice to establish a price for this supply item. Instead we received pricing information from two sources: A weighted median of claims data with the cost of the other direct PE inputs removed, and a top-down approach calculating the cost of the supply per service based on summing

the total costs of the health care provider and dividing by the total number of tests furnished. The former methodology yielded a supply price of approximately $440 while the latter methodology produced an estimated supply price of $416.85. Stakeholders also submitted a series of invoices from the clinical study marketplace with a price of $595, which we rejected as we typically require an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item.

After consideration of the information, we proposed to employ a crosswalk to an existing supply for use as a proxy price until we received pricing information to use for the ''extended external ECG patch, medical magnetic tape recorder'' item. We proposed to use the ''kit, percutaneous neuro test stimulation'' (SA022) supply as our proxy item at a price of $413.24. We believed the kit to be the closest match from a pricing perspective to employ as a proxy until we would be able to arrive at an invoice that is representative of commercial market pricing. We welcomed the submission of invoices or other additional information for use in pricing the ''extended external ECG patch, medical magnetic tape recorder'' supply. In response to our proposal, we received conflicting information from commenters and in the CY 2021 PFS final rule (85 FR 84631), we ultimately finalized contractor pricing for CY 2021 for the four codes that include this supply input (CPT codes 93241, 93243, 93245, and 93247) to allow additional time to receive more pricing information.

We note that stakeholders have continued to engage with CMS and the MACs on payment for this service. We remain concerned that we continue to hear that the supply costs as initially considered in our CY 2021 PFS proposal are much higher than they should be. At the same time, we also have heard that the resource costs, as reflected in the contractor based payments do not adequately cover the incurred cost for the SD339 supply that is used to furnish these services. In consideration of continued access to these services for Medicare beneficiaries, we once again solicited public comments and information to support CMS' future rulemaking to establish a uniform national payment that appropriately reflects the PE that are used to furnish these services. As previously stated, invoices or other additional information, including for example, which proxy supply items could be used to establish cost for the SD339 supply, information on use/application and potential alternatives (as appropriate) to the supply items, will be ideal for us to use in establishing fair and stable pricing for these services. We note that in the absence of such additional and actionable information (that is, information that provides further context to information that has already been considered) we proposed to maintain contractor pricing for these services.

Comment: Many commenters supported establishing national payment rates in CY 2022 for CPT codes 93241, 93243, 93245, and 93247. Commenters stated that the establishment of national payment rates would enable Medicare beneficiaries to access these technologies at fair and stable rates representing relative resources typically used to furnish these services. Commenters detailed the clinical benefits associated with the use of extended ECG monitoring and stated that the establishment of national pricing would ensure payment stability and increase beneficiary access to this form of care.

Response: We agree with the commenters that establishing national payment rates for CPT codes 93241, 93243, 93245, and 93247 would help remove disparities in pricing for these services and could potentially increase access to extended ECG monitoring services. However, we were previously unable to determine accurate pricing for the ''extended external ECG patch, medical magnetic tape recorder'' (SD339) supply due to conflicting information. Because this supply makes up a disproportionate amount of the costs associated with CPT codes 93241, 93243, 93245, and 93247, we were unable to finalize national payment rates in CY 2021. We believe that we require accurate pricing of the relative resource costs associated with this supply item before we can finalize national payment for these services. Additionally, we note that we did not receive public comments requesting that CMS maintain contractor pricing for these codes.

Comment: Several commenters submitted invoices for use in pricing the SD339 supply item. We received ten invoices in total describing several different types of patches that commenters stated were analogous to the pricing of the SD339 supply. These invoices averaged out to a price of $200.15. Some commenters requested that CMS use the submitted invoices to establish appropriate national payment for CPT codes 93241, 93243, 93245, and 93247; other commenters requested that CMS identify an appropriate proxy supply item from a list of supplies that they provided. One commenter suggested crosswalking the price of the SD339 supply to the catheter, balloon, esophageal or rectal (graded distention test) (SD214) supply at its CY 2021 price of $325.98.

Response: We appreciate the submission of invoices and additional information for use in pricing the SD339 supply from the commenters. Based on the information in the submitted invoices, we are finalizing an updated price of $200.15 for the extended external ECG patch, medical magnetic tape recorder'' (SD339) supply based on the average of the ten invoices we received. We believe that the invoice data for this supply item, which ranged from a minimum price of $179.80 to a maximum price of $241.99, suggests that our updated price of $200.15 is more accurate than the suggested crosswalk to the SD214 supply at a price of $325.98.

Comment: Several commenters requested that CMS add additional clinical labor and equipment time to CPT codes 93241, 93243, 93245, and 93247 above what the RUC recommended and CMS proposed in CY 2021. Commenters stated that the clinical labor inputs recommended by the RUC and proposed by CMS understate what is needed to perform the data analysis and report generation for extended ECG monitoring and requested additional clinical labor time to review the data obtained during the service. Commenters also stated that the equipment time recommended by the RUC and proposed by CMS understated the proprietary software and visualization technologies used to improve the accuracy and reproducibility of the human work. One commenter requested adding 104 minutes of equipment time for both the CEM system (EQ297) and the EEG analysis software (EQ013) equipment. A different commenter requested an increase to the equipment costs by using as proxies the equipment costs used in other cardiac monitoring and described by the Holter analysis system (EQ309) and the patient worn telemetry system (EQ340).

Response: We do not agree with the commenters that there are additional clinical labor and equipment costs above what the RUC recommended and we proposed in CY 2021 for CPT codes 93241, 93243, 93245, and 93247. In the CY 2022 PFS proposed rule, we requested invoices or other additional information regarding supply costs, including for example which proxy supply items could be used to establish cost for the SD339 supply, for use in

establishing fair and stable pricing for these services; we did not request information regarding clinical labor or equipment inputs. We continue to believe that the other direct PE inputs proposed in CY 2021 are accurate for CPT codes 93241, 93243, 93245, and 93247; for a full discussion of this topic, we direct readers to the CY 2021 PFS proposed rule (85 FR 50164) and our responses to commenters in the CY 2021 PFS final rule (85 FR 84631).

After consideration of the comments, we are finalizing an updated price of $200.15 for the extended external ECG patch, medical magnetic tape recorder'' (SD339) supply based on the average of the 10 invoices we received. Although we did request and receive pricing information as requested from stakeholders, we note that these services have a high utilization, and as a result any changes to the PE for these services would noticeably impact our BN adjustments for CY 2022. We believe that in light of a potential impact to payment for other services under the PFS, a proposal to establish national payment for these services based on this new pricing information should take into account broader stakeholder feedback. Therefore, we are not finalizing national pricing at this time and are finalizing our proposal to maintain contractor pricing for CPT codes 93241, 93243, 93245, and 93247 for CY 2022. However, we encourage stakeholders to continue to provide feedback regarding invoices or other additional information which could be used to establish pricing for the SD339 supply to assist CMS in setting national prices for these CPT codes for the CY 2023 rulemaking cycle. Stakeholders are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

(42) Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting

During the PHE for COVID–19, several stakeholders have contacted CMS with concerns about the additional costs borne by physician and NPPs due to the pandemic that may impact the professional services furnished to Medicare beneficiaries. For example, we have heard from stakeholders about higher costs due to additional supplies, such as personal protective equipment, and increased time that physicians, NPPs and their clinical staff may spend with patients to mitigate further spread of infection when, for example, stakeholders are working to rule out a COVID–19 infection, or furnishing other services to a patient with a confirmed COVID–19 infection. While costs such as these may diffuse into Medicare payment rates over a period of time, our payment systems, including the PFS, are not generally designed to accommodate more acute increases in resource costs, even if they are widespread. We acknowledge the circumstances stakeholders have identified that may lead to additional costs borne by physicians and NPPs during the PHE, and we have developed and implemented policies, as appropriate and where possible, to maintain beneficiary access to necessary services during the PHE. We are continuing to think broadly about the concerns raised, and specifically about the types of resource costs that may not be fully reflected in payment rates for existing services, or costs that could be accounted for by establishing new payment rates for new services. We were interested in feedback from stakeholders about additional strategies to account for PHE-related costs, including feedback on the specific types of services and costs that may benefit from further review, such as infectious disease control measures, research-related activities and services, or PHE-related preventive or therapeutic counseling services. We were interested in detailed feedback from stakeholders to help inform whether we should consider making changes to payments for services or develop separate payments for such services in future rulemaking.

Comment: Many commenters suggested the use of a new modifier that infectious disease physicians and other clinicians could append to current E/M codes that would help ensure that resources are available for the increased work associated with care during an outbreak. Commenters noted that the use of a modifier would provide CMS with two useful safeguards: (1) CMS could set documentation requirements regarding the existence of the outbreak (for example, parameters associated with the timeframe that public health officials have declared an infectious disease/public health emergency (PHE) or reporting associated diagnosis codes); and (2) CMS could set documentation requirements to justify the enhanced services that were provided during the outbreak (for example, evidence in the medical record that one or more of the aforementioned activities were delivered or influenced care). Commenters noted that there are other mechanisms that could achieve the same policy goals, but a mechanism such as a modifier would allow CMS to more narrowly tailor the directing of resources based on cases where the enhanced care is delivered in a way that supports program integrity. Commenters stated that a payment modifier would ensure that physicians, regardless of specialty designation, receive reimbursement commensurate with the atypical activities associated with treating patients during an outbreak or pandemic.

Commenters noted that a permanent mechanism or ''outbreak activation'' policy to reimburse clinicians for critical activities associated with managing future infectious disease outbreaks would promote certainty for both physicians and CMS, and facilitate rapid responses at the beginning of an outbreak when speed is critical to stop the spread of infections and save lives. Commenters noted that the payment enhancements made to address the current resource challenge were not predictable, were temporary in nature, and are specific to the COVID–19 outbreak, and therefore, cannot be used as a base for a permanent mechanism.

Response: We appreciate the commenters' feedback and will consider this feedback in the context of potential future rulemaking.

Comment: Many commenters urged CMS to implement and pay for CPT code 99072 (*Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease*) to compensate practices for the additional staffing and personal protection equipment (PPE) and other supplies needed during the COVID–19 pandemic, without patient cost-sharing or BN adjustments. Some commenters expressed urgency as physicians continue to incur increased expenses in an effort to safely care for patients during the PHE, and the commenters encouraged the issuance of an interim final rule to separately pay for CPT code 99072. Other commenters stated that CPT code 99072 does not capture the myriad of activities and tasks that are required of hospitalists and other types of physicians during a pandemic and that even if CMS were to assign a value to this code, it still would not meet the needs of the physician community as it would not account for specific services provided during a pandemic. One commenter suggested that CPT code 99483 (*Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or*

rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (e.g., basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (e.g., functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (e.g., home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neurocognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.), HCPCS code G2064 (*Comprehensive care management services for a single high-risk disease, e.g., principal care management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities*), and HCPCS code G0108 (*Diabetes outpatient self-management training services, individual, per 30 minutes*) would be appropriate crosswalk codes for valuation and inputs.

Response: We appreciate the commenters' feedback and will consider this feedback in the context of potential future rulemaking.

Comment: One commenter suggested separate, additional payment for pandemic costs that are free from BN considerations. The commenter noted that CMS could pay for CPT code 99072, or create a pandemic ''pack'' of standardized inputs for services, similar to the E/M supply pack.

Response: We appreciate the commenters' feedback and will consider this feedback and our regulatory and statutory authority in future rulemaking.

(43) Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management

Adequate treatment of pain is a significant public health challenge. Centers for Disease Control and Prevention (CDC) data indicate 50 million adults in the United States have chronic daily pain, with nearly 20 million experiencing high impact pain that interferes with daily life or work. Pain is the most common reason individuals seek medical care, and more than 20 percent of office visits are associated with pain.[3] In the United States, 42.6 percent of adults report having pain on some days in the past 6 months,[4] and chronic pain and high-impact chronic pain are experienced by 20.4 percent and 8 percent of adults, respectively.[5] The high prevalence of pain exacts a substantial economic toll: Medical expenditures and lost productivity related to pain result in a cost to the United States estimated at up to $635 billion.[6]

In 2010, HHS, through the National Institutes of Health (NIH), contracted with the Institute of Medicine to make recommendations ''to increase the recognition of pain as a significant public health problem in the United States.'' In its 2011 report entitled *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,* the Institute of Medicine, through a study mandated by Congress, recommended significant improvements in pain prevention, care, education, and research and development of a population health-level strategy to address pain care.[7] The report described that the unique experience of pain requires a combination of person-centered therapies and coping techniques influenced by genes, cultural attitudes, stress, depression, ability to understand health information, and other behavioral, cultural, and emotional factors. It noted that individualized care can require adequate extra time to counsel patients and caregivers, promote self-management, and consult with other health care providers, but current reimbursement systems are not designed to efficiently pay for this approach. HHS subsequently convened an expert committee to oversee creation of the *National Pain Strategy* (NPS), issued in 2016.[8] The NPS addressed six key areas of care: Population research, prevention and care, disparities, service delivery and payment, professional education and training, and public education/communication. In this report, NPS' vision is to ''decrease the prevalence of pain across its continuum from acute to high-impact chronic pain and its associated morbidity and disability across the lifespan,'' and aim ''to reduce the burden of pain for individuals, their families, and society as a whole.''

This work was followed by HHS' 2019 release of its *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations (PMTF Report).*[9] The PMTF Report focuses on the development of patient-centered pain treatment plans to establish diagnosis and set measurable outcomes such as improvements in quality of life, function, and activities of daily living. It emphasized multi-modal, multi-disciplinary approaches that include various modalities for acute and chronic pain. The PMTF Report also identified five broad treatment categories: Medications including opioids and non-opioids, restorative therapies, interventional approaches, behavioral approaches, and complementary and integrative health. It stressed the importance of special populations including older adults and persons with relapsing conditions, Veterans, and people who receive palliative care. The PMTF Report recognized the importance of proper opioid stewardship for individuals who need opioids to effectively manage their pain. As the Task Force noted, there are ongoing concerns regarding suicide and suicidal ideation due to pain, and a lack of

[3] Daubresse M, Chang HY, Yu Y, Viswanathan S, Shah ND, Stafford RS, Kruszewski SP, Alexander GC. Ambulatory diagnosis and treatment of non-malignant pain in the United States, 2000–2010. Medical care. 2013 Oct;51(10).

[4] *Erratum:* Vol. 66, No. 29. MMWR Morb Mortal Wkly Rep 2017;66:1238. DOI: *http://dx.doi.org/10.15585/mmwr.mm6644a10external* icon.

[5] Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006. DOI: *http://dx.doi.org/10.15585/mmwr.mm6736a2.*

[6] Gaskin DJ, Richard P. The economic costs of pain in the United States. The Journal of Pain. 2012 Aug 1;13(8):715–24.

[7] *https://www.nap.edu/catalog/13172/relieving-pain-in-america-a-blueprint-for-transforming-prevention-care.*

[8] *https://www.iprcc.nih.gov/national-pain-strategy-overview/national-pain-strategy-report.*

[9] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

access to pain treatment, including appropriate access to opioid medications. The PMTF Report noted that management of pain conditions often requires multidisciplinary coordination among health care professionals, and that the experience of pain can intensify other health issues such as delayed recovery from surgery, or exacerbate behavioral health conditions. Many health care professionals, including primary care providers, have opted out entirely in treating pain, worsening an existing shortage of pain specialists and making chronic pain care hard to access, including for people who frequently experience disparities in pain care such as rural dwellers, racial/ethnic minorities, and people with disabilities. The COVID–19 PHE has also had an impact on the ability of many older adults and people with disabilities' access to care, although telehealth modalities have shown promise in broadening access to services and supports.

At the same time individuals are experiencing difficulties finding pain care, the country is also coping with a worsening opioid and SUD crisis. The current environment involves shifting ''waves'' of overdose deaths associated with heroin, synthetic opioids, and prescription drugs, and intensifying stimulant and polysubstance use. Preliminary Centers for Disease Control and Prevention data released in April 2021 show a 29 percent rise in overdose deaths from October 2019 through September 2020—the most recent data available—compared with the previous 12-month period.[10] Illicitly manufactured fentanyl and other synthetic opioids were the primary drivers, although many fatal overdoses have also involved stimulant drugs, particularly methamphetamine. In December 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) released a preliminary report from its Drug Abuse Warning Network, which captures data on emergency department (ED) visits related to recent substance use and misuse such as alcohol use, illicit drug use, suicide attempts, and nonmedical use of pharmaceuticals. Most commonly associated with ED visits in the participating hospitals are illicit substances and central nervous system agents. Among illicit drugs, stimulants (including methamphetamine and illicit amphetamine) are the most common, followed by cannabinoids (including marijuana and synthetic cannabinoids).[11]

The PMTF Report urged clinicians to use a comprehensive, individualized, person-centered approach to the diagnosis and treatment of pain featuring multiple therapeutic modalities. The uptake of this approach is an urgent concern as growing numbers of older adults are enrolling in Medicare. Some estimates indicate about half of older adults have pain that interferes with function. Primary care clinicians and specialists are already facing challenges in treating pain and associated chronic disease in the Medicare population, where conditions such as arthritis, bone/joint disorders, back and neck pain, cancer and other conditions that inform and at times inhibit employing the full spectrum of pain management therapies are common. We believe untreated and inappropriately treated pain may translate to increased costs to the Medicare program as more beneficiaries experience functional decline, incapacitation, and frailty. Additional risks in untreated pain include individuals using illicit drugs such as cannabis; inadequate treatment of mental disorders such as depression and anxiety, misuse of prescription drugs, alcohol and other drug use disorder, and increased suicide risk and suicide.

In 2019 HHS issued the *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics* (the Guide) to support the thoughtful, deliberative, and measured discontinuation of long-term opioid analgesics, and mitigate harm and risk to patients who are working with their clinicians to undergo appropriate tapering or discontinuation.[12] The Guide notes that decisions to continue or reduce opioid medications for pain should be collaborative and based on the individual patient's goals and circumstances and clinicians should consider, for example, whether opioid medications continue to support patients meeting treatment goals; if opioids are exposing the person to an increased risk for serious adverse events or an opioid use disorder; and whether benefits continue to outweigh risks of opioids. Whether or not opioids are used in treatment, safe and effective non-opioid treatments can be integrated into patients' pain management plans based on an individualized assessment of benefits and risks, and considering the patient's diagnosis, goals and circumstances.[13] Unique needs and coordination across the health care team is critical and clinicians and care teams have a responsibility to provide, or arrange for, coordinated management of patients' pain including any medication-related issues. The system of care should not ultimately result in patient abandonment. The FDA issued a safety announcement in 2019, advising—including through required updates to opioid analgesic prescribing information—that health care professionals should not abruptly discontinue opioids in patients who are physically dependent and that patient-specific plans should be created to gradually taper off opioids, in part due to the risk of adverse events including abrupt withdrawal symptoms, increased pain, mood changes, mental health impact, psychosocial impact, and importantly, suicide risk.[14]

In 2020 the National Academy of Medicine, as part of its ''Action Collaborative to Countering the U.S. Opioid Epidemic,'' began an effort to understand more about the state of chronic pain management, and to bring greater awareness to any intended and unintended consequences of opioid prescribing metrics as they pertain to the delivery, access, and coordination of chronic pain management and care. CMS is one of the sponsors of this work. The aim of this project is to visually illustrate the chronic pain management journey and accelerate the uptake of a range of pain treatments by outlining approaches to effective communication that leads to strong clinical relationships and optimal quality of life for people with pain.[15]

The SUPPORT Act (Pub. L. 115–271, October 24, 2018) outlines national strategies to help address America's opioid and substance use disorders (SUD) crisis, and advances policies to improve the treatment of pain and SUD. The SUPPORT Act recognizes the importance of opioid-related medication management, as well as the overall need to identify SUD in the Medicare beneficiary population. Sections 2002 and 6086 of the SUPPORT Act are of particular importance regarding pain management. For beneficiaries with chronic pain, section 2002 of the

[10] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[11] *https://www.samhsa.gov/data/report/preliminary-dawn-data-review.*

[12] *https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.*

[13] *https://www.cdc.gov/drugoverdose/pdf/assessing_benefits_harms_of_opioid_therapy-a.pdf.*

[14] *https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.*

[15] *https://nam.edu/event/living-with-chronic-pain-perspectives-from-persons-with-lived-experience/.*

SUPPORT Act amended sections 1861(ww) and (hhh)(2) of the Act to include a review of any current opioid prescriptions in conjunction with the initial preventive physical examination (the ''Welcome to Medicare'' visit) and annual wellness visit (AWV). The opioid prescription review is to include a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individual's pain severity and current treatment plan, the provision of information on non-opioid treatment options, and referral to a specialist, if appropriate. Section 2002 also amended sections 1861(ww) and (hhh)(2) of the Act to add a screening for potential SUDs to the Welcome to Medicare visit and the AWV, and to add referral to a specialist, as appropriate, to the AWV.

Section 6086 of the SUPPORT Act, the *Dr. Todd Graham Pain Management Study,* will provide HHS and CMS with key information about services delivered to Medicare beneficiaries with acute or chronic pain, help in understanding the current landscape of pain relief options for Medicare beneficiaries, and inform decisions around payment and coverage for pain management interventions, including those that minimize the risk of SUD. CMS has worked with the Agency for Healthcare Research and Quality, which has undertaken three topic briefs and two systematic reviews to inform Medicare coverage for the treatment of acute and chronic pain. CMS has also worked with HHS' Office of the Secretary for Planning and Evaluation to write a Report on the Study, which will be submitted to Congress. CMS will post a completed copy of the Report on our website. The Report will address questions regarding coverage and payment for evidence-based interventions for acute and chronic pain in Medicare, barriers to access, costs and benefits of expanding or revising benefits not currently covered, and legislative and administrative options to improve pain interventions.

We believe it is important to highlight the role of a person-centered approach to pain care. The National Quality Forum, which as its core work defines measures and health care practices as the best, evidence-based approaches to improving care, has defined person-centered planning as ''a facilitated, individual-directed, positive approach to the planning and coordination of a person's services and supports based on individual aspirations, needs, preferences, and values,'' and stated that the ''goal of person-centered planning is to create a plan that will optimize the person's self-defined quality of life, choice, and control, and self-determination through meaningful exploration and discovery of unique preferences and needs and wants in areas including, but not limited to, health and well-being, relationships, safety, communication, residence, technology, community, resources, and assistance.'' [16] These general principles should also apply in the treatment of individuals with pain, where clinicians confirm and affirm the individual's recovery and/or maintenance goals, and focus on those, where treatment is a means to an end.[17] For example, one goal might be to not rely on aiming to reduce a simple pain score, such as a numeric or visual score, but to evaluate function for example, through a tool such as the Defense and Veterans Pain Rating scale,[18] which integrates functional status, and then aim to optimize physical function and mental function in the beneficiary with chronic pain.

We recognize that there are no existing codes that specifically describe the work of the clinician involved in performing the tasks necessary to perform pain management care. We believe there are complexities in treating pain management patients that could include lifestyle discussion, ongoing medication management (such as opioid tapering or discontinuation, when appropriate), behavioral health care, preparation and updating of a care plan, consideration of Federal and other opioid prescribing limits and guidelines, Prescription Drug Monitoring Program checks, electronic prescribing requirements, special licensing requirements (controlled substance licenses; buprenorphine ''X-waivers''), interdisciplinary interactions, prescription drug coverage, CMS high-prescriber oversight, consideration of out-of-pocket costs, and other issues. As one example, decreasing or discontinuing opioid treatment requires careful, person-centered consideration of all of these aspects of providing care. These unique challenges often adversely impact the delivery of care, and subsequent access to care, for beneficiaries with chronic pain. Current Medicare payment methodologies such as Chronic Care Management (CCM) support chronic disease management, though may not provide adequate payment to health care providers or systems to holistically care for beneficiaries with chronic pain; we believe the complexity and resources required for safe and effective pain management may not be adequately captured and paid through these codes.

We believe that creating separate or add-on payment for care and management for people with pain might provide opportunities to better leverage services furnished using telecommunications technology and non face-to-face care while expanding access to treatment for pain. Such an additional payment could potentially be effective in preventing or reducing the need for acute services such as fall avoidance, and reduce the need for treatment for mental disorders such as depression, anxiety, and sleep disorders which may occur in some individuals with pain. There is also reason to believe that addressing chronic pain (for example, pain that lasts more than 3 months) early in its course may result in averting the development of ''high-impact'' chronic pain in some individuals, where they experience at least one major activity restriction (for example, unable to work, go to school, perform household chores). These individuals report more severe pain, more difficulty with self-care, and higher health care use than others with chronic pain. From a social determinants of health perspective, Blacks, Native Americans, persons of Asian/Indian descent, older adults, and people with less education, and single individuals report more high impact chronic pain.[19]

In 2019, 12.2 million individuals were enrolled in both Medicaid and Medicare, including people age 65 and older and younger beneficiaries with disabilities. Many have multiple chronic conditions, physical disabilities, behavioral health conditions, and cognitive impairments and on average, use more services and supports than those enrolled in only Medicaid or Medicare, with higher per capita costs. Dually eligible beneficiaries often have multiple social risk factors such as housing insecurity and homelessness, food insecurity, inadequate access to transportation, and low health literacy. A 2019 study [20] on dually eligible beneficiaries using ''high dose'' opioids to treat pain between 2006 through 2015 indicated that the common conditions in beneficiaries studied were chronic pain, migraine, rheumatoid arthritis,

[16] *https://www.qualityforum.org/Home.aspx.*

[17] *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=89422.*

[18] *https://www.va.gov/painmanagement/resources.asp.*

[19] *https://www.nccih.nih.gov/research/research-results/prevalence-and-profile-of-high-impact-chronic-pain.*

[20] *https://www.macpac.gov/wp-content/uploads/2020/06/Chapter-1-Integrating-Care-for-Dually-Eligible-Beneficiaries-Background-and-Context.pdf.*

osteoporosis, HIV/AIDS, viral hepatitis, and SUD.[21]

We solicited comment on whether we should consider creating separate coding and payment for medically necessary activities involved with chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment. These activities could include, but are not limited to the following:

- Diagnosis;
- Assessment and monitoring;
- Administration of a validated rating scale(s);
- Development and maintenance of a person-centered care plan;
- Overall treatment management;
- Facilitation and coordination of any needed behavioral health treatment;
- Medication management;
- Patient education and self-management;
- Crisis care;
- Specialty care coordination such as complementary and integrative pain care, and SUD care; and
- Other aspects of pain and/or behavioral health services, including care rendered through telehealth modalities.

We indicated in the proposed rule that we are interested in feedback regarding whether the resource costs involved in furnishing these activities will be best captured through an add-on code to be billed with an E/M visit or a standalone code. To price such a code, we could consider using a crosswalk to the valuation and inputs for reference codes such as CPT code 99483 (*Assessment of and care planning for a patient with cognitive impairment*), HCPCS code G2064 (*Comprehensive care management services for a single high-risk disease, e.g., principal care management, at least 30 minutes of physician or other qualified health care professional time per calendar month*), HCPCS code G0108 (*Diabetes outpatient self-management training services, individual, per 30 minutes*), or other services paid under the PFS with similar resource costs.

We also solicited information on the health care settings in which safe and effective pain management care is occurring, as well as what types of practitioners furnish these services. We solicited comments on whether the specific activities we identify above are appropriate, and whether there are other activities that should be included. We are interested in stakeholder feedback regarding how we could define and value separate coding or an E/M add-on code. We solicited comments on whether any components of the service could be provided ''incident to'' the services of the billing physician who is managing the beneficiary's overall care similar to the structure of the Behavioral Health Integration (BHI) codes, which can include BHI services that are not delivered personally by the billing practitioner and delivered by other members of the care team (except the beneficiary), under the direction of the billing practitioner on an incident to basis (as an integral part of services delivered by the billing practitioner), subject to applicable State law, licensure, and scope of practice. The other care team members are either employees or working under contract to the practitioner who bills for BHI services.

We welcome feedback from stakeholders and the public on potential separate coding or an E/M add-on code for chronic pain management for our consideration for CY 2022 or for future rulemaking

We received over 1,900 public comments on potential separate coding for chronic pain management. The following is a brief summary of the comments we received and our responses.

Comment: Generally, commenters agreed that efforts are needed to effectively support the complex needs of beneficiaries with chronic pain. Many commenters supported the creation of separate coding and payment for chronic pain management under the PFS. One commenter suggested that CMS either clarify or modify existing codes so they can support services for patients with chronic pain or significant acute pain, as well as beneficiaries with a chronic disease or behavioral health condition, stating that using the existing codes would avoid any concerns about overpayment for patients with both a chronic disease and pain, while also making it more feasible for small practices to employ care management staff and provide customized care management services for all the patients who need them. Some commenters recommended creating stand-alone codes rather than E/M add-on codes and several commenters included feedback about what specific activities should be included in such codes. One commenter recommended that ''CMS establish a multi-stakeholder working group to determine operational details and resource allocation'' and requested that CMS ''establish a pilot program using innovative payment methodologies.''

Response: We thank the commenters for all of the information submitted in recognizing the needs of beneficiaries with pain. We will carefully consider this feedback for future rulemaking.

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[21] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/Downloads/OpioidsDataBrief_2006-2015_10242018.pdf.*

TABLE 20: CY 2022 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
00537	Anesthesia for cardiac electrophysiologic procedures including radiofrequency ablation	7.00	12.00	10.00	No
01937	Anesthesia for percutaneous image guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic	NEW	4.00	4.00	No
01938	Anesthesia for percutaneous image guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral	NEW	4.00	4.00	No
01939	Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic	NEW	4.00	4.00	No
01940	Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral	NEW	4.00	4.00	No
01941	Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures (eg. kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic	NEW	6.00	5.00	No
01942	Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures (eg. kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral	NEW	6.00	5.00	No
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more	NEW	C	C	No
21315	Closed treatment of nasal bone fracture with manipulation; without stabilization	1.83	2.00	0.96	No
21320	Closed treatment of nasal bone fracture with manipulation; with stabilization	1.88	2.33	1.59	No
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	13.50	15.00	15.00	No
28001	Incision and drainage, bursa, foot	2.78	2.00	2.00	No
28002	Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space	5.34	3.50	2.79	No
28003	Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas	9.06	5.28	5.28	No
33897	Percutaneous transluminal angioplasty of native or recurrent coarctation of the aorta	NEW	14.00	10.81	No
33894	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches	NEW	21.70	18.27	No
33895	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; not crossing major side branches	NEW	17.97	14.54	No
33267	Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	NEW	18.50	18.50	No
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	NEW	2.50	2.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
33269	Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	NEW	14.31	14.31	No
33370	Transcatheter placement and subsequent removal of / cerebral embolic protection device(s), including arterial / access, catheterization, imaging, and radiological / supervision and interpretation, percutaneous	NEW	2.50	2.50	No
35600	Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, open	NEW	4.00	3.59	No
33509	Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic	NEW	3.75	3.34	No
38505	Biopsy or excision of lymph node(s); by needle, superficial (eg, cervical, inguinal, axillary)	1.14	1.59	1.59	No
42975	Drug induced sleep endoscopy; with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing; flexible, diagnostic	NEW	1.90	1.90	No
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])	NEW	15.50	13.29	No
46020	Placement of seton	3.00	3.50	1.86	No
46030	Removal of anal seton, other marker	1.26	2.00	1.48	No
53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance	NEW	C	C	No
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance	NEW	C	C	No
53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon	NEW	C	C	No
53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	NEW	C	C	No
61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion	NEW	20.00	19.06	No
61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)	NEW	24.00	22.67	No
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment	NEW	4.44	3.19	No
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment	NEW	5.55	4.25	No
64582	Open implantation of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	NEW	16.00	14.00	No
64583	Revision or replacement of hypoglossal nerve neruostimulator array and distal respiratory sensor electrode or electrode array, including connection to an existing pulse generator	NEW	16.50	14.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
64584	Removal of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	NEW	14.00	12.00	No
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint	3.84	3.42	3.31	No
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint	1.32	1.32	1.32	No
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint	3.78	3.42	3.32	No
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint	1.16	1.16	1.16	No
64628	Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; first two vertebral bodies, lumbar or sacral	NEW	8.25	7.15	No
64629	Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; each additional vertebral body, lumbar or sacral	NEW	4.87	3.77	No
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent	12.85	8.53	7.62	No
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent	13.60	10.25	9.34	No
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation	10.25	10.25	10.25	No
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation	7.35	7.35	7.35	No
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	C	13.15	C	Yes
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	C	10.25	C	Yes
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or	NEW	12.13	10.31	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more				
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	NEW	9.23	7.41	No
67141	Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage; cryotherapy, diathermy	6.15	2.53	2.53	No
67145	Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage; photocoagulation	6.32	2.53	2.53	No
67311	Strabismus surgery, recession or resection procedure; 1 horizontal muscle	7.77	5.93	5.93	No
67312	Strabismus surgery, recession or resection procedure; 2 horizontal muscles	9.66	9.50	9.50	No
67314	Strabismus surgery, recession or resection procedure; 1 vertical muscle (excluding superior oblique)	8.79	5.93	5.93	No
67316	Strabismus surgery, recession or resection procedure; 2 or more vertical muscles (excluding superior oblique)	10.93	10.31	10.31	No
67318	Strabismus surgery, any procedure, superior oblique muscle	9.12	9.80	9.80	No
67320	Transposition procedure (eg, for paretic extraocular muscle), any extraocular muscle (specify)	5.40	3.00	3.00	No
67331	Strabismus surgery on patient with previous eye surgery or injury that did not involve the extraocular muscles	5.13	2.00	2.00	No
67332	Strabismus surgery on patient with scarring of extraocular muscles (eg, prior ocular injury, strabismus or retinal detachment surgery) or restrictive myopathy (eg, dysthyroid ophthalmopathy)	5.56	3.50	3.50	No
67334	Strabismus surgery by posterior fixation suture technique, with or without muscle recession	5.05	2.06	2.06	No
67335	Placement of adjustable suture(s) during strabismus surgery, including postoperative adjustment(s) of suture(s)	2.49	3.23	3.23	No
67340	Strabismus surgery involving exploration and/or repair of detached extraocular muscle(s)	6.00	5.00	5.00	No
68841	Insertion of drug-eluting implant, including punctal dilation, when performed, into lacrimal canaliculus, each	NEW	0.49	0.49	No
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor	14.45	8.69	8.69	No
69717	Revision/replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor	15.43	8.80	8.80	No
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	NEW	9.77	9.77	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
69719	Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	NEW	9.77	9.77	No
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor	NEW	5.93	5.93	No
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	NEW	7.13	7.13	No
74301	Cholangiography and/or pancreatography; additional set intraoperative, radiological supervision and interpretation	0.21	0.21	0.21	No
77089	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual x-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk	NEW	0.20	0.20	No
77090	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere	NEW	0.00	0.00	No
77091	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only	NEW	0.00	0.00	No
77092	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture risk only, by other qualified healthcare professional	NEW	0.20	0.20	No
80503	Pathology clinical consultation; for a clinical problem with limited review of patient's history and medical records and straightforward medical decision making. When using time for code selection, 5-20 minutes of total time is spent on the date of the consultation.	NEW	0.50	0.43	No
80504	Pathology clinical consultation; for a moderately complex clinical problem, with review of patient's history and medical records and moderate level of medical decision making. When using time for code selection, 21-40 minutes of total time is spent on the date of the consultation.	NEW	0.91	0.91	No
80505	Pathology clinical consultation; for a highly complex clinical problem, with comprehensive review of patient's history and medical records and high level of medical decision making. When using time for code selection, 41-60 minutes of total time is spent on the date of the consultation.	NEW	1.80	1.71	No
80506	Pathology clinical consultation; prolonged service, each additional 30 minutes	NEW	0.80	0.80	No
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report	2.49	2.24	2.24	No
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report	1.00	1.00	0.90	No
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report	NEW	2.41	2.41	No
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ecg data storage (retrievable with query) with ecg triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional	0.52	0.52	0.48	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional	0.00	0.00	0.00	No
93319	3D echocardiographic imaging and postprocessing during transesophageal echocardiography or transthoracic echocardiography for congenital cardiac anomalies for the assessment of cardiac structure(s) (eg, cardiac chambers and valves, left atrial appendage, intraterial septum, interventricular septum) and function, when performed	NEW	0.50	0.50	No
93621	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium	2.10	1.75	1.50	No
93653	Comprehensive electrophysiologic evaluation including with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	14.75	18.49	14.75	Yes
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed	19.75	19.75	19.75	No
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia	7.50	6.50	5.50	No
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including	19.77	20.00	19.77	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and his bundle recording, when performed				
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation	7.50	6.50	5.50	No
93593	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections	NEW	3.99	3.99	No
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections	NEW	6.10	6.10	No
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections	NEW	6.00	5.50	No
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections	NEW	7.91	6.84	No
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal connections	NEW	9.99	8.88	No
93598	Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects	NEW	1.75	1.44	No
94625	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)	NEW	0.55	0.36	No
94626	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)	NEW	0.69	0.56	No
98975	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment	NEW	0.00	0.00	No
98976	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days	NEW	0.00	0.00	No
98977	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days	NEW	0.00	0.00	No
98980	Remote therapeutic monitoring treatment, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication	NEW	0.62	0.62	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	with the patient/caregiver during the calendar month; first 20 minutes				
98981	Remote therapeutic monitoring treatment, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes	NEW	0.61	0.61	No
99439	Chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; • comprehensive care plan established, implemented, revised, or monitored.: each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	0.54	0.70	0.70	No
99487	Complex chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, • comprehensive care plan established, implemented, revised, or monitored, • moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	1.00	1.81	1.81	No
99489	Complex chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, • comprehensive care plan established, implemented, revised, or monitored, • moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	0.50	1.00	1.00	No
99490	Chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; • comprehensive care plan established, implemented, revised, or monitored.: first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	0.61	1.00	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
99491	Chronic care management services with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;, • comprehensive care plan established, implemented, revised, or monitored.; first 30 minutes, provided personally by a physician or other qualified health care professional, per calendar month.	1.45	1.50	1.50	No
99437	Chronic care management services with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;, • comprehensive care plan established, implemented, revised, or monitored.; each additional 30 minutes by a physician or other qualified health care professional, per calendar month	NEW	1.00	1.00	No
99424	Principal care management services, for a single high-risk disease, with the following required elements: • one complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan, • the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities • ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month	NEW	1.45	1.45	No
99425	Principal care management services, for a single high-risk disease, with the following required elements: • one complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan, • the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities • ongoing communication and care coordination between relevant practitioners furnishing care; additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month	NEW	1.00	1.00	No
99426	Principal care management services, for a single high-risk disease, with the following required elements; • one complex chronic condition expected to last at least	NEW	1.00	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan, • the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities, • ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month.				
99427	Principal care management services, for a single high-risk disease, with the following required elements; • one complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan, • the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities, • ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	NEW	0.71	0.71	No
GXXAB	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area	NEW	-	C	No
GXXAC	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; each additional 25 sq cm wound surface area, or part thereof	NEW	-	C	No
GXXAD	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children	NEW	-	C	No
GXXAE	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	NEW	-	C	No
GXXAF	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area	NEW	-	C	No
GXXAG	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin	NEW	-	C	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	substitute; each additional 25 sq cm wound surface area, or part thereof				
GXXAH	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children	NEW	-	C	No
GXXAI	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	NEW	-	C	No

TABLE 21: CY 2022 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
46020	Placement of seton	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
46020	Placement of seton	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.67
46020	Placement of seton	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
46020	Placement of seton	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-5.90
46020	Placement of seton	L037D	RN/LPN/MTA	F	Coordinate post-procedure services	3	0	G1: See preamble text	-1.77
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services (including test results)	3	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Complete preservice diagnostic and referral forms	5	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.95
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Provide preservice education/obtain consent	7	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.13

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	5	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.18
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Coordinate post-procedure services	3	0	G1: See preamble text	-1.77
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	10	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.13
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	5	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.18
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Complete pre-procedure phone calls and prescription	3	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
61736	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.67
61736	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
61736	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	20	10	L8: Standard preservice clinical labor time for	-5.90

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					(including test results)			procedures with 0/10 day global periods	
61736	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
61737	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
61737	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
61737	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.67
61737	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-5.90
68841	Insj rx elut implt lac canal	EL006	lane, screening (oph)	NF		9	5	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.55
69714	Impltj oi implt skl perq esp	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	108	99	L9: Refined clinical labor to align with number of post-operative visits	-5.31
69717	Revj/rplcmt oi implt prq esp	L037D	RN/LPN/MTA	F	Post-operative	108	99	L9: Refined clinical labor to align with number of post-operative visits	-5.31

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					visits (total time)				
80503	Path clin consltj sf 5-20	EP024	microscope, compound	NF		15	0	G1: See preamble text	-0.47
80503	Path clin consltj sf 5-20	L035A	Lab Tech/Histotechnologist	NF	Accession and enter information	4	0	L2: Clinical labor task redundant with clinical labor task PA008	-2.48
80504	Path clin consltj mod 21-40	EP024	microscope, compound	NF		30	0	G1: See preamble text	-0.95
80504	Path clin consltj mod 21-40	L035A	Lab Tech/Histotechnologist	NF	Accession and enter information	4	0	L2: Clinical labor task redundant with clinical labor task PA008	-2.48
80505	Path clin consltj high 41-60	EP024	microscope, compound	NF		54	0	G1: See preamble text	-1.70
80505	Path clin consltj high 41-60	L035A	Lab Tech/Histotechnologist	NF	Accession and enter information	4	0	L2: Clinical labor task redundant with clinical labor task PA008	-2.48
80506	Path clin consltj prolng svc	EP024	microscope, compound	NF		30	0	G1: See preamble text	-0.95
91111	Esophageal capsule endoscopy	L037D	RN/LPN/MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	9	6	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-1.77
93228	Remote 30 day ecg rev/report	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	10	5	G1: See preamble text	
93229	Remote 30 day ecg tech supp	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	24	24	G1: See preamble text	
94625	Phy/qhp op pulm rhb w/o mntr	L042B	Respiratory Therapist	NF	Provide education/obtain consent	15	2	L1: Refined time to standard for this clinical labor task	-9.10

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
94626	Phy/qhp op pulm rhb w/mntr	L042B	Respiratory Therapist	NF	Provide education/obtain consent	15	2	L1: Refined time to standard for this clinical labor task	-9.10

TABLE 22: CY 2022 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
69714	Impltj oi implt skl perq esp	EF008	chair with headrest, exam, reclining	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.12
69714	Impltj oi implt skl perq esp	EQ170	light, fiberoptic headlight w-source	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
69714	Impltj oi implt skl perq esp	EQ183	microscope, operating	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.25
69714	Impltj oi implt skl perq esp	EQ234	suction and pressure cabinet, ENT (SMR)	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
69717	Revj/rplcmt oi implt prq esp	EF008	chair with headrest, exam, reclining	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.12
69717	Revj/rplcmt oi implt prq esp	EQ170	light, fiberoptic headlight w-source	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
69717	Revj/rplcmt oi implt prq esp	EQ183	microscope, operating	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.25
69717	Revj/rplcmt oi implt prq esp	EQ234	suction and pressure cabinet, ENT (SMR)	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
91111	Esophageal capsule endoscopy	EF023	table, exam	NF		44	41	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
91111	Esophageal capsule endoscopy	EQ146	kit, capsule endoscopy recorder	NF		64	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
94625	Phy/qhp op pulm rhb w/o mntr	EQ118	exercise equipment (treadmill, bike, stepper, UBE, pulleys, balance board)	NF		93	80	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
94626	Phy/qhp op pulm rhb w/mntr	EQ118	exercise equipment (treadmill, bike,	NF		93	80	E15: Refined equipment time to conform to changes in clinical labor time	-0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			stepper, UBE, pulleys, balance board)						
94626	Phy/qhp op pulm rhb w/mntr	EQ211	pulse oximeter w-printer	NF		93	80	E15: Refined equipment time to conform to changes in clinical labor time	-0.09

TABLE 23: CY 2022 Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
88341, 88342, 88344	E-Bar Printer Ribbon (Ventana 1632900) (prints 8100 labels)	SL476	$117.40	$141.67	21%	3	1,772,367
88341, 88342, 88344, 88360, 88361	Reaction buffer 10X (Ventana 950-300)	SL478	$0.030	$0.037	23%	3	2,020,210
88341, 88342, 88344, 88360, 88361	Liquid coverslip (Ventana 650-010)	SL479	$0.030	$0.051	70%	3	2,020,210
88341, 88342, 88344, 88360, 88361	SSC (10X) (Ventana 950-110)	SL480	$0.010	$0.051	405%	3	2,020,210
88341, 88342, 88344, 88360, 88361	EZ Prep (10X) (Ventana 950-102)	SL481	$0.034	$0.034	-1%	3	2,020,210
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	$16.12	$18.01	12%	3	247,843
91110, 91111	kit, capsule endoscopy recorder	EQ146	$21,285.44	$17,701.58	-17%	5	24,027
91110, 91111	video system, capsule endoscopy (software, computer, monitor, printer)	ES029	$9,425.40	$10,181.55	8%	1	24,027

TABLE 24: CY 2022 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
0001A, 0002A, 0011A, 0012A, 0021A, 0022A, 0031A	refrigerator, vaccine medical grade, w-data logger sngl glass door	EF049	7,674.43	2	-
0001A, 0002A	freezer, under counter, ultra cold 3.7 cu ft	EF050	16,516.36	1	-
91113	PillCam COLON capsule	SD346	625.00	4	0
93229	MCT Electrode Patch Kit	SD345	4.85	1	251,398
93319	3D Echocardiography Probe	ER121	31,754.30	1	1
98977	Remote musculoskeletal therapy system	EQ402	1,000.00	1	TBD
No codes	PillCam sensor sleeves	SD347	5.00	5	0

TABLE 25: CY 2022 No PE Refinements

HCPCS	Description
00537	Anesth cardiac electrophys
01937	Anes drg/aspir crv/thrc
01938	Anes drg/aspir lmbr/sac
01939	Anes nulyt agt crv/thrc
01940	Anes nulyt agt lmbr/sac
01941	Anes neuromd/ntrvrt crv/thrc
01942	Anes neuromd/ntrvrt lmbr/sac
21315	Clsd tx nsl fx mnpj wo stblj
21320	Clsd tx nsl fx w/mnpj&stablj
22867	Insj stablj dev w/dcmprn
28001	Drainage of bursa of foot
28002	Treatment of foot infection
28003	Treatment of foot infection
33267	Open excl laa any method
33269	Thrscp excl laa any method
38505	Needle biopsy lymph nodes
42975	Dise eval slp do brth flx dx
43497	Transorl lwr esophgl myotomy
64582	Opn mpltj hpglsl nstm ary pg
64583	Rev/rplct hpglsl nstm ary pg
64584	Rmvl hypglsl nstim ary pg
64633	Destroy cerv/thor facet jnt
64634	Destroy c/th facet jnt addl
64635	Destroy lumb/sac facet jnt
64636	Destroy l/s facet jnt addl
64628	Trml dstrj ios bvn 1st 2 l/s
66174	Translum dil eye canal
66175	Trnslum dil eye canal w/stnt
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
66987	Xcapsl ctrc rmvl cplx w/ecp
66988	Xcapsl ctrc rmvl w/ecp
66989	Xcpsl ctrc rmvl cplx insj 1+
66991	Xcapsl ctrc rmvl insj 1+
67141	Proph rta dtchmnt crtx dthrm
67145	Proph rta dtchmnt pc
67311	Revise eye muscle
67312	Revise two eye muscles
67314	Revise eye muscle
67316	Revise two eye muscles
67318	Revise eye muscle(s)
69716	Impltj oi implt skl tc esp
69719	Revj/rplcmt oi implt tc esp
69726	Rmvl oi implt skl perq esp
69727	Rmvl oi implt skl tc esp
77089	Tbs dxa cal w/i&r fx risk
77090	Tbs techl prep&transmis data
77091	Tbs techl calculation only
77092	Tbs i&r fx rsk qhp
91110	Gi tract capsule endoscopy
91113	Gi trc img intral colon
93319	3d echo img cgen hrt anomal
98975	Rem ther mntr 1st setup&edu
98976	Rem ther mntr dev sply resp
98977	Rem ther mntr dv sply mscskl
98980	Rem ther mntr 1st 20 min
98981	Rem ther mntr ea addl 20 min
99439	Chrnc care mgmt staf ea addl
99487	Cplx chrnc care 1st 60 min
99489	Cplx chrnc care ea addl 30
99490	Chrnc care mgmt staff 1st 20
99491	Chrnc care mgmt phys 1st 30
99437	Chrnc care mgmt phys ea addl
99424	Prin care mgmt phys 1st 30
99425	Prin care mgmt phys ea addl
99426	Prin care mgmt staff 1st 30
99427	Prin care mgmt staff ea addl

BILLING CODE 4120–01–C

F. Evaluation and Management (E/M) Visits

Over the past several years, CMS has engaged with the AMA and other stakeholders in a process to update coding and payment for office/outpatient evaluation and management (E/M) visits, with recent changes taking effect January 1, 2021 (see 85 FR 84548 through 84574). In light of these changes, we are engaged in an ongoing review of other E/M visit code sets and proposed a number of refinements to our current policies. The following section discusses several policies we proposed regarding split (or shared) visits, critical care services, and teaching physician visits.

1. Split (or Shared) Visits

a. Background

A split (or shared) visit refers to an E/M visit that is performed (''split'' or ''shared'') by both a physician and an NPP who are in the same group. Because the Medicare statute provides a higher PFS payment rate for services furnished by physicians than services furnished by NPPs, we need to address whether and when the physician can bill for split (or shared) visits. For visits in the non-facility (for example, office) setting for which the physician and NPP each perform portions of the visit, the physician can bill for the visit rather than the NPP, as long as the visit meets the conditions of payment in our regulations at § 410.26(b)(1) for services furnished ''incident to'' a physician's professional services. However, for visits furnished under similar circumstances in facility settings (for example, in a hospital), our current regulations provide for payment only to the physician or NPP who personally performs all elements of the service, and no payment is made for services furnished ''incident to'' the billing professional's services.

As stated in our regulation at § 410.26(b)(1), Medicare Part B pays for services and supplies furnished ''incident to'' a physician's (or other practitioner's) professional services if those services and supplies are furnished in a noninstitutional setting to noninstitutional patients. In certain institutional (or ''facility'') settings, our longstanding split (or shared) billing

policy allows a physician to bill for an E/M visit when both the billing physician and an NPP in their group each perform portions of the visit, but only if the physician performs a substantive portion of the visit. When the physician bills for such a split (or shared) visit, in accordance with section 1833(a)(1)(N) of the Act, the Medicare Part B payment is equal to 80 percent of the payment basis under the PFS, which, under section 1848(a)(1) of the Act, is the lesser of the actual charge or the fee schedule amount for the service. In contrast, if the physician does not perform a substantive portion of such a split (or shared) visit and the NPP bills for it, in accordance with section 1833(a)(1)(O) of the Act, the Medicare Part B payment is equal to 80 percent of the lesser of the actual charge or 85 percent of the fee schedule rate.

Previously, our policy for billing these split (or shared) visits was reflected in several provisions of our Medicare Claims Policy Manual (sections 30.6.1(B), 30.6.12, and 30.6.13(H)) which were withdrawn effective May 9, 2021, in response to a petition under the Department's Good Guidance regulations at 45 CFR 1.5 (see Transmittal 10742 available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10742cp*). In the absence of these manual provisions, the Medicare statute and various broadly applicable regulations continue to apply. In addition to withdrawing the manual provisions, we issued our response to the petition and an accompanying enforcement instruction on May 26, 2021, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/Evaluation-and-Management-Visits*). In those documents, we indicated that we intend to address split (or shared) visits and critical care services (addressed below) through rulemaking; and that until we do, we will limit review to the applicable statutory and regulatory requirements for purposes of assessing payment compliance.

The list of applicable statutory and regulatory requirements includes the CY 2021 PFS final rule (85 FR 84549), where CMS generally adopted new CPT prefatory language and code descriptors for office/outpatient E/M visits. The new CPT guidelines for E/M services introduced a CPT definition of a split (or shared) visit for the first time, effective January 1, 2021. This new CPT definition was part of CPT's new guidelines indicating how to select the visit level based on time, which can be done for all office/outpatient E/M visits starting in 2021. The CPT guidelines that we are referring to are published in the CPT Codebook, in a section titled ''Evaluation and Management Services (E/M) Guidelines.'' [22] In this section of our final rule, we use the term ''CPT E/M Guidelines'' to refer to this material.

In the CY 2021 PFS final rule (85 FR 84549), we stated that we are generally adopting the CPT E/M Guidelines for the new office/outpatient E/M visit codes. However, the CPT E/M Guidelines do not address many issues that arise in the context of PFS payment for split (or shared) visits, such as which practitioner should report the visit when elements of the visit are performed by different practitioners; whether a substantive portion of the visit must be performed by the billing practitioner; whether practitioners must be in the same group to bill for a split (or shared) visit; or the settings of care where split (or shared) visits may be furnished and billed. The CPT E/M Guidelines simply state, ''A split or shared visit is defined as a visit in which a physician and other qualified health care professional(s) jointly provide the face-to-face and non-face-to-face work related to the visit. When time is being used to select the appropriate level of services for which time-based reporting of shared or split visits is allowed, the time personally spent by the physicians and other qualified health care professional(s) assessing and managing the patient on the date of the encounter is summed to define total time. Only distinct time should be summed for split or shared visits (that is, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).'' [23]

In contrast, to ensure appropriate PFS payment, our policy for split (or shared) visits, as expressed in the recently withdrawn manual provisions, is that the physician may bill for a split (or shared) visit only if they perform a substantive portion of the visit, and the practitioners must be in the same group and furnishing the visit in specified settings in order to bill for a split (or shared) visit. Our manual also limited billing for split (or shared) visits to services furnished to established patients. In our proposed rule, we made a number of proposals to address the recently withdrawn manual sections and improve transparency and clarity regarding our policies on billing for split (or shared) visits, to update them to account for recent revisions to E/M visit coding and payment, and to revise our regulations to reflect these policies.

We received many public comments on our proposals for split (or shared) visits. In general, the commenters appreciated the need to clarify and refine our policies, although some were worried about increased administrative burden, disruption to current practice patterns, or perceived disadvantages to physicians or NPPs. There was no consensus on what the substantive portion of a split (or shared) visit should be, although many commenters recommended we find a way to recognize medical decision-making (MDM) as the substantive portion. The following is a summary of the comments we received and our responses.

b. Definition of Split (or Shared) Visits

We proposed to define a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group, in accordance with applicable laws and regulations. We proposed to add this definition to a new section of our regulations at 42 CFR 415.140.

Additionally, we proposed to define split (or shared) visits as those that:

- Are furnished in a facility setting by a physician and an NPP in the same group, where the facility setting is defined as an institutional setting in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under our regulation at § 410.26(b)(1).
- Are furnished in accordance with applicable law and regulations, including conditions of coverage and payment, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting (rather than as a split (or shared) visit).

We proposed to revise our regulations at § 415.140 to codify this definition.

We believed that limiting the definition of split (or shared) visits to include only E/M visits in institutional settings, for which ''incident to'' payment is not available, would allow for improved clarity, and clearly distinguish, the policies applicable to split (or shared) visits, from the policies applicable to services furnished incident to the professional services of a physician. We did not see a need for split (or shared) visit billing in the office setting, because the ''incident to'' regulations govern situations where an NPP works with a physician who bills

[22] 2021 CPT Codebook, p.5.

[23] 2021 CPT Codebook, p.7.

for the visit, rather than billing under the NPP's own provider number.

We also proposed to modify our policy to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain Skilled Nursing Facility/Nursing Facility (SNF/NF) E/M visits. We proposed these modifications to the current policy and conditions of payment for split (or shared) visits, discussed below, to account for changes that have occurred in medical practice patterns, including the evolving role of NPPs as part of the medical team.

Comment: While most commenters were generally supportive of our definition and appreciative of clarifications to current policy, a few commenters recommended that we allow billing of split (or shared) visits in all settings, both institutional and non-institutional. Commenters noted that split (or shared) visit billing might be appropriate or necessary for new patient visits in the office setting, since payment for services furnished incident to the services of physicians and other clinicians is only available for established patients.

Response: We have been reviewing this aspect of our ''incident to'' policy, independent of its relationship to split (or shared) visit billing. Since we are considering addressing requirements for new and established patients in future rulemaking in a broader context, and this is the only situation raised by commenters where ''incident to'' payment would not be available in a non-institutional setting, we do not believe we should address it through split (or shared) visit policies. We will continue to consider this issue in the context of potential future rulemaking. We are finalizing our definition of split (or shared) visits as proposed, and codifying it in a new section of our regulations at § 415.140, as proposed.

c. Definition of Substantive Portion

(1) More Than Half of the Total Time

As stated earlier, we proposed that only the physician or NPP who performs the substantive portion of the split (or shared) visit would bill for the visit. We proposed to define ''substantive portion'' as more than half of the total time spent by the physician and NPP performing the split (or shared) visit. We noted that our withdrawn manual instructions contained a few definitions of ''substantive portion.'' For example, one section defined substantive portion as any face-to-face portion of the visit, while another section defined it as one of the three key components of an E/M visit— either the history of present illness (HPI), physical exam, and/or MDM. Given recent changes in the CPT E/M Guidelines, HPI and physical exam are no longer necessarily included in all E/M visits, because as noted above, for office/outpatient E/M visits, the visit level can now be selected based on either MDM or time, and history and exam are performed only as medically appropriate. Accordingly, defining ''substantive portion'' as one of these three key components is no longer a viable approach. Similarly, MDM is not easily attributed to a single physician or NPP when the work is shared, because MDM is not necessarily quantifiable and can depend on patient characteristics (for example, risk). We believed that time is a more precise factor than MDM to use as a basis for deciding which practitioner performs the substantive portion of the visit.

We also did not believe it would be appropriate to consider the performance of any portion of the visit—with or without direct patient contact—as a substantive portion. For instance, we did not believe it would be appropriate to consider a brief or minor interaction, with or without direct patient contact, such as where the physician merely ''pokes their head'' into the room, to be a substantive portion of the visit. Therefore, we proposed to define ''substantive portion'' as more than half of the total time spent by the physician and NPP performing the split (or shared) visit. We proposed to revise our regulation at § 415.140 to codify this definition.

We recognized that the billing practitioner, who would be the practitioner providing the substantive portion of the visit, could select the level for the split (or shared) visit based on MDM, but we nonetheless proposed to base the definition of substantive portion on the amount of time spent by the physician and NPP providing the visit. We recognized that this policy would necessitate the practitioners' tracking and documenting the time they spent for these visits. However, we believed that practitioners are likely to increasingly time their visits for purposes of visit level selection independent of our split (or shared) visit policies, given recent changes to the CPT E/M Guidelines, and the fact that critical care visits are already timed. Accordingly, we did not believe this would comprise a substantial new burden.

Comment: The commenters agreed that the individual who performs the substantive portion should bill for the visit. Approximately half of the commenters supported our proposal, noting that it was appropriate and would provide a clear rule. However, approximately half of the public comments recommended alternative definitions of substantive portion, including:

- A lower percentage of time (25 to 30 percent of the total time) (several comments).
- MDM (several comments).
- Some portion of MDM, such as a majority or critical element of MDM, more than half of the time or the portion of the visit in which the MDM is performed, or physician involvement in the MDM (several comments).
- Choice of MDM or time, for example, based on whichever is used to select visit level (several comments).
- One of the three key components of history, exam, or MDM, at least until the AMA completes changes for E/M visit coding and the CPT E/M Guidelines that the commenters expect for 2023 (several comments).
- Some combination of the above, for example, more than half of the MDM or more than half of total time (several comments).
- Working with the CPT Editorial Panel to develop a policy (several comments).

The commenters who recommended using MDM (or part thereof) were concerned that using only time to determine the substantive portion implies that MDM and non-patient-facing work is less significant than time, and that time spent in front of the patient is most critical. The commenters were also concerned that tracking time would result in an administrative burden, or remove their ability to use MDM to select visit level. Some commenters were concerned about disrupting current practice patterns. Some commenters noted that using time would disadvantage physicians, because NPPs receive significantly less education, training, and certification than osteopathic and allopathic (DOs and MDs) physicians, making physicians more skilled, efficient, and proficient than NPPs. They stated that MDM is used more often to determine visit level. Commenters also noted, in many instances, the activities performed by the physician, which are the key portion of the visit, take less time than the activities that are required to provide the additional information needed for MDM and the plan of care. The commenters stated that an NPP may be involved in tasks that require significant time, such as preparing the medical record, taking a history, performing a physical exam, inputting orders, obtaining lab or test results, requesting consultations, and doing

preliminary documentation. However, synthesizing the patient's symptoms and other information such as test results and then devising the plan of care are the substance of the visit and typically are done by a physician.

Response: Regarding recommendations to consider the substantive portion to be a lower percentage of time, having reviewed our current policy, we do not believe that the higher physician payment rate under the PFS should be made when a physician performs less than half of the visit, such as a quarter or a third of the total time or less than half of the MDM.

We do not believe MDM is necessarily the most critical or central component of E/M visits, and it is not the only service component included in the PFS payment for the service. We are also not clear how it could be known that MDM is used most often to determine visit level. PFS payment rates incorporate and assume a certain amount of physician time per visit, reflected in the assigned RVUs and reflected annually in our physician time files. PFS payment rates reflect the typical amount of time spent on visits, and the Act requires us to reflect both time and intensity of work (physician and practitioner) in our payment rates. We do not believe this in any way devalues the unique education, training, experience, or expertise of physicians, but rather that both time and expertise are important and included in payment under the PFS.

We continue to believe that MDM cannot be readily attributed to only the physician or the NPP, or definitively divided between them. MDM has three parts: the number and complexity of problem(s) that are addressed during the encounter; the amount and/or complexity of data to be reviewed and analyzed; and the risk of patient management decisions made at the visit.[24] Both the physician and the NPP would be addressing the same problem(s) during the encounter, and both are likely to be reviewing and analyzing data. No key or critical portion of MDM is identified by CPT. Therefore, we do not see how MDM (or its critical portion, or other component part) can be attributed to only one of the practitioners, or how we could distinguish these for purposes of assigning appropriate payment when visits are shared.

We believe the commenters overestimate the administrative burden of tracking and attributing time, given the advent of EHRs and new E/M visit coding structures. However, we understand that an adjustment period may be needed to establish systems to track and attribute time for split (or shared) visits, especially since the coding for E/M visits in many facility settings will not use MDM or time to distinguish visit levels until 2023. Therefore, we are finalizing our definition of substantive portion for split (or shared) visits as proposed (more than half of the total time spent by the physician and NPP performing the split (or shared) visit) beginning January 1, 2023. However, we are modifying our proposed policy for one transitional year. For CY 2022, except for critical care visits, the substantive portion will be defined as one of the three key components (history, exam, or MDM), or more than half of the total time spent by the physician and NPP performing the split (or shared) visit). In other words, for CY 2022, the practitioner who spends more than half of the total time, or performs the history, exam, or MDM can be considered to have performed the substantive portion and can bill for the split (or shared) E/M visit. We wish to be clear that practitioners can still use MDM to select visit level for the E/M split (or shared) visit, as proposed. We also are clarifying that when one of the three key components is used as the substantive portion in 2022, the practitioner who bills the visit must perform that component in its entirety in order to bill. For example, if history is used as the substantive portion and both practitioners take part of the history, the billing practitioner must perform the level of history required to select the visit level billed. If physical exam is used as the substantive portion and both practitioners examine the patient, the billing practitioner must perform the level of exam required to select the visit level billed. If MDM is used as the substantive portion, each practitioner could perform certain aspects of MDM, but the billing practitioner must perform all portions or aspects of MDM that are required to select the visit level billed.

For visits that are already timed (that is, critical care services), the substantive portion will not be based on performance of the history, exam, or MDM. For critical care visits, starting for services furnished in CY 2022, the substantive portion will be more than half of the total time, as proposed. A unique listing of qualifying activities for purposes of determining the substantive portion of critical care visits will apply, as proposed (see section II.F.2. of this final rule where we discuss critical care).

We are codifying this definition of substantive portion for split (or shared) visits in our regulations at § 415.140. We will continue to review and consider any future changes by the AMA/CPT Editorial Panel to the CPT E/M Guidelines for split (or shared) visits. We also intend to monitor the claims data for split (or shared) visits, such as how frequently practitioners use or rely upon this billing construct, and what specialties they represent (see modifier requirement below). We summarize our final policies in Table 26.

TABLE 26: Final Definition of Substantive Portion for E/M Visit Code Families

E/M Visit Code Family	2022 Definition of Substantive Portion	2023 Definition of Substantive Portion
Other Outpatient*	History, or exam, or MDM, or more than half of total time	More than half of total time
Inpatient/Observation/Hospital/Nursing Facility	History, or exam, or MDM, or more than half of total time	More than half of total time
Emergency Department	History, or exam, or MDM, or more than half of total time	More than half of total time
Critical Care	More than half of total time	More than half of total time

Acronyms: E/M (Evaluation and Management), MDM (medical decision-making).
*Office visits will not be billable as split (or shared) services.

[24] 2021 CPT Codebook, p. 14.

(2) Distinct Time

We proposed that the distinct time of service spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine total time and who provided the substantive portion (and therefore, bills for the visit). This would be consistent with the CPT E/M Guidelines stating that, for split (or shared) visits, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted.[25] For example, if the NPP first spent 10 minutes with the patient and the physician then spent another 15 minutes, their individual time spent would be summed to equal a total of 25 minutes. The physician would bill for this visit since they spent more than half of the total time (15 of 25 total minutes). If, in the same situation, the physician and NPP met together for five additional minutes (beyond the 25 minutes) to discuss the patient's treatment plan, that overlapping time could only be counted once for purposes of establishing total time and who provided the substantive portion of the visit. The total time would be 30 minutes, and the physician would bill for the visit since they spent more than half of the total time (20 of 30 total minutes).

Comment: One commenter stated it would be burdensome for practitioners to track how much of their time was spent jointly meeting with or discussing the patient, as opposed to time spent individually. However, a number of commenters recommended generally that we should align our split (or shared) visit policies with the CPT E/M Guidelines to reduce administrative burden.

Response: We believe that we should align with the CPT E/M Guidelines on this point, to reduce administrative burden, and are finalizing as proposed that, for split (or shared) visits, when two or more individuals jointly meet with or discuss the patient, only the time of one individual can be counted.

(3) Qualifying Time

Drawing on the CPT E/M Guidelines, we proposed a listing of activities that could count toward total time for purposes of determining the substantive portion. For visits that are not critical care services, we proposed the CPT listing of activities that can count when time is used to select an E/M visit level, specifically the following activities, when performed and regardless of whether or not they involve direct patient contact:

- Preparing to see the patient (for example, review of tests).
- Obtaining and/or reviewing separately obtained history.
- Performing a medically appropriate examination and/or evaluation.
- Counseling and educating the patient/family/caregiver.
- Ordering medications, tests, or procedures.
- Referring and communicating with other health care professionals (when not separately reported).
- Documenting clinical information in the electronic or other health record.
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver.
- Care coordination (not separately reported).

Practitioners would not count time spent on the following:

- The performance of other services that are reported separately.
- Travel.
- Teaching that is general and not limited to discussion that is required for the management of a specific patient.[26]

Since critical care services can include additional activities that are bundled into the critical care visit code(s), we proposed a different listing of qualifying activities, discussed in our section below on split (or shared) critical care services. Additionally, we solicited public comments on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) emergency department (ED) visits, since those visits also have a unique construct.

Comment: The commenters were generally supportive of our proposal to use the CPT E/M Guidelines listing of qualifying activities for time. We received mixed comments about applying it to ED visits. Some commenters noted our proposed listing could apply equally to office/outpatient and ED visits. Other commenters noted that the CPT Editorial Panel should weigh in on this issue and develop a consensus on whether for ED visits, there should be a different listing of qualifying activities. One commenter recommended several revisions to our proposed listing, to remove time-based activities and to better represent MDM as the driving force determining the substantive portion of an ED visit, specifically:

- Obtaining and/or reviewing separately obtained history.
- Performing and/or reviewing a medically appropriate examination and/or evaluation.
- Formulation of a differential diagnosis.
- Reviewing and amending (as appropriate) clinical information in the electronic or other health record.
- Ordering medications, tests, or procedures.
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver.
- Consulting with other health care professionals as appropriate.
- Counseling and educating the patient/family/caregiver.
- Formulating and instituting a final treatment plan.
- Determining appropriate disposition.

Practitioners would not count the following activities:

- The performance of other services that are reported separately.
- Teaching that is general and not limited to discussion that is required for the management of a specific patient.

Response: Having reviewed the public comments and consulted with our medical officers, we do not believe that an alternative listing for ED visits is the best approach at this time. As we discussed above, only for 2022, we will allow history, or exam, or MDM, or more than half of the total time (inclusive of activities on the finalized listing), to comprise the substantive portion of any E/M visit (including ED visits) except critical care. Starting in 2023, the finalized listing of qualifying activities will apply to all split (or shared) E/M visits except critical care, for purposes of determining the substantive portion. (Critical care will have a different listing of qualifying activities, discussed in the critical care section below). We would expect all aspects of MDM to be included or reflected in the listing of qualifying activities. Many of the additions recommended by the ED physicians' association (for example, formulating and instituting a final treatment plan, determining appropriate disposition, formulation of a differential diagnosis) appear to be more detailed descriptions of MDM activities that could be interpreted as already included in the current CPT listing of qualifying activities. Perhaps additional levels of detail or specificity should be considered by the CPT Editorial Panel for inclusion in its listing of qualifying

[25] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p. 7.

[26] 2021 CPT Codebook, p. 8, as clarified in the CPT 2021 Errata and Technical Corrections dated June 7, 2021 and available on the AMA website at *https://www.ama-assn.org/system/files/2021-06/cpt-corrections-errata-2021.pdf.*

activities. However, we agree with the commenters who noted that a consensus should be reached at CPT before we adopt alternative language. Regarding suggested deletions from the listing, we do not believe it is necessary to exclude travel, even though ED visits do not involve travel, as long as there is one listing applicable for all E/M visit code families (other than critical care, as discussed below). Finally, we recognize the related, controversial issue of whether or not all ED visits should include time (not just split or shared ED visits). Therefore, starting in 2023, our final policy for ED visits will be to use the CPT listing of qualifying activities for time, as proposed. Meanwhile, we will continue to monitor any related changes that may be made by the CPT Editorial Panel.

Comment: Several commenters asked us to clarify whether our intent in our proposed rule was to require both practitioners to have face-to-face contact with the patient, or only one of them. These commenters were concerned that the CPT language could be interpreted to mean that both practitioners do not need to perform face-to-face work, which they believed would reduce transparency, harm quality assessment, and reduce program integrity.

Response: The current CPT E/M Guidelines state, ''The E/M services for which these guidelines apply require a face-to-face encounter with the physician or other qualified health care professional. For office or other outpatient services, if the physician's or other qualified health care professional's time is spent in the supervision of clinical staff who perform the face-to-face services of the encounter, use 99211. A shared or split visit is a visit in which a physician and other qualified health care professional(s) jointly provide the face-to-face and non-face-to-face work related to the visit.'' [27] The list of qualifying activities for time do not specify whether each activity is face-to-face or not. To our knowledge, CPT has not defined the terms ''face-to-face'' and ''non-face-to-face,'' but in this context we interpret face-to-face to mean in-person. We note that certain prolonged service CPT codes use the terms ''with direct patient contact'' and ''without direct patient contact'' instead of ''face-to-face.''

Our intent was that only one of the practitioners must perform the in-person part of an E/M visit when it is split (or shared), although either or both can do so. We acknowledge that Medicare policy on this was not clear in the past, since one manual section defined substantive portion as any face-to-face portion of the encounter, and another section defined it as a key component (which could have included, for example, MDM). We are finalizing as proposed that the substantive portion can be comprised of time that is with or without direct patient contact. Since by 2023 (except for critical care visits), the physician must perform more than half of the total time in order to bill a split (or shared) visit, we believe our final policy ensures enough physician involvement to support their billing for the service, even though the physician might not have direct patient contact. Our final policy is that for all split (or shared) visits, one of the practitioners must have face-to-face (in-person) contact with the patient, but it does not necessarily have to be the physician, nor the practitioner who performs the substantive portion and bills for the visit. The substantive portion could be entirely with or without direct patient contact, and will be determined by the proportion of total time, not whether the time involves direct or in-person patient contact. We will continue to consider this issue going forward and any changes or clarifications that may be made by the CPT Editorial Panel on this topic.

(4) Application to Prolonged Services

For office/outpatient E/M visits, as discussed in our CY 2021 PFS final rule (85 FR 84572), HCPCS code G2212 can be used to report prolonged services in 15-minute increments of time beyond the maximum time for a level 5 office/outpatient E/M visit. For all other E/M visits (except critical care and emergency department visits), CPT codes 99354–9 can be used to report prolonged time with or without direct patient contact, when required time increments above the typical time is spent (see CY 2017 PFS final rule, 81 FR 80228–80230 and the Medicare Claims Processing Manual (Pub. 100–02), chapter 12, section 30.6.15 available on our website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*).

Our withdrawn manual provisions instructed that practitioners cannot bill prolonged services as a split (or shared) visit. Having reviewed this policy, we believed that codes that are billed as add-on codes for prolonged service time for an E/M visit, which could be furnished and billed as a split (or shared) visit under our proposed policy, should be considered to be part of that E/M visit. Therefore, we proposed to change our policy to allow a practitioner to bill for a prolonged E/M visit as a split (or shared) visit. Specifically, the physician or practitioner who spent more than half the total time (that is, performed the substantive portion described above) would bill for the primary E/M visit and the prolonged service code(s) when the service is furnished as a split (or shared) visit, if all other requirements to bill for the services were met. The physician and NPP would sum their time together, and whomever furnished more than half of the total time, including prolonged time, (that is, the substantive portion) would report both the primary service code and the prolonged services add-on code(s), assuming the time threshold for reporting prolonged services is met. We noted that for critical care visits, the practitioner would not bill prolonged E/M services because the practitioners would instead aggregate their time, as proposed below, to report additional units of critical care services.

Comment: We did not receive many comments specifically on this proposed policy, and the comments we received were supportive of our proposal.

Response: We thank the commenters for their support. Starting in 2023, our policy will be as proposed. Specifically, the physician or practitioner who spent more than half the total time (the substantive portion starting in 2023) will bill for the primary E/M visit and the prolonged service code(s) when the service is furnished as a split (or shared) visit, if all other requirements to bill for the services are met. The physician and NPP will add their time together, and whomever furnished more than half of the total time, including prolonged time, (that is, the substantive portion) will report both the primary service code and the prolonged services add-on code(s), assuming the time threshold for reporting prolonged services is met.

The same policy will apply for services furnished in the 2022 transition year when practitioners use a majority of total time as the substantive portion; but when practitioners use a key component as the substantive portion, there will need to be different approaches for office/outpatient E/M visits than other kinds of E/M visits. For shared office/outpatient visits where practitioners use a key component as the substantive portion, prolonged services can be reported by the practitioner who reports the primary service, when the combined time of both practitioners meets the threshold for reporting prolonged office/outpatient services (HCPCS code G2212). For all other types of E/M visits (except ED and critical care visits), prolonged services can be reported by the practitioner who reports the primary service, when the

[27] 2021 CPT Codebook, p.7.

combined time of both practitioners meets the threshold for reporting prolonged E/M services other than office/outpatient E/M visits (60 or more minutes beyond the typical time in the CPT code descriptor of the primary service). (We remind readers that ED and critical care visits are not reported as prolonged services). While this is a complex approach for the CY 2022 transition year, we note that prolonged services historically are not frequently reported. We summarize these policies in Table 27.

TABLE 27: Reporting Prolonged Services for Split (or Shared) Visits

E/M Visit Code Family	2022		2023
	If Substantive Portion is a Key Component…	**If Substantive Portion is Time…**	**Substantive Portion Must Be Time**
Other Outpatient*	Combined time of both practitioners must meet the threshold for reporting HCPCS G2212	Combined time of both practitioners must meet the threshold for reporting HCPCS G2212	Combined time of both practitioners must meet the threshold for reporting HCPCS G2212
Inpatient/Observation/Hospital/Nursing Facility	Combined time of both practitioners must meet the threshold for reporting CPT 99354-9 (60+ minutes > typical)	Combined time of both practitioners must meet the threshold for reporting CPT 99354-9 (60+ minutes > typical)	Combined time of both practitioners must meet the threshold for reporting prolonged services
Emergency Department	N/A	N/A	N/A
Critical Care	N/A	N/A	N/A

Acronyms: E/M (Evaluation and Management).
*Office visits will not be billable as split (or shared) services.

d. New and Established Patients, and Initial and Subsequent Visits

Our withdrawn manual provisions stated that when an E/M service is furnished as a split or shared encounter, between a physician and an NPP (that is, an NP, PA, CNS or CNM), the service is considered to have been performed ''incident to'' if the requirements for ''incident to'' are met and the patient is an established patient. This provision was generally interpreted to mean that split (or shared) visits cannot be billed for new patients. The withdrawn manual provisions also did not specify whether the practitioner who bills for the split (or shared) visit could bill for initial, versus subsequent, split (or shared) visits in the facility setting. After conducting an internal review, including consulting our medical officers, in our proposed rule we stated our belief that the practice of medicine has evolved toward a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by practitioners in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued the manual instructions may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care. After considering and reevaluating our policy, we saw no reason to preclude the physician or NPP from billing for split (or shared) visits for a new patient, in addition to an established patient, or for initial and subsequent split (or shared) visits. Therefore, we proposed to permit the physician or NPP to bill for split (or shared) visits for both new and established patients, as well as for initial and subsequent visits. We believed this approach would also be consistent with the CPT E/M Guidelines for split (or shared) visits, which does not exclude these types of visits from being billed when furnished as split (or shared) services.

Comment: We received many comments on this proposal, all in support of it.

Response: We thank the commenters for their support. After consideration of public comments, we are finalizing as proposed.

e. Settings of Care

The concept of split (or shared) visits was developed as an analog in the facility setting to payment policies for services and supplies furnished incident to a physician's or an NPP's professional services in the non-institutional setting. Section 410.26(a)(6) of our regulations defines the non-institutional setting as all settings other than a hospital or SNF. We proposed to allow billing of split (or shared) visits, including critical care visits, when they are performed in any institutional setting and proposed to codify the definition of facility setting in the regulation at § 415.140. We discuss our proposals regarding billing for critical care split (or shared) E/M services below (see section II.F.2. of this final rule).

Our withdrawn manual provisions did not allow practitioners to bill for split (or shared) visits that are critical care services or SNF/NF visits. The manual stated that the split (or shared) E/M policy did not apply to critical care services or procedures, and that a split (or shared) E/M service performed by a physician and a qualified NPP of the same group (or employed by the same employer) cannot be reported as a critical care service. It also stated that a split (or shared) E/M visit cannot be reported in the SNF/NF setting. We proposed to define split (or shared) visits to be limited to services furnished in institutional settings, as discussed above. As discussed below, we did not see any reason to preclude billing for split (or shared) visits for critical care services, although we sought public comment on this issue in particular. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models

that employ a more team-based approach to care. Where a physician and NPP in the same group take a team approach to furnishing care, as would be the case for split (or shared) visits, even for new patients, initial visits, critical care visits, or SNF/NF visits, we were less concerned about potential disruptions in continuity of care than we might once have been. Rather, we believed that when a visit is shared between a physician and an NPP in the same group, there would be close coordination and an element of collaboration in providing care to the beneficiary.

We did not see any reason to preclude billing for split (or shared) visits for the subset of SNF/NF visits that are not required by our regulations to be performed in their entirety by a physician. Under our current policy, no E/M services can be furnished and billed as split (or shared) visits in the SNF setting. We refer readers to our Conditions of Participation in 42 CFR 483.30 for information regarding the SNF/NF visits that are required to be performed in their entirety by a physician. That regulation requires that certain SNF/NF visits must be furnished directly and solely by a physician. Therefore, our proposal would not apply to the SNF/NF visits that are required to be performed in their entirety by a physician; any SNF/NF visit that is required to be performed in its entirety by a physician cannot and would not be able to be billed as a split (or shared) visit. However, for other visits to which the regulation at § 483.30 does not apply, there is no requirement for a physician to directly and solely perform the visit. We proposed that those visits could be furnished and billed as split (or shared) visits.

Comment: We received many comments on this proposal, all in support of it.

Response: We thank the commenters for their support. After consideration of the public comments, we are finalizing as proposed.

f. Same Group

In accordance with the current policy outlined in the withdrawn manual provisions, we proposed that a physician and NPP must be in the same group in order for the physician and NPP to bill for a split (or shared) visit. We believed that in circumstances when a split or (shared) visit is appropriately billed, a physician and NPP are working jointly to furnish all of the work related to the visit with the patient. However, if a physician and NPP are in different groups, we would expect the physician and NPP to bill independently, and only for the services they specifically and fully furnish. Further, consistent with our withdrawn manual guidance, we noted that Medicare does not pay for partial physician's visits, so CPT modifier –52 (reduced services) could not be used to report split (or shared) visits. Thus, if a physician and an NPP who are in different groups each furnished part of an E/M service, but not all of it, then we would not consider either service to be a billable service. Similarly, if two physicians, each in their own private practice, both saw the same patient in the hospital, but neither one fully furnished a billable service—there would be no basis on which to combine their efforts or minutes of service into one billable E/M visit.

We sought public comment on whether we should further define ''group'' for purposes of split (or shared) visit billing. While we did not propose a definition in the proposed rule, we considered several options, such as requiring that the physician and NPP must be in the same clinical specialty, in which case we would use the approach outlined in the CPT E/M Guidelines; that is the NPP is considered to be in the same specialty and subspecialty as the physician with whom they are working.[28] We were also considering an approach under which we would align the definition of ''group'' with the definition of ''physician organization'' at § 411.351. The term ''physician organization'' is defined at § 411.351 for purposes of section 1877 of the Act and our regulations in 42 CFR part 411, subpart J (collectively, the physician self-referral law), and explained further in frequently asked questions available on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf.* Another approach would be to consider practitioners with the same billing tax identification number (TIN) as being in the same group. We were concerned that this particular approach may be too broad in multi-specialty groups or health care systems that include many practitioners who do not typically work together to furnish care to patients in the facility setting. We noted that some of these approaches may not align with the definition of ''group'' used for purposes of Medicare enrollment.

Comment: We did not receive comments disagreeing with our proposal that the physician and NPP should be in the same group. Commenters agreed that the appropriate definition of group in the context of split (or shared) visits is a complex issue. Some commenters did not recommend that we further define ''group'' in this context, suggesting that the liability to a physician taking on the responsibility of billing for an NPP's work under their NPI, or assuming supervisory responsibility for an NPP, will only split (or share) visits with NPPs in whom they have confidence.

Some other commenters recommended various ways to define group. These included:

- Having the same TIN.
- Being an employee or independent contractor of the same entity.
- Being in the same clinical specialty or clinical specialty practice.
- Working as part of the team that provides the same clinical services. For example, if an NPP is working with a group of orthopedic surgeons to treat the patient, the NPP should be considered part of the orthopedic surgery group when determining whether split (or shared) visits can be provided.
- Being members of a care team working in the same practice.
- Presence of a supervisory or liability relationship between the physician and NPP.
- Professional service agreements that the physician has with the institution, or other care-coordination models under the Quality Payment Program.
- Aligning with the CPT E/M Guidelines in which the NPP is considered to be in the same specialty and subspecialty as the physician with whom they are working.

One commenter objected to classifying NPPs as being in the same specialty or subspecialty of the physician with whom they work. The commenter stated that split (or shared) visits across specialties are important for multidisciplinary care (for example, a PA specializing in cardiology should be able to split (or share) critical care services with a pulmonologist in the same group practice to provide the most appropriate, interdisciplinary care to manage life threatening illness or injury). However, another commenter noted that requiring different specialties may have the unintended consequence of NPPs always being in different specialties than the physicians with whom they work under the PFS specialty taxonomy.

A few commenters stated that using the definition of physician organization at § 411.352 would be too burdensome, prescriptive, and extensive. These commenters stated that under this

[28] 2021 CPT Codebook, p. 6, ''When advanced practice nurses and physician assistants are working with physicians, they are considered as working in the exact same specialty and exact same subspecialties as the physician.''

definition, a solo physician with NPP(s) in their practice (as is common in rural areas) would be disadvantaged, because the group would be required to have at least two physicians who are members of the group (whether employees or direct or indirect owners).

Several commenters stated that the definition should include TIN but also professional service agreements that the physician has with the institution, or other care-coordination models under the Quality Payment Program that could include multiple TINs. Commenters acknowledged that a given TIN could encompass a health system or multiple specialties.

One commenter recommended that being in the same group should mean being employed by, or an independent contractor affiliated with, the same entity, or an independent contractor who is billing through the same entity, or where the physician is obligated to perform the supervisory service for that particular NPP on the patient's date of service for the particular split (or shared) visit regardless of the billing entity status. The commenters noted it would be important for the physician to be legally responsible for the care being provided by the NPP.

Some commenters recommended that we work with the AMA Workgroup on E/M to create a proposal to the CPT Editorial Panel to address this issue and to clarify the reporting in CPT E/M Guidelines. One commenter stated that the physician and NPP do not necessarily need to be the same specialty, but should be practicing as part of a team providing coordinated clinical care. The commenter stated that the definition of initial and subsequent E/M visits for 2023 will include guidance that aligns with the clinical team concept.

Response: After consideration of the public comments, we are finalizing as proposed that the physician and NPP must be in the same group, but we are not further defining ''group'' at this time. We intend to monitor our claims data, and we thank the commenters for their recommendations and insights into current practice, which we may consider for future rulemaking.

g. Medical Record Documentation

To ensure program integrity and quality of care, we proposed that documentation in the medical record must identify the two individual practitioners who performed the visit. The individual who performed the substantive portion (and therefore, bills the visit) would be required to sign and date the medical record. We proposed to revise our regulation at § 415.140 to reflect the conditions of payment for split (or shared) visits as discussed in this section.

We received public comments on the medical record documentation. The following is a summary of the comments we received and our responses.

Comment: We did not receive many comments to our documentation proposal. A few commenters supported our proposal. Several other commenters did not support it, because they believe each practitioner should document what they perform or, in the inpatient setting, sign, date, and time their documentation in the medical record. A few commenters recommended that we work with the AMA/CPT to develop consensus on a single set of clarifying guidelines. One commenter opposed the requirement that the billing provider sign and date the medical record, stating that this is a needless administrative requirement that will not support program integrity.

Response: Recently, we finalized a policy through notice and comment rulemaking that any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team (85 FR 84594 through 84596). We emphasized that, while any member of the medical team may enter information into the medical record, only the reporting clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills.

We continue to believe that we should only require the reporting clinician to review and verify medical records documenting the services provided by themselves and other individuals during an E/M visit for which they bill, because the reporting clinician assumes responsibility for those services by signing off on the medical record. It may be helpful for each practitioner providing the split (or shared) visit to directly document and time their activities in the medical record, to track and attribute time, in order to determine who performed the substantive portion and should therefore bill. However, we believe we should leave it to the discretion of individual practitioners and the groups they work in to decide how time will be tracked. For split (or shared) visits, we continue to believe that documentation in the medical record needs to identify the two individual practitioners who split (or shared) the visit. Therefore, after consideration of public comments, we are finalizing as proposed that documentation in the medical record must identify the two individual practitioners who performed the visit. The individual who performed the substantive portion (and therefore, bills the visit) must sign and date the medical record. We are revising our regulation at § 415.140 to include these requirements.

h. Claim Identification

We proposed to create a modifier to describe split (or shared) visits, and we proposed to require that the modifier must be appended to claims for split (or shared) visits, whether the physician or NPP bills for the visit. Currently, we cannot identify through claims that a visit was performed as a split (or shared) visit, which means that we could know that a visit was performed as a split (or shared) visit only through medical record review. We believed it is important for program integrity and quality considerations to have a way to identify who is providing which E/M services, and how often we are paying at the physician rate for services provided in part by NPPs. (Please see the documentation section above for additional information). The modifier would give CMS insight, directly through our claims data instead of only through medical record review, into the specific circumstances under which these split (or shared) visits are furnished. Such information would be helpful to CMS for program integrity purposes, and could be instructive in considering whether we may need to offer additional clarification to the public, or further revise the policy for these E/M visits in future rulemaking.

We proposed to revise our regulation at § 415.140 to reflect the conditions of payment for split (or shared) visits as discussed in this section.

Consistent with our current policy, Medicare does not pay for partial E/M visits for which all elements of the service are not furnished. Therefore, we proposed that the modifier identified by CPT for purposes of reporting partial services (modifier –52 (reduced services)) could not be used to report partial E/M visits, including any partial services furnished as split (or shared) visits. We noted that we were also considering whether it is necessary to amend our regulations to explicitly state that Medicare does not pay for partial E/M visits and were interested in public comments on this issue.

We received public comments on the claim identification and partial visit

policy proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of a modifier to identify split (or shared) visits on claims. Several commenters stated that this would allow for tracking the contributions of NPPs more easily, increasing transparency and allowing providers, employers, and CMS to better evaluate those contributions. These commenters stated that accurate attribution of services is needed for quality assessment, resource utilization determinations, and future policy considerations. However, many commenters opposed the adoption of a modifier to identify split (or shared) visits because they believe it will increase administrative burden. One association recommended a one-year delay, to allow for practitioner education. Another commenter noted that we did provide a sufficient rationale, and asked about the agency's program integrity experience with split (or shared) services.

Response: We agree with commenters that accurate attribution of services is needed for transparency and program integrity, quality assessment, resource utilization determinations, and future policy considerations. We agree with the commenters that, given the differential PFS payment rates for physicians and NPPs, we need to be able to identify when visits are furnished by these different types of practitioners to improve payment accuracy.

We disagree that reporting a modifier on a claim comprises a substantial administrative burden, and believe that any potential burden is outweighed by policy considerations of quality, payment accuracy and program integrity, as described above.

After consideration of the public comments, we are finalizing as proposed that, for services furnished beginning in CY 2022, we will require a modifier to be reported on the claim to identify split (or shared) visits as such.

Comment: We received few public comments on our proposal that the modifier identified by CPT for purposes of reporting partial services (modifier –52 (reduced services)) could not be used to report partial E/M visits, including any partial services furnished as split (or shared) visits. One commenter agreed with our view that PFS payment is not made for partial E/M visits, and did not believe that an explicit prohibition needs to be codified. Another commenter stated that split (or shared) visits should not be defined as partial or incomplete services, because they are neither.

Response: We thank the commenters for their support. In this final rule, we are clarifying that Medicare does not pay for partial E/M visits, and that the modifier identified by CPT for purposes of reporting partial services (modifier –52 (reduced services)) cannot be used to report partial E/M visits, including any partial services furnished as split (or shared) visits.

2. Critical Care Services (CPT Codes 99291–99292)

As stated previously, in light of updates that we previously finalized for coding and payment for office/outpatient E/M visits, we proposed a number of refinements to other E/M code sets including critical care. Historically, our policy for billing critical care services was reflected in several provisions in the Medicare Claims Processing Manual (sections 30.6.1(B), 30.6.12, and 30.6.13(H)) that were withdrawn effective May 9, 2021, in response to a petition under the Department's Good Guidance regulation at 45 CFR 1.5 (see Transmittal 10742 available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10742cp*). In the absence of these manual provisions, Medicare statute and various broadly applicable regulations continue to apply. In addition to withdrawing the manual provisions, we issued our response to the petition and accompanying enforcement instruction issued on May 26, 2021, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/Evaluation-and-Management-Visits.*

In those documents, we indicated that we intend to address split (or shared) visits (see the previous section) and critical care services (addressed in this section) through rulemaking and that until we do, we will limit review to the applicable statutory and regulatory requirements for purposes of assessing payment compliance. The list of applicable statutory and regulatory requirements includes the CY 2021 PFS final rule (85 FR 84549), where CMS generally adopted new CPT prefatory language and code descriptors for office/outpatient E/M visits. Therefore, we proposed to update our critical care E/M visit policies to improve transparency and clarity, and to account for recent revisions to E/M visit coding and payment.

Specifically, we made a number of proposals related to critical care visits in the CY 2021 PFS proposed rule (86 FR 39207 through 39211). The CPT 2021® Professional Codebook (hereafter, CPT Codebook) provides guidelines for critical care services in the CPT E/M Guidelines on pp. 5–9 and in prefatory language, code descriptors, and parentheticals on pp. 31–33. We proposed to adopt the CPT prefatory language for critical care services as currently described in the CPT Codebook, except as otherwise specified. Should CPT make changes to the guidance for critical care services in a subsequent edition of the CPT Codebook, we could revisit these policies in future rulemaking.

We proposed to clarify our definition of critical care visits, as well as requirements governing how critical care visits are reported under various circumstances, including when:

- A single practitioner furnishes critical care.
- More than one practitioner or specialty furnishes critical care visits.
- A critical care visit is furnished as a split (or shared) visit.
- A critical care visit and another E/M visit occur on the same day.
- Critical care is furnished in the context of global surgery.
- Documenting critical care visits.

a. Definition of Critical Care

Critical care visits are described by CPT codes 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes*) and 99292 (*each additional 30 minutes (List separately in addition to code for primary service*). The CPT 2021® Professional Codebook (hereafter, CPT Codebook) defines critical care services in prefatory language on pp. 31–33.

Critical care services were defined in the withdrawn provisions of the Medicare Claims Processing Manual (IOM). The IOM definition tracked closely with the CPT Codebook prefatory language regarding critical care services. To improve transparency and clarity, we proposed to adopt the CPT prefatory language as the definition of critical care visits. The CPT prefatory language states that critical care is the direct delivery by a physician(s) or other qualified healthcare professional (QHP) of medical care for a critically ill/injured patient in which there is acute impairment of one or more vital organ systems, such that there is a probability of imminent or life-threatening deterioration of the patient's condition.[29] It involves high complexity decision-making to treat single or multiple vital organ system failure and/

[29] 2021 CPT Codebook, p.31.

or to prevent further life-threatening deterioration of the patient's condition. In the proposed rule, we stated our belief that the CPT Codebook appropriately delineates coding and definitions for critical care services in order to distinguish them as more intense services that are valued relatively higher than other E/M services. Thus, we proposed to adopt the CPT prefatory language as the definition of critical care visits and referred readers to the CPT Codebook for additional details.

We stated that, under current Medicare policy, a QHP is an individual who is qualified by education, training, licensure/regulation (when applicable), facility privileging (when applicable), and the applicable Medicare benefit category to perform a professional service within their scope of practice and independently report that service (see, for example, 80 FR 70957; 85 FR 84543, 84593). Because the CPT Codebook provides that critical care services can be delivered by a physician or QHP, we proposed that critical care services may be reported by a physician or NPP who is a QHP (as explained above). In this section of our final rule, we refer to such an individual as an NPP.

In our proposed rule, we also noted that the CPT prefatory language specifies that critical care may be furnished on multiple days, and is typically furnished in a critical care area, which can include an intensive care unit or emergency care facility. CPT prefatory language also states that critical care requires the full attention of the physician or NPP, and therefore, for any given time period spent providing critical care services, the practitioner cannot provide services to any other patient during the same period of time. We proposed to adopt this CPT prefatory language to improve transparency and clarity of our policy for critical care for Medicare billing purposes.

CPT prefatory language also provides billing and coding guidance. The guidance bundles several services into critical care visits furnished by a given practitioner when performed during the critical period by the practitioners providing critical care. We proposed to adopt CPT's listing of bundled services that are part of critical care visits: Interpretation of cardiac output measurements (CPT codes 93561, 93562), chest X rays (CPT codes 71045, 71046), pulse oximetry (CPT codes 94760, 94761, 94762), blood gases, and collection and interpretation of physiologic data (for example, ECGs, blood pressures, hematologic data); gastric intubation (CPT codes 43752, 43753); temporary transcutaneous pacing (CPT code 92953); ventilator management (CPT codes 94002–94004, 94660, 94662); and vascular access procedures. As a result, these codes would not be separately billable by a practitioner during the time-period when the practitioner is providing critical care for a given patient. We also proposed to adopt the CPT prefatory language stating that time spent performing separately reportable procedures or services should be reported separately and should not be included in the time reported as critical care time.

Comment: The public comments were supportive of our proposed definition of critical care. Several commenters expressed concern about the services that are bundled into the critical care codes. In particular, they disagreed with the inclusion of vascular access procedures in the bundled services. The commenters stated that bundling all of the vascular access procedures (not merely peripheral access, but also central venous and arterial lines) into critical care billing is not advisable because of the significant additional risk potential of central venous and arterial access procedures. The commenters added that the central venous and arterial access procedures require significant additional procedural training and skill on the part of the practitioner and that not all those who practice critical care have this additional competency. The commenters suggested the peripheral vascular access procedures could be bundled into critical care services, but not the central venous/arterial access procedures.

Response: We appreciate the commenters' support of our proposed definition of critical care. For administrative simplicity, we believe we should adopt the CPT listing of bundled services. We note that we included vascular access procedures in the list of bundled services because page 31 of the CPT Codebook states that vascular access procedures are included in critical care bundle when performed during the critical period by the physician(s) providing clinical care. Therefore, we are finalizing as proposed the CPT listing of services bundled into critical care. We will review and consider any future changes made by CPT to the listing of bundled services, if future changes are made by the CPT Editorial Panel.

After consideration of public comments, we are finalizing our proposal to adopt the CPT definition of critical care services and the current CPT listing of bundled services.

b. Critical Care by a Single Physician or NPP

Our withdrawn manual provisions and the prefatory language in the CPT Codebook both describe the time duration for the correct reporting of critical care services by a single physician or NPP. To improve transparency and clarity of our policy, we proposed to adopt the CPT prefatory language. Under our proposal, the physician or NPP would report CPT code 99291 for the first 30–74 minutes of critical care services provided to a patient on a given date. The CPT Codebook indicates that CPT code 99291 should be used only once per date even if the time spent by the practitioner is not continuous on that date. Thereafter, the physician or NPP would report CPT code 99292 for additional 30-minute time increments provided to the same patient. The prefatory language states that CPT codes 99291 and 99292 are used to report the total duration of time spent by the physician or QHP (NPP) providing critical care services to a critically ill or critically injured patient, even if the time spent by the practitioner on that date is not continuous; and that non-continuous time for medically necessary critical care services may be aggregated. We proposed to adopt these rules for critical care services furnished by a single physician or NPP. We noted that the prefatory language does not indicate how practitioners should report critical care when a service lasts beyond midnight. We solicited public comments about how practitioners should report CPT codes 99291 and 99292 when critical care services extend beyond midnight to the following calendar day. We referred readers to the CPT Codebook (page 32) for examples of the total duration of critical care visits.

Comment: We received a few comments regarding this proposal. Commenters expressed support for allowing time to be aggregated when reporting the total duration of time spent by a physician or NPP providing critical care services, even if the time spent by the practitioner on that date is not continuous. Several commenters submitted suggestions for how practitioners might report CPT codes 99291 and 99292 when a service extends beyond midnight to the following calendar date. One commenter urged us to work with the AMA to develop guidance to be added to the CPT prefatory language, so that consistent guidance exists across payers. Other commenters recommended that

when critical care extends over midnight, the entire period be attributed to the calendar day the critical care service was initiated. Another commenter suggested that the practitioner should conclude the distinct episode of critical care provision, tally the time, and attribute the service to the initial date. One other commenter recommended that, when critical care services extend beyond midnight, we should adopt the same rule that applies in the Outpatient Prospective Payment System (OPPS): Critical care services should be billed with the date of service they began.

Response: We thank the commenters for their support and suggestions. After consideration of public comments, we are finalizing as proposed that the physician or NPP will report CPT code 99291 for the first 30–74 minutes of critical care services provided to a patient on a given date. CPT code 99291 will be used only once per date even if the time spent by the practitioner is not continuous on that date. Thereafter, the physician or NPP will report CPT code 99292 for additional 30-minute time increments provided to the same patient. CPT codes 99291 and 99292 will be used to report the total duration of time spent by the physician or NPP providing critical care services to a critically ill or critically injured patient, even if the time spent by the practitioner on that date is not continuous; and non-continuous time for medically necessary critical care services may be aggregated.

Regarding critical care crossing midnight, since the publication of the CY 2022 PFS proposed rule, we identified CPT guidance that defines how a service is to be billed when the service extends across calendar dates. According to CPT introductory language, ''Some services measured in units other than days extend across calendar dates. When this occurs, a continuous service does not reset and create a first hour. However, any disruption in the service does create a new initial service. For example, if intravenous hydration (96360, 96361) is given from 11 p.m. to 2 a.m., 96360 would be reported once and 96361 twice. For continuous services that last beyond midnight (that is, over a range of dates), report the total units of time provided continuously'' (CPT Codebook, page xvii). We are adopting this rule for critical care being furnished by a single physician or NPP when the critical care crosses midnight.

c. Critical Care Visits Furnished Concurrently by Different Specialties

The CPT Codebook does not provide special instruction about how to report critical care visits furnished concurrently by more than one physician or practitioner, whether in a split (or shared) visit context or other contexts that might be relevant given the unique nature of critical care and the long timeframes over which patients may receive these services. The CPT E/M Guidelines state broadly that concurrent care is the provision of similar services (for example, hospital visits) to the same patient by more than one physician or other QHP on the same day. The CPT E/M Guidelines state that when concurrent care is provided, no special reporting is required.[30] The CPT E/M Guidelines also state broadly that when time is being used to select the appropriate level of services for which time-based reporting of split (or shared) visits is allowed), the time personally spent by the physician and other QHP(s) assessing and managing the patient on the date of the encounter is summed to define total time; and that only distinct time should be summed for split (or shared) visits (that is, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).[31]

In the context of critical care services, our withdrawn manual provisions provided guidance on concurrent care, and stated that there are situations where physicians or NPPs within a group provide coverage or follow-on care for one another on a single day. The manual also stated that critically ill or injured patients may require the care of more than one practitioner from more than one specialty (regardless of group affiliation), and this work could transpire simultaneously or could overlap.

Consistent with our current policy, and to improve transparency and clarity of our policy for critical care services, we proposed that concurrent care occurs where more than one physician or qualified NPP furnishes services to the same patient on the same day. Medicare policy for physicians' services is that concurrent care exists where more than one physician renders services more extensive than consultative services during a period of time.[32] The reasonable and necessary services of each physician rendering concurrent care could be covered where each is required to play an active role in the patient's treatment (for example, because of the existence of more than one medical condition requiring diverse specialized medical services). In our proposed rule, we noted that, in the context of critical care services, a critically ill patient may have more than one medical condition requiring diverse specialized medical services and thus requiring more than one practitioner having different specialties to play an active role in the patient's treatment. Thus, we proposed that critical care visits may be furnished as concurrent care (or concurrently) to the same patient on the same date by more than one practitioner in more than one specialty (for example, an internist and a surgeon, allergist and a cardiologist, neurosurgeon and NPP), regardless of group affiliation, if the service meets the definition of critical care and is not duplicative of other services. Additionally, as for most Medicare-covered services, these critical care visits would need to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. We solicited public comments on our proposal to better understand current clinical practice for critical care, and when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide critical care services.

Comment: We received a few comments, all in support of our proposal.

Response: We thank commenters for their support, and are finalizing as proposed.

d. Critical Care Furnished Concurrently by Practitioners in the Same Specialty and Same Group (Follow-Up Care)

Physician(s) or NPP(s) in the same specialty and in the same group may provide concurrent follow-up care, such as a critical care visit subsequent to another practitioner's critical care visit. This may be as part of continuous staff coverage or follow-up care to critical care services furnished earlier in the day on the same calendar date.

According to CPT coding and billing conventions, a practitioner who furnishes a timed service such as a critical care visit would typically need to report the primary service or procedure code before reporting an add-on code. However, we stated that because practitioners in the same specialty and same group cover for one another, we believed the total time for

[30] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p.8.

[31] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p.7.

[32] Medicare Benefit Policy Manual (Pub. 100–04) Chapter 15, Section 30.D.

critical care services furnished to a patient on the same day by the practitioners in the same group with the same specialty should be reflected as if it were a single set of critical care services furnished to the patient. We proposed that, when critical care is furnished concurrently, by two or more practitioners in the same specialty and in the same group, to the same patient on the same date, the individual physician(s) or NPP(s) providing the follow-up or subsequent care would report their time using the code for subsequent time intervals (CPT code 99292), and would not report the primary service code (CPT code 99291). CPT code 99291 would not be reported more than once for the same patient on the same day by these practitioners. This proposal recognizes that multiple practitioners in the same specialty and the same group can maintain continuity of care by providing follow-up care for the same patient on the same day, and is consistent with our current policy as described in the withdrawn manual provisions.

We proposed that in the situation where a practitioner furnishes the initial critical care service in its entirety and reports CPT code 99291, that the practitioner(s) reporting subsequent critical care services would report CPT code 99292. This proposal recognizes that multiple practitioners in the same specialty and group can furnish critical care services concurrently to a patient on a single day.

We also proposed that when one practitioner begins furnishing the initial critical care service, but does not meet the time required to report CPT code 99291, another practitioner in the same specialty and group can continue to deliver critical care to the same patient on the same day. We stated that the total time spent by the practitioners could be aggregated to meet the time requirement to bill CPT code 99291. Under this proposal, once the cumulative required critical care service time is met to report CPT code 99291, CPT code 99292 could not be reported by a practitioner in the same specialty and group unless and until an additional 30 minutes of critical care services are furnished to the same patient on the same day (74 minutes + 30 minutes = 104 total minutes).

Finally, we stated that the aggregated time spent on critical care visits must be medically necessary and each visit must meet the definition of critical care in order to add the times for purposes of meeting the time requirement to bill CPT code 99291.

Comment: Several comments supported our proposal to aggregate time for critical care furnished concurrently by practitioners in the same specialty and same group (Follow-Up Care). A couple of commenters noted our math miscalculation (86 FR 39209). We incorrectly stated that 70 minutes + 34 minutes = 114 minutes when in fact it equals 104 minutes.

Response: We appreciate the support of commenters and thank them for letting us know about our addition error. We have revised the total number of minutes.

After consideration of public comments, we are finalizing our proposal for aggregating time when critical care is furnished concurrently, by two or more practitioners in the same specialty and in the same group, to the same patient on the same date (follow-up care).

e. Split (or Shared) Critical Care Visits

Under current CMS policy, critical care services cannot be billed as split (or shared) E/M services. As previously discussed in section II.F.1. of this final rule for split (or shared) visits, we believe the practice of medicine has evolved toward a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by clinicians in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued current policy may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care. In considering and reevaluating this policy, we believed it would be appropriate to revise our policy to allow critical care services to be reported when furnished as split (or shared) services. Therefore, we proposed that critical care visits may be furnished as split (or shared) visits. The proposals described for other types of split (or shared) visits would apply (except for the listing of qualifying activities for determining the substantive portion, discussed below), and service time would be counted for CPT code 99292 in the same way as for prolonged E/M services. In other words, we proposed that the total critical care service time provided by a physician and NPP in the same group on a given calendar date to a patient would be summed, and the practitioner who furnishes the substantive portion of the cumulative critical care time would report the critical care service(s).

Since unlike other types of E/M visits, critical care services can include additional activities that are bundled into the critical care visits code(s), we proposed a different listing of qualifying activities for split (or shared) critical care. These qualifying activities are described in prefatory language on pp. 31–32 of the 2021 CPT Codebook. When critical care services are furnished as a split (or shared) visit, we proposed to define the substantive portion as more than half the cumulative total time in qualifying activities that are included in CPT codes 99291 and 99292.

Similar to our proposal for split (or shared) prolonged visits, the billing practitioner would first report CPT code 99291 and, if 75 or more cumulative total minutes were spent providing critical care, the billing practitioner could report one or more units of CPT code 99292. We would require practitioners to include the proposed split (or shared) visit modifier on the claim, and the same documentation rules would apply as for other types of split (or shared) E/M visits. We noted that, in contrast to our proposals regarding concurrent critical care services, when a critical care service is furnished as a split (or shared) visit, when two or more practitioners spend time jointly meeting with or discussing the patient, the time could be counted only once for purposes of reporting the split (or shared) critical care visit. This is consistent with our proposed policy for all split (or shared) visits. It is also consistent with the CPT E/M Guidelines stating that, for split (or shared) visits, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).[33]

We sought public comment on these proposals to ensure they reflect a clinically appropriate approach, and to help us assess whether we should instead require that an individual physician or NPP directly perform the entirety of each critical care visit. We sought public comment to better understand current clinical practice for critical care, and when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide critical care to a patient.

Comment: We did not receive any public comments opposing any aspect of our proposals regarding split (or shared) critical care visits.

Response: We thank the commenters for their support. After consideration of

[33] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p.7.

the public comments, we are finalizing as proposed.

f. Critical Care Visits and Same-Day Emergency Department, Inpatient or Office/Outpatient Visits

The CPT Codebook states that critical care and other E/M services may be provided to the same patient on the same date by the same individual. However, our general policy as described in the Medicare Claims Processing Manual states that physicians in the same group who are in the same specialty must bill and be paid for services under the PFS as though they were a single physician. If more than one E/M visit is provided on the same day to the same patient by the same physician, or by more than one physician in the same specialty in the same group, only one E/M service may be reported unless the E/M services are for unrelated problems. Instead of billing separately, the physicians should select a level of service representative of the combined visits and submit the appropriate code for that level.[34]

This policy is intended to ensure that multiple E/M visits for a patient on a single day are medically necessary and not duplicative. With respect to office/outpatient E/M visits specifically, our current manual instructs, ''As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off campus-outpatient hospital, or on campus-outpatient hospital setting which could not be provided during the same encounter.'' [35]

For hospital visits and hospital ED visits furnished on the same day as critical care services, the Medicare Claims Processing Manual states, ''When a hospital inpatient or office/outpatient E/M service are furnished on a calendar date at which time the patient does not require critical care and the patient subsequently requires critical care both the critical care services (CPT codes 99291 and 99292) and the previous E/M service may be paid on the same date of service. Hospital ED services are not paid for [on] the same date as critical care services when provided by the same physician to the same patient.'' [36]

We expressed concern about adopting the CPT rule that states that critical care and other E/M visits may be furnished to the same patient on the same date by the same practitioner. We stated in the past that we believe multiple E/M visits by the same practitioner, or by practitioners in the same specialty within a group, on the same day as another E/M service ordinarily would not be medically necessary (83 FR 59639). We noted that the CPT rule allowing billing for critical care and other E/M visits on the same day, by practitioners in the same group and of the same specialty, could lead to duplicative payment, particularly given the frequently long duration of critical care services, the CPT prefatory language indicating that time spent furnishing critical care may be non-continuous, and the relatively higher valuation of critical care services compared to other E/M services. Thus, we proposed that no other E/M visit can be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty in the same group.

We suggested several alternative approaches to addressing our concerns about medical necessity and duplicative payment for E/M services furnished to a patient on the same day by the same practitioner or a practitioner in the same group. We previously considered an MPPR for standalone office/outpatient E/M visits that occur on the same day as a procedure. An MPPR would address efficiencies (for example, in preservice and postservice clinician work and PE) that are not accounted for in the current payment rates (83 FR 59639). These visits could be identified on the claim with modifier –25 (significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service) and CMS could assign a reduced payment rate to one of the visits. CMS could also require documentation to support the medical necessity and non-duplicative nature of a claim for critical care services on the same calendar date as another E/M visit provided to a patient by the same practitioner or practitioner of the same specialty in a group.

We recognized that our proposal not to allow an E/M visit to be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty within a group, might be appropriate only in certain clinical situations. For example, it is possible that a patient might not require critical care services at the time of an ED visit, but then be admitted to the hospital on the same calendar date as the ED visit and require care that meets the definition of critical care services. It is also possible that the practitioner who furnished the ED visit might provide the critical care services to the same patient on the same calendar date. Thus, we solicited public comments on our proposal to better understand clinical practice for critical care when E/M services are furnished on the same date as critical care services and the services are furnished by the same practitioner or practitioners in the same specialty in the same group, while also reducing the potential for duplicative payment.

Comment: We received many public comments on our proposal regarding critical care visits and same-day emergency department, inpatient or office/outpatient E/M visits. Many commenters opposed the proposal. These commenters stated that the proposal was contrary to the CPT Codebook which states that critical care and other E/M services may be provided to the same patient on the same date by the same individual. Other commenters stated that same-day emergency department, inpatient or office/outpatient visits are separate services that can be independent of critical care services. Many commenters offered examples where an E/M visit might occur on the same day as critical care services and concluded by stating that there may be instances when a patient would need both types of services on the same day. Commenters stated that we should maintain enough flexibility around provision of these services to allow practitioners to bill an E/M visit on the same date as a critical care service in those instances where it is clinically appropriate and for which there is documentation of the specific services provided by each practitioner.

Response: We appreciate the many comments we received on this proposal. We remain concerned about adopting the CPT rule that states that critical care and other E/M visits may be furnished to the same patient on the same date by the same practitioner. As we have stated in the past, we believe that multiple E/M visits by the same practitioner or practitioners in the same specialty within a group, on the same date as another E/M service would not seem to

[34] Medicare Claims Processing Manual (Pub. 100–02), Chapter 12, Section 30.6.5, *Physicians In Group Practice.*

[35] Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.7.B., available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

[36] Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.9.B., available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

be medically necessary (83 FR 59639). We appreciate the examples that commenters sent describing situations where a patient might require a same-day E/M visit, as well as critical care services, and understand that in certain circumstances the E/M visit could be independent of the critical care services. We also agree that flexibility is important; although, we do not presume the billing of critical care with other E/M visits on the same day as a typical situation. We note that the CPT rule allowing billing for critical care and other E/M visits on the same day, by practitioners in the same group and of the same specialty, could lead to duplicative payment, particularly given the frequently long duration of critical care services.

After consideration of the public comments, we are finalizing a policy similar to the policy in our withdrawn manual. Specifically, as long as the physician documents that the E/M service was provided prior to the critical care service at a time when the patient did not require critical care, that the service is medically necessary, and that the service is separate and distinct, with no duplicative elements from the critical care service provided later in the day, practitioners may bill for both services. Practitioners must use modifier –25 on the claim when reporting these critical care services. We may consider in future rulemaking a payment adjustment similar to our MPPR that would more broadly apply to same-day E/M visits and procedures.

g. Critical Care Visits and Global Surgery

Critical care visits are sometimes needed during the global period of a procedure, whether pre-operatively, on the same day or during the post-operative period. In many cases, preoperative and postoperative critical care visits are included in procedure codes that have a global surgical period. In the CY 2015 PFS final rule, we discussed our concerns related to accurately accounting for the number of visits included in the valuation of 10- and 90-day global packages (79 FR 67548, 67582). The 10- and 90-day global packages can include critical care visits. finalized a policy to change all global periods to 0-day global periods, as well as to allow separate payment for post-operative E/M visits.

Our concerns were based on a number of key points including: The lack of sufficient data on the number of visits typically furnished during the global periods, questions about whether we would be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and concerns about how our global payment policies could affect services that are actually furnished. Section 1848(c)(8)(B) of the Act, which was added by section 523(a) of the Medicare Access and CHIP Reauthorization Act (MACRA), required us to collect data to value surgical services. Because critical care visits are included in some 10- and 90-day global packages, we proposed to bundle critical care visits with procedure codes that have a global surgical period. We noted that this proposal differs from current policy as described in the Medicare Claims Processing Manual which states that critical care visits are unbundled from procedures with a global surgical period as long as the critical care service was unrelated to the procedure.[37] As we have made clear in previous rulemaking, we are continuing to assess values for global surgery procedures (84 FR 2452), including the number and level of preoperative and postoperative visits, which can include critical care services. Because this work is still ongoing, we proposed to bundle critical care visits with procedure codes that have a global surgical period.

Comment: We received many public comments on our proposal to bundle critical care services with procedure codes with a global surgical period. Many commenters opposed our proposal. These commenters stated that this policy, if finalized, would have a significant negative impact on the quality and safety of patient care, health system resiliency, health equity, and the surgical workforce. Most commenters recommended that we continue to pay separately for critical care services that are billed with surgical procedures that do not contain critical care services as part of a global surgical package. A few commenters wrote in favor of maintaining modifiers –24 (Unrelated E/M service by the same physician during a postoperative period) and –25 (Significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service) to indicate that the critical care service was unrelated to the surgical procedure and can be billed and paid at full value when unrelated to the procedure.

Response: We appreciate the many informative comments shared by stakeholders on this topic. We found the detailed comments about how our proposal would negatively impact the quality and safety of patient care, health system resiliency, health equity, and the surgical workforce especially compelling. Thus, after considering public comments, we are choosing not to finalize our proposal to always bundle critical care visits with procedure codes that have a global surgical period. Instead, we are maintaining our current policy that critical care visits may be separately paid in addition to a procedure with a global surgical period, as long as the critical care service is unrelated to the procedure. Preoperative and/or postoperative critical care may be paid in addition to the procedure if the patient is critically ill (meets the definition of critical care) and requires the full attention of the physician, and the critical care is above and beyond and unrelated to the specific anatomic injury or general surgical procedure performed (for example, trauma, burn cases). We are creating a new modifier that we will require on such claims to identify that the critical care is unrelated to the procedure. If care is fully transferred from the surgeon to an intensivist (and the critical care is unrelated), modifiers –54 (surgical care only) and –55 (postoperative management only) must also be reported to indicate the transfer of care. The surgeon will report modifier –54. The intensivist accepting the transfer of care will report both modifiers –55 and the new unrelated modifier. As usual, medical record documentation must support the claims. We may consider in future rulemaking an MPPR-like adjustment that would be used to identify critical care that is billed in conjunction with a global surgical procedure, and would discount one of the services rather than paying for both in their entirety.

h. Medical Record Documentation Requirements

Because critical care is a time-based service, we proposed to require practitioners to document in the medical record the total time that critical care services were provided by each reporting practitioner (not necessarily start and stop times). We stated that documentation would need to indicate that the services furnished to the patient, including any concurrent care by the practitioners, were medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. To support coverage and payment determinations regarding concurrent care, we indicated that services would need to be sufficiently documented to allow a medical reviewer to determine the role

[37] Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 40.2.A.9, available on the CMS website.

each practitioner played in the patient's care (that is, the condition or conditions for which the practitioner treated the patient). We stated that, in order to support coverage and payment determinations regarding split (or shared) critical care services, documentation requirements for all split (or shared) E/M visits would apply to critical care visits also (see section II.F.1. of this final rule).

Comment: We received a few public comments in support of our proposed documentation requirements. Commenters stated that critical care time should include total time, not a range or threshold met, that services must be medically reasonable and necessary to treat a critical condition, and that documentation should demonstrate the role played by the medical practitioner (especially if there is split or shared billing).

Response: We agree with the commenters that medical record documentation is especially important for split (or shared) critical care visit billing, as well as same-day multiple visits and billing of critical care in conjunction with a global surgical procedure, discussed above. After consideration of public comments, we are finalizing the documentation requirements for critical care time as proposed. We also refer readers to the sections above on critical care billed the same day as other E/M visits, and critical care billed in conjunction with a global surgical procedure, for additional discussion of documentation requirements in support of services billed.

3. Payment for the Services of Teaching Physicians

As part of the CPT office/outpatient E/M visit coding framework that we finalized beginning for CY 2021 (85 FR 84548 through 84574), practitioners can select the office/outpatient E/M visit level to bill, based either on the total time personally spent by the reporting practitioner or MDM. Stakeholders have asked us how teaching physicians who involve residents in furnishing care should consider time spent by the resident in selecting the office/outpatient E/M visit level.

For teaching physicians, section 1842(b) of the Act specifies that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought.

Regulations regarding PFS payment for teaching physician services are codified in 42 CFR part 415. In general, under § 415.170, payment is made under the PFS for services furnished in a teaching hospital setting if the services are personally furnished by a physician who is not a resident, or the services are furnished by a resident in the presence of a teaching physician, with exceptions as specified in subsequent regulatory provisions in part 415. Medicare separately pays for the time spent by the resident through direct graduate medical education (GME) under Medicare Part A.

a. General Policy for Evaluation and Management Visits

Under our regulation at § 415.172 and absent a public health emergency (PHE), if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service. For residency training sites that are located outside a metropolitan statistical area, PFS payment may also be made if a teaching physician is present through audio/video real-time communications technology (that is, ''virtual presence''). In the case of E/M services, the teaching physician must be present during the portion of the service that determines the level of service billed.

We proposed that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. We believe it is appropriate to include only the time of the teaching physician because the Medicare program makes separate payment for the program's share of the graduate medical training program, which includes time spent by a resident furnishing services with a teaching physician, under Medicare Part A. During the PHE, the time of the teaching physician when they are present through audio/video real-time communications technology may also be included in the total time considered for visit level selection. We noted that, outside the circumstances of the COVID–19 PHE, the teaching physician presence requirement can be met virtually, through audio/video, real-time communications technology, only in residency training sites that are located outside of a metropolitan statistical area.

This proposal is consistent with our previously finalized policy that practitioners can use total time personally spent by the reporting practitioner on the date of the encounter to select office/outpatient E/M visit level. It is also consistent with our regulation at § 415.172 that states that PFS payment is made when a teaching physician involves a resident in providing care only if the teaching physician is present for the key or critical portions of the service, including the portion that is used to select the visit level.

We received public comments on the general policy for E/M visits. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported our proposed clarification concerning the specific portion of total time that can be used to determine separate payment for teaching physician services under the PFS for an office/outpatient (O/O) E/M visit involving residents. These commenters supported our clarification that since the Medicare program already pays for a resident's care as part of a graduate medical education (GME) training program, only the time personally spent by the teaching physician furnishing services should be used to select the level of O/O E/M visits services that are separately billed under the Medicare Part B PFS for teaching physician services. Medicare Part A payment for graduate medical training programs includes the time that a resident spends furnishing services with a teaching physician.

Response: We appreciate the overall support for our proposal and the consensus that it is a reasonable approach to prevent duplicative program payment for services furnished by teaching physicians involving residents. Our proposal is also consistent with our approach to the primary care exception discussed below.

Comment: One commenter disagreed with our proposal to make separate payment under the Medicare Part B PFS only to teaching physicians and not residents, opining it will cause a hardship for organizations that accept residents but are not recipients of the Medicare Part A GME payment. The commenter stated that such organizations rely on billing and separate payment under the Medicare PFS to a teaching physician for the total time spent for an O/O E/M visit to compensate for the time and effort of training a resident.

Response: We appreciate that organizations that are not hospitals with a teaching program or teaching hospital primary care centers may accept residents and provide education and training opportunities for such individuals. However, if an organization

other than a teaching hospital with an accredited GME program ''accepts residents'' for training, it would either be a ''non-hospital site'' associated with a teaching hospital's GME program (in which case the hospital presumably would count and be paid for the FTE resident time spent there), or the ''resident'' would not be performing services as part of the GME program at all—they would be ''moonlighting.'' Program regulations at 42 CFR 410.200 state that services furnished in hospitals by residents in approved GME programs are specifically excluded from being paid as ''physician services'' defined in § 414.20. We also note that program regulations at § 415.208(b)(4) state that no payment is made for teaching physician services associated with services furnished by a moonlighting resident.

Comment: One commenter requested clarity on what specific teaching physician activities count toward the time the teaching physician was present, as well as whether face-to-face time is required or if non-face-to-face time as described in Current Procedural Terminology (CPT) guidelines counts. However, the commenter urged CMS to delay making changes or clarifications to this policy until 2023, when CPT could make substantial changes to E/M codes as it continues to review and revise the E/M code set.

Response: We appreciate the commenters' suggestion. At this time, the qualifying activities for selecting office/outpatient E/M visit level using the reporting practitioner's time are specified by CPT. Earlier this year, the CPT Editorial Panel published an erratum or technical correction to the 2021 CPT E/M Guidelines which addressed teaching physician time by excluding time spent in ''teaching that is general and not limited to discussion that is required for the management of a specific patient.'' [38] Therefore, we are clarifying that only time spent by the teaching physician performing qualifying activities listed by CPT (with or without direct patient contact on the date of the encounter), including the time the teaching physician is present when the resident is performing such activities, may be counted for purposes of visit level selection. This excludes teaching time that is general and not limited to discussion that is required for the management of a specific patient. As CPT reviews and revises the E/M visit code set, we will consider in future rulemaking any pertinent changes that may be made by the CPT Editorial Panel on this topic, and whether further clarifications or changes may be needed to the current regulations at § 415.172 regarding the billing requirements for teaching physician services.

Comment: Several commenters urged CMS to make permanent beyond the COVID–19 pandemic, the ability of teaching physicians to include in the total time considered for visit level selection, their virtual presence through audio/video, real-time communications technology, when billing for office/outpatient E/M visits in residency training centers located inside, as well as outside of a metropolitan statistical area (MSA).

Response: We appreciate the commenters' recommendation. However, the issue of making the virtual presence flexibility permanent beyond the COVID–19 pandemic and extending this flexibility to include residency training centers located inside an MSA was not part of our proposal for general primary care office/outpatient E/M visit level selection.

Comment: A few commenters requested that CMS use ''provider-neutral'' language in all regulatory rulemaking, including in the definition of ''teaching physician services'' to reflect the full spectrum of healthcare professionals delivering care to their communities. A commenter encouraged CMS to clarify that physician assistants (PAs) and advanced practice registered nurses (APRNs) can count the total time they were present with residents, students, and other trainees toward selecting the E/M visit level.

Response: Payment is made under the Medicare PFS for teaching physicians' services as described in part 415 of our regulations. We define a teaching physician in § 415.152 as a physician other than a resident who involves residents in the care of their patients. Additionally, teaching physicians are involved in training residents as part of an approved GME residency program in a teaching hospital, which includes only programs in medicine, osteopathy, dentistry, or podiatry. For each of these program areas under a GME residency program, section 1861(r) of the Act uses the term ''physician'' in connection with the performance of any function or action by a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, and a doctor of podiatric medicine. NPPs are not included under the statutory definition of a physician.

After considering the public comments, we are finalizing our proposal that only the teaching physician's total time is counted when total time is used to determine the office/outpatient E/M visit level, not including the time spent by the resident furnishing care without the presence of the teaching physician. We are clarifying that only time spent by the teaching physician performing qualifying activities listed by CPT (with or without direct patient contact on the date of the encounter), including time the teaching physician is present when the resident is performing those activities, may be counted for purposes of visit level selection. This excludes teaching time that is general and not limited to discussion that is required for the management of a specific patient.

b. Primary Care Exception Policy

The regulation at § 415.174 sets forth an exception to the conditions for PFS payment for services furnished in teaching settings in the case of certain E/M services furnished in certain primary care centers. Under the so-called ''primary care exception,'' Medicare makes PFS payment in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. We expanded the list of services that residents could furnish without the physical presence of the teaching physician for the duration of the PHE to include all levels of an office/outpatient E/M visit, among other services. Upon the conclusion of the PHE, levels 4–5 office/outpatient E/M visits will no longer be included in the primary care exception (85 FR 84585 through 84590).

Section 415.174(a)(3) requires that the teaching physician must not direct the care of more than four residents at a time, and must direct the care from such proximity as to constitute immediate availability (that is, provide direct supervision), and must review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. Section 415.174(a)(3) also requires that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, and ensure that the services furnished are appropriate.

We proposed that under the primary care exception, only MDM can be used to select office/outpatient E/M visit level. The intent of the primary care exception as described in § 415.174 is that E/M visits of lower and mid-level complexity furnished by residents are simple enough to permit a teaching

[38] 2021 CPT Codebook, p. 8, as clarified in the CPT 2021 Errata and Technical Corrections dated June 7, 2021 and available on the AMA website at *https://www.ama-assn.org/system/files/2021-06/cpt-corrections-errata-2021.pdf.*

physician to be able to direct and manage the care of up to four residents at any given time and direct the care from such proximity as to constitute immediate availability. In the context of teaching hospital primary care centers that are staffed by residents and teaching physicians, we believe that MDM will be a more accurate indicator of the complexity of the visit as opposed to time. Because residents are in training, they may need more time than is reflected in the code descriptor to furnish a visit that has a low-level of medical decision making. For example, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter*) involves a low level of MDM and between 20–29 minutes of total time. If time was used for level selection instead of MDM, it is possible that residents may need more than 20–29 minutes of time, including any conferring with the teaching physician, to furnish CPT code 99213. Thus, residents may be less efficient relative to a teaching physician in furnishing care.

Office/outpatient E/M visits requiring 30 or more minutes of total time are described by visit levels 4–5. After the expiration of the COVID–19 PHE, office/outpatient levels 4–5 will no longer be included in the primary care exception. In the CY 2021 PFS final rule, we expressed concern that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. We noted that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision-making, the ability to be immediately available to other residents could be compromised, potentially putting patients at risk (85 FR 84586). Thus, to guard against the possibility of residents furnishing visits that are of more than lower and mid-level complexity, we proposed that only MDM may be used for office/outpatient E/M visit level selection for services furnished by residents under the primary care exception.

We acknowledge that under the new CPT office/outpatient E/M visit coding framework, it is possible that time is an accurate indicator of the complexity of the visit. Thus, we solicited public comments on this proposal, including our assumption that MDM is a more accurate indicator of the appropriate level of the visit relative to time in the context of the primary care exception for services furnished by residents and billed by teaching physicians in primary care centers. We also solicited comments on whether time is an accurate indicator of the complexity of the visit and how teaching physicians might select office/outpatient E/M visit level using time when directing the care of a patient that is being furnished by a resident in the context of the primary care exception.

We received public comments on the primary care exception policy. The following is a summary of the comments we received and our responses.

Comment: Most of the commenters support and concur with our proposal to use medical decision making (MDM) only to select the visit level for office/outpatient E/M visits under the primary care exception.

Response: We appreciate the commenters' support for our approach.

Comment: Several commenters opposed our proposal to use MDM exclusively to select the office/outpatient E/M visit level for services furnished under the primary care exception. These commenters were concerned that the exclusive use of MDM may create incentives for physicians to quickly move residents from patient to patient, rather than furnish the appropriate clinical care. They stated that without evidence that MDM is a more accurate indicator than time in selecting the E/M visit level under the primary care exception, both time and MDM should be allowed as options for visit level selection. The commenters noted that time spent by the teaching physician reviewing the chart, looking at images, discussing with consultants, etc., should all still count in determining the E/M level, just as it does in a non-teaching situation.

Response: We acknowledge the commenters' opposition to our proposal to allow MDM as the only option for E/M visit level selection under the primary care exception. However, under our primary care exception policy, we believe that using MDM to inform office/outpatient E/M visit level selection rather than time is appropriate given our concerns about the accuracy of counting time spent by residents in training to inform office/outpatient E/M visit level selection. We believe that the use of MDM is far more practical and less burdensome, because it allows for the likelihood that residents in training might take more time to perform services because they are potentially less efficient. As a result, time is not necessarily an accurate reflection of the visit level. Also, under the primary care exception, the teaching physician is allowed to participate simultaneously in the services furnished by up to four residents and bill separately for teaching physician services under the PFS for each of these residents. Under these circumstances, when a teaching physician must direct and manage the care of up to four residents at a given time and direct the care from such proximity as to constitute immediate availability, it is difficult to discern which time should be counted.

Comment: We received some comments that are outside the scope of the teaching physician proposals and comment solicitation we included in the proposed rule. One of these comments stated that the increased investment in primary care expected from the 2021 E/M visit code revaluation has not materialized in many cases, expressing the view that this is because the employers of many family physicians are not reflecting the increased RVUs or Medicare payment allowances in their employment contracts. The other commenter suggested that CMS should adjust the values of the E/M postoperative visits included in the 10- and 90-day global codes to reflect the 2021 updates to the office/outpatient E/M code payment increases.

Response: We will not be addressing the concerns raised in these comments in this final rule because they are not within the scope of topics addressed in this CY 2022 PFS rulemaking.

After considering public comments, we are finalizing our proposal that MDM is used to determine the visit level for office/outaptient E/M visits furnished under the primary care exception.

G. Billing for Physician Assistant (PA) Services

Under the respective Medicare statutory benefit categories for the services of PAs, nurse practitioners (NPs), and clinical nurse specialists (CNSs), these nonphysician practitioners (NPPs) are authorized to furnish services that would be physicians' services if they were furnished by a physician, and which they are legally authorized to perform by the State in which the services are furnished; and such services that are provided incident to these NPPs' professional services (but only if no facility or other provider charges or is paid any amount for the services). Additionally, the payment amount for the services of PAs, NPs, and CNSs, as specified under section 1833(a)(1)(O) of

the Act, is equal to 80 percent of the lesser of the NPP's actual charge or 85 percent of the amount that would be paid to a physician under the PFS. However, while NPs and CNSs are authorized to bill the Medicare program and be paid directly for their professional services, section 1842(b)(6)(C)(i) of the Act has required since the inception of the PA benefit (with a narrow exception not relevant here), that payment for PA services must be made to the PA's employer. Accordingly, our regulation at § 410.74(a)(2)(v) specifies that PA services are covered under Medicare Part B only when billed by the PA's employer. Our regulation that addresses to whom Medicare Part B payment is made, at § 410.150(b)(15), further provides that payment is made to the qualified employer of a PA, and specifies that the PA could furnish services under a W–2 employment relationship, an employer-employee relationship, or as an independent contractor through a 1099 employment relationship. The regulation also specifies that a group of PAs that incorporate to bill for their services is not a qualified employer. Given the statutory requirement that we make payment to the PA's employer, PAs are precluded from directly billing the Medicare program and receiving payment for their services, and do not have the ability to reassign Medicare payment rights for their services to any employer, facility, or billing agent.

Section 403 of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260, December 27, 2020), amended section 1842(b)(6)(C)(i) of the Act to remove the requirement to make payment for PA services only to the employer of a PA effective January 1, 2022. With the removal of this requirement, PAs will be authorized to bill the Medicare program and be paid directly for their services in the same way that NPs and CNSs do. Effective with this amendment, PAs also may reassign their rights to payment for their services, and may choose to incorporate as a group comprised solely of practitioners in their specialty and bill the Medicare program, in the same way that NPs and CNSs may do. We note that the amendment made by section 403 of the CAA changed only the statutory billing construct for PA services. It changed neither the statutory benefit category for PA services, including the requirement that PA services are performed under physician supervision, at section 1861(s)(2)(K)(i) of the Act, nor the statutory payment percentage applicable to PA services specified in section 1833(a)(1)(O) of the Act. However, with the amendments to the PA physician supervision requirement under § 410.74(a)(2)(iv) made beginning in CY 2020, PAs have flexibility to meet the statutory physician supervision requirement through collaborating with physicians and forming partnerships as long as this is in accordance with their State scope of practice laws. Now that PAs are authorized to bill Medicare directly, we believe that PAs will furnish more services under collaborative relationships with physicians, likely in rural areas or underserved communities where Medicare beneficiaries may have less direct access to care by physicians because of a lack of physicians.

We proposed to amend pertinent sections of our regulations to reflect the amendment made by section 403 of the CAA. Specifically, we proposed to amend § 410.74(a)(2)(v) to specify that the current requirement that PA services must be billed by the PA's employer in order to be covered under Medicare Part B is effective only until December 31, 2021. We also proposed to amend § 410.150(b) to redesignate the current requirements in paragraph (b)(15) as § 410.150(b)(15)(i), and to provide that Medicare payment is made for PA services to the qualified employer of the PA for services furnished prior to January 1, 2022. In § 410.150, we further proposed to add a new paragraph (b)(15)(ii) to state that, effective for services furnished on or after January 1, 2022, payment is made to a PA for their professional services, including services and supplies provided incident to their services. We proposed to conform this new paragraph with the regulation at § 410.150(b)(16) regarding to whom payment is made for NP or CNS services. As such, the new paragraph at § 410.150(b)(15)(ii) would provide that payment is made to a PA for professional services furnished by a PA in all settings in both rural and non-rural areas; and that payment is made only if no facility or other provider charges or is paid any amount for services furnished by a PA. We would also update our program manual instructions to reflect the statutory change made by section 403 of the CAA and the changes to our regulations.

We received public comments on these proposals to amend the current requirements. The following is a summary of the comments we received and our responses.

Comment: Overall, the commenters supported this proposal that authorizes PAs to bill the Medicare program and be paid directly for their services. Commenters stated that this billing authorization simplifies the billing process for PAs in that it does not tie billing for PA services directly to employment which eliminates an administrative burden for employers; and, it provides billing parity between PAs and other NPPs such as NPs and CNSs, which may help to increase access to PA services, particularly in rural areas. Additionally, these commenters expressed their appreciation for this new billing authority that makes PAs eligible for the option to reassign payment for their services to their employer, independent contractor, or group practice and, to incorporate as a group of PAs and bill the Medicare program for PA services.

Response: We appreciate that commenters support the changes we proposed to implement section 403 of the CAA effective January 1, 2022.

Comment: A few commenters opposed our proposals to implement section 403 of the CAA. These commenters disapprove of the change to the statutory billing construct that authorizes PAs to bill the Medicare Part B program directly beginning January 1, 2022. Instead, these commenters support continued third-party payment to the PA's employer or independent contractor for PA services furnished collaboratively with physicians to deliver care led by physicians in integrated practice arrangements.

Response: While we appreciate the commenters' concerns, section 403 of the CAA amended the statute effective January 1, 2022. Our proposals simply implement the amended Medicare law.

Comment: Several commenters expressed concerns that this direct billing authority for PAs might undermine the proven physician-led-team based care model under which PAs, NPs and CNSs are integral team members, and instead encourage independent practice by these NPPs. These commenters requested that CMS establish oversight of PA billing practices to ensure that PAs are practicing in accordance with State law and scope of practice rules; that quality of care for Medicare beneficiaries is maintained; and, that the Medicare Trust Fund is protected.

Response: We do not anticipate that this change will impact the participation of NPPs as vital team members of physician-directed-team care models, or otherwise diminish the quality of health care furnished to Medicare beneficiaries. As provided in Medicare law at section 1861(s)(2)(K)(i) of the Act, PA services must be furnished under the supervision of a physician and, also in our regulation at § 410.74(a), PA services are covered

only when furnished in accordance with State law and scope of practice rules.

Comment: One commenter suggested that allowing PAs to bill the Medicare program directly would require updates to Medicare enrollment and billing for PAs, and that the program should consider adopting a grace period to allow CMS to implement revisions to the CMS–855I, CMS–855R and related enrollment forms.

Response: We appreciate the concerns the commenter raised about the time required to update necessary reassignment and enrollment forms. However, we have prepared to update these forms to accommodate the change to allow direct billing by PAs effective January 1, 2022.

After considering public comments, we are finalizing our proposals to implement section 403 of the CAA as proposed.

H. Therapy Services

1. Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

We are implementing the third and final part of the amendments made by section 53107 of the Bipartisan Budget Act (BBA of 2018) (Pub. L. 115–123, February 9, 2018). The BBA of 2018 added a new section 1834(v) of the Act. Section 1834(v)(1) of the Act requires CMS to make a reduced payment for physical therapy and occupational therapy services furnished in whole or in part by PTAs and OTAs at 85 percent of the otherwise applicable Part B payment for the service, effective January 1, 2022.

Section 1834(v)(2) of the Act requires that: (1) By January 1, 2019, CMS must establish a modifier to indicate that a therapy service was furnished in whole or in part by a PTA or OTA; and, (2) beginning January 1, 2020, each claim for a therapy service furnished in whole or in part by a PTA or an OTA must include the modifier. Section 1834(v)(3) of the Act requires CMS to implement these amendments through notice and comment rulemaking.

In the CY 2019 PFS final rule (83 FR 59654 through 59660), we established the CQ and CO modifiers that were required to be used by the billing practitioner or therapy provider to identify therapy services provided in whole or in part by PTAs and OTAs, respectively, beginning January 1, 2020. We require these payment modifiers to be appended on claims for therapy services, alongside the GP and GO therapy modifiers which are used to indicate the services are furnished under a physical therapy or occupational therapy plan of care, respectively. The payment modifiers are defined as follows:

- CQ modifier: Physical therapy services furnished in whole or in part by PTAs.
- CO modifier: Occupational therapy services furnished in whole or in part by OTAs.

In the CY 2019 PFS final rule (83 FR 59654 through 59660), we did not finalize our proposed definition of ''furnished in whole or in part by a PTA or OTA'' as a service for which any minute of a therapeutic service is furnished by a PTA or OTA. Instead, in response to public comments, we finalized a *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA.

In the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852, and 83 FR 59654 through 59660, respectively), we explained that the CQ and CO modifiers would not apply to claims for outpatient therapy services that are furnished by, or incident to, the services of, physicians or NPPs including NPs, PAs, and CNSs. This is because our outpatient physical and occupational therapy services regulations require that the individual who performs outpatient therapy services incident to the services of a physician or NPP must meet the qualifications and standards for a therapist (other than State licensure). As such, only therapists, and not therapy assistants, can perform outpatient therapy services incident to the services of a physician or NPP (83 FR 59655 through 59656); and the modifiers to describe services furnished in whole or in part by a PTA or OTA are not applicable to the claim for a therapy service billed by a physician or NPP incident to their professional services. We indicated that we would add this distinction in the provision of the Medicare Benefit Policy Manual (MBPM) Chapter 15 that discusses therapy services furnished incident to the physician's or NPP's services at section 230.5, as well as the sections that discuss PTA and OTA services at sections 230.1 and 230.2, respectively.

In the CY 2020 PFS proposed and final rules (84 FR 40558 through 40564 and 62702 through 62708, respectively), we explained that the CQ/CO modifiers and the *de minimis* policy would apply to both untimed and timed codes. The untimed codes are evaluation and reevaluation codes, group therapy and supervised modalities, and when these are billed, only one unit is reflected in the ''units'' portion of the claim. When the PTA/OTA provides more than 10 percent of the service, the code is billed with a CQ/CO modifier. For timed codes, that is, those codes defined in 15-minute increments, the services are typically performed in multiple units of the same and/or different codes for a patient on one treatment day. We explained that under our policy, the therapist or therapy assistant needs to find the total time of all these 15-minute timed codes in order to determine the number of units that can be billed for that day. For example, if the PT/OT and/or the PTA/OTA, as appropriate, furnished between 8 minutes through 22 minutes, one unit can be billed; if 23 minutes through 37 minutes are provided, 2 units can be billed; if 38 minutes through 52 minutes are furnished, 3 units can be billed. Once the total number of units to bill is determined, the qualified professional (therapist or assistant) then needs to decide whether the CQ/CO modifier is applicable.

In the CY 2020 PFS proposed rule (84 FR 40558 through 40564), we proposed that the time the PTA/OTA spent together with the PT/OT in performing a service, as well as the time the PTA/OTA spent independent of the PT/OT treating the patient, is considered time for which the service is furnished in whole or in part by the PTA/OTA. As explained in the CY 2020 PFS final rule (84 FR 62702 through 62708), many commenters objected to our proposal to include as time that the therapy service is furnished ''in whole or in part'' by the PTA/OTA both the minutes spent by the PTA/OTA concurrently with and separately from the therapist. These commenters also expressed concerns that this policy would unfairly discount services that are fully furnished by therapists, and in which the therapy assistant supports them while they provide a service. We were persuaded by commenters to finalize a policy to not include as minutes furnished in whole or in part by a PTA/OTA the minutes in which the PTA/OTA worked concurrently with the PT/OT. We agreed with the commenters that when a therapy assistant and therapist furnish care to a patient at the same time, the patient requires both professionals, and this reflects a clinical scenario where the assistant is helping the therapist to provide a highly skilled procedure or one in which both professionals are needed for safety reasons. We modified our proposed regulation text at §§ 410.59 (outpatient occupational therapy), 410.60 (physical therapy), and 410.105 (for PT and OT Comprehensive

Outpatient Rehabilitation Facility (CORF) services) accordingly.

For purposes of deciding whether the 10 percent *de minimis* standard is exceeded, we offered two different ways to compute this.

- The simple method: Divide the total of the PTA/OTA + PT/OT minutes by 10, round to the nearest integer then add 1 minute to get the number of minutes needed to exceed the *de minimis* standard at and above which the CQ/CO modifier applies.
- The percentage method: Divide the PTA/OTA minutes by the sum of the PTA/OTA and therapist minutes and then multiply this number by 100 to calculate the percentage of the service that involves the PTA/OTA, if this number is greater than 10 percent the CQ/CO modifier applies.

Hypothetical examples of each of these methods are included later in this section. In response to our proposal that all the units of one service needed to be considered when determining if the *de minimis* is applied, commenters requested that we consider each 15-minute unit instead—noting that they would be able to apply the CQ/CO modifier on one claim line for a service that was provided by the PTA/OTA and report another claim line without the CQ/CO for the service provided by the PT/OT. We were persuaded by stakeholders, and finalized a policy under which the *de minimis* standard is applied for each 15-minute unit of a service. This allows the separate reporting, on two different claim lines, of the number of 15-minute units of a code to which the therapy assistant modifiers do not apply, and the number of 15-minute units of a code to which the therapy assistant modifiers do apply. However, we neglected to modify the text of our regulations to reflect this final policy for applying the *de minimis* standard; therefore, we proposed to revise our regulation text to specify that the *de minimis* rule is applied to each 15-minute unit of a service, rather than to all the units of a service at §§ 410.59(a)(4)(iii)(B), 410.60(a)(4)(iii)(B), and 410.105(d)(3)(ii). The specific revisions are discussed below.

To recap, we finalized a *de minimis* standard to identify when the CQ/CO modifiers apply and when they do not apply as follows:

- Portions of a service furnished by the PTA/OTA independent of the physical therapist/occupational therapist, as applicable, that do not exceed 10 percent of the total service (or 15-minute unit of a service) are not considered to be furnished in whole or in part by a PTA/OTA, so are not subject to the payment reduction;
- Portions of a service that exceed 10 percent of the total service (or 15-minute unit of a service) when furnished by the PTA/OTA independent of the therapist must be reported with the CQ/CO modifier, alongside of the corresponding GP/GO therapy modifier; are considered to be furnished in whole or in part by a PTA/OTA, and are subject to the payment reduction; and
- Portions of a service provided by the PTA/OTA together with the physical therapist/occupational therapist are considered for this purpose to be services provided by the therapist.

In the CY 2020 PFS proposed rule (84 FR 40558 through 40564), we proposed to adopt a documentation requirement that a short phrase or statement must be added to the daily treatment note to explain whether the therapy assistant modifier was or was not appended for each therapy service furnished. We also sought comment on whether it would be appropriate to also require documentation of the minutes spent by the therapist or therapy assistant along with the CQ/CO modifier explanation as a means to avoid possible additional burden associated with a contractor's medical review process conducted for these services. Many commenters stated that: (1) The statute does not require documentation to explain why a modifier was or was not applied for each code; (2) the proposed documentation requirements are exceedingly burdensome and conflict with the agency's ''Patients over Paperwork Initiative''; (3) the proposed documentation requirement that calls for a narrative phrase in the treatment note and requires documentation of the minutes is duplicative of current requirements that requires adding the total timed code minutes and total treatment time (includes timed and untimed codes) to the daily treatment note; and, (4) the Medicare Benefit Policy Manual (MBPM) already includes extensive documentation requirements. In response to the feedback, we did not finalize the proposed documentation requirement; nor did we finalize a requirement that the therapist and therapy assistant minutes be included in the documentation. Instead, we reminded therapists and therapy providers that correct billing requires sufficient documentation in the medical record to support the codes and units reported on the claim, including those reported with and without an assistant modifier. Further, in agreement with many commenters, we clarified that we would expect the documentation in the medical record to be sufficient to know whether a specific service was furnished independently by a therapist or a therapist assistant, or was furnished ''in part'' by a therapist assistant, in sufficient detail to permit the determination of whether the 10 percent standard was exceeded.

In the CY 2020 PFS proposed rule, we also provided multiple typical clinical billing scenarios to illustrate when the CQ/CO modifier would and would not be applicable. Because these clinical scenarios did not convey our finalized policies as modified in response to public comments, we indicated in the CY 2020 PFS final rule that we would provide further detail regarding the clinical scenario examples to illustrate how to use the therapy assistant modifiers through information we would post on the *cms.gov* website. We clarified that our revised finalized policy applied generally in the same way as illustrated in those examples, except for the difference in the minutes of time that are counted toward the 10 percent standard (not counting the minutes furnished together by a therapist and therapy assistant), the application of the 10 percent standard to each billed unit of a timed code rather than to all billed units of a timed code, and the billing on two separate claim lines of the units of a timed code to which the therapy assistant modifiers do and do not apply.

In early March 2021, we posted on our Therapy Services website at *https://www.cms.gov/Medicare/Billing/TherapyServices* general guidance on how to assign the CQ/CO modifiers for multiple billing scenarios. In the guidance, we provided general examples for 8 different billing scenarios in which multiple units of 15-minute codes are provided by PTs/OTs and PTAs/OTAs and one billing example that used the untimed code for group therapy performed for equal minutes by a PT and a PTA.

We noted that prior to applying our rules to determine appropriate application of the CQ/CO modifiers, the PTA/OTA or PT/OT first needs to determine how many 15-minute units can be billed in a single treatment day for a patient. For information on this topic, we referred readers to the chart in section 20.2.C of Chapter 5 of the Medicare Claims Processing Manual (MCPM) that describes how to count minutes for timed codes defined by 15-minute units, since the therapist or assistant should use the same counting rule, commonly known as the ''8-minute rule,'' that they have used previously.

Once the therapist or therapy assistant has identified the number of 15-minute units that can be billed for a patient on

a single treatment day, we provided the following information to clarify how to apply our policy for application of the CQ and CO modifiers, as follows:

Step 1. Identify the Timed HCPCS Codes Furnished for 15 Minutes or More: List the code numbers of each of the services furnished along with the number of minutes in total done by the PT, PTA, OT, or OTA. When a PT, PTA, OT, or OTA provides at least 15 minutes and less than 30 minutes of a service on a single treatment day, assign 1 unit; when multiples of 15 minutes are furnished, for example, 30 minutes (assign 2 units) and 45 minutes (assign 3 units), etc. This needs to be the first step whenever it is applicable to the billing scenario. When any of these services, that is, full 15-minute increments, are provided by a PTA/OTA, the CQ/CO modifiers apply.

Step 2. Identify Services for Which the PT/OT and PTA/OTA Provide Minutes of the Same HCPCS Code: After applying Step 1, where applicable, identify any minutes (including remaining minutes from Step 1) performed by a PT/OT and PTA/OTA for the same service/code. Add the minutes furnished by the PT/OT and the PTA/OTA together, then divide the total by 10 and round to the nearest integer—this is the 10 percent *de minimis* time standard. Then add 1 minute to get the fewest number of minutes performed by the PTA/OTA that would exceed the 10 percent time standard for that service—if the PTA/OTA minutes meet or exceed this number, the CQ/CO modifier would be appended. This is the ''simple'' method for calculating the *de minimis* number of minutes.

Step 3. Identify Services Where the PT/OT and PTA/OTA Furnish Services of Two Different Timed HCPCS Codes: After applying Step 1 for each service, compare the remaining minutes furnished by the PT/OT for one service with the remaining minutes furnished by the PTA/OTA for a different service. Assign the CQ/CO modifier to the service provided by the PTA/OTA when the time they spent is greater than the time spent by the PT/OT performing the different service. The CQ/CO modifier does not apply when the minutes spent delivering a service by the PT/OT are greater than the minutes spent by the PTA/OTA delivering a different service.

Step 4. Identify the Different HCPCS Codes Where the PT/OT and the PTA/OTA Each Independently Furnish the Same Number of Minutes: Once Step 1 is completed for each service (when applicable), and when the remaining minutes for each service—one provided by the PT/OT and the other provided by the PTA/OTA—are the same, either service may be billed. If the service provided by the PT/OT is billed, the CQ/CO modifier does not apply. However, if the service provided by the PTA/OTA is billed, the CQ/CO modifier does apply.

The below two examples are taken from our guidance on the CMS website. These are examples of when the PT and PTA provide minutes of the same service:

Example #1

PTA—23 minutes 97110
PT—13 minutes 97110
PT—30 minutes 97140
Total = 66 minutes—qualifies for billing 4 units (53 minutes through 67 minutes)

Billing Explanation:

- *First Step:* Assign units to services based on those that have at least 15 minutes or codes that were provided in multiples of 15 minutes. For 97110, assign one unit of 97110 with the CQ modifier because the PTA furnished at least 15 minutes of 97110 (therapeutic exercise). Then, assign two units of 97140 without the modifier, because the PT furnished the full 30 minutes of manual therapy.
- *Second Step:* Determine if the PTA furnished more than 10 percent of the remaining minutes of the 97110 service. To do this via the simple method: Add the PTA's 8 remaining minutes to the PT's 13 minutes for a total time of 21 minutes. Divide the total by 10 to get 2.1 minutes and round to the nearest integer, which is 2 minutes (the 10 percent time standard for this service). Add 1 minute to find the threshold number of minutes that would exceed the *de minimis* standard, which in this example is 3 minutes. Using the percentage method, divide the PTA's remaining 8 minutes by the total 21 minutes of the service (8 PTA + 13 PT = 21 minutes) to get 0.38, then multiply the result × 100 = 38 percent.

Final Step: Because 8 minutes meets or exceeds the 3-minute threshold, and 38 percent is greater than 10 percent, a second unit of 97110 is billed with the CQ modifier.

Example #2

PTA—19 minutes of 97110
PT—10 minutes of 97110
Total = 29 minutes—two units of 97110 can be billed (23 minutes through 37 minutes).

Billing Explanation:

- *First Step:* Bill one unit of 97110 with the CQ modifier because a full 15 minutes was provided by the PTA, with 4 minutes remaining.
- *Second Step:* Determine if the PTA's 4 remaining minutes exceed the 10 percent de minimis standard. Simple method: Add together the PTA's 4 remaining minutes and the 10 PT minutes to get the total time of 14 minutes and divide by ten to get 1.4 minutes and round to the nearest integer = 1 minute to get the 10 percent de minimis standard. Then add 1 minute to get a threshold minimum of 2 minutes for PTA time. If the PTA minutes are at or above the threshold, the CQ modifier applies. Percentage method: Divide the PTA's 4 remaining minutes by the total time of 14 to get 0.29 then multiply by 100 = 29 percent. If the resulting percentage is greater than 10 percent, the PTA modifier applies.
- *Final Step:* Bill another unit of 97110 with the CQ modifier since 4 minutes is greater than the 2-minute threshold minimum and 29 percent is greater than 10 percent.

After reviewing the information posted on the CMS Therapy Services web page, therapy stakeholders reached out to CMS to express concern that certain aspects of the billing scenarios described in the guidance contradict their interpretation of our de minimis policy, especially as it applies to a final unit of a multiple-unit timed service. The therapy stakeholders suggested that the guidance we offered would lead to confusion for the same-service billing scenarios (including examples #1 and #2 above). We consider the unit of measure for a timed therapy service code to be 15 minutes. In billing scenarios with multiple units, we would consider the combined time for same or different services in 15-minute unit increments.

The stakeholders agree that the de minimis standard is applied to the last unit of a timed therapy service code in two separate cases. The first case happens when the PTA/OTA and the PT/OT each furnish less than 8 minutes for that final unit of a service. For example, if the PTA/OTA provided 7 minutes and the PT/OT furnished 5 minutes—using the simple method: 12 minutes divided by 10 equals 1.2, rounded to the nearest integer is 1, plus 1 equals 2—if the PTA/OTA provides 2 or more minutes, the CQ/CO modifier is applied. The second case occurs when the PTA/OTA provides 8 or more minutes and the PT/OT furnishes less than 8 minutes—in which event, the de minimis standard is exceeded and the CQ/CO modifier is applied.

We note that the therapy stakeholders' interpretation of when the de minimis policy applies for a final 15-minute unit of a multiple unit timed service is based on what is commonly termed the ''8-minute rule'' which recognizes a unit of a 15-minute timed therapy service code

as 8 minutes (more than the midpoint of the service or 7.5 minutes), but only when it applies to the final unit billed. Applied to the above two examples, the stakeholders informed us that they believe the second unit of CPT code 97110 in both examples should not be billed with an assistant modifier because the therapist provided enough minutes of the service on their own, that is, 8 minutes or more, to bill for the last unit without the assistant's additional minutes. The stakeholders indicated that the therapist would have a financial incentive to not have the PTA/OTA provide the additional minutes at all if the CQ or CO modifier would apply. We note that, in addition to the two cases discussed above, there is another billing scenario to address in the context of our de minimis policy—specifically, where the PT/OT and PTA/OTA each furnish between 9 and 14 minutes of a 15-minute timed service when the total time of therapy services furnished in combination by the PTA/OTA and PT/OT is at least 23 but no more than 28 minutes, and there are two remaining units left to be billed. These ''two remaining unit'' cases with time ranges between 9 and 14 minutes include the following PTA/OTA:PT/OT (or vice versa) time splits: 9:14, 10:13, 11:12, 12:12, 12:13, 12:14, 13:13; 13:14; and 14:14.

We believe that the stakeholder's interpretation of the de minimis standard is not consistent with the de minimis policy we finalized in the CY 2020 PFS final rule (84 FR 62702 through 62708). However, in working through the billing scenarios with the stakeholders, we identified where we could make refinements to our policy to address some of the confusion and concerns expressed by stakeholders and to address the ''two remaining unit'' cases noted above. These refinements may also avoid implementing a payment policy that could be perceived to penalize the provision of additional care by a therapy assistant when those minutes of service would lead to a reduced payment for a unit of a service. The stakeholders criticized the finalized de minimis policy because they believed it provides an inherent financial incentive for the therapist to ensure that PTAs/OTAs provide services in exactly 15-minute intervals—to avoid any leftover PTA/OTA minutes that could necessitate application of the CQ/CO modifier, and reduced payment, for the service that the therapist is also providing—without regard to the clinical needs of the individual patient. The stakeholders suggested that if we were to recognize their ''8-minute rule'' and recommended policy, we would remove the incentive for the therapist to avoid providing appropriate minutes of therapy services performed by the PTA/OTA.

To address the concerns expressed by the stakeholders and the ''two remaining unit'' cases we identified in our review, we proposed to modify our existing policy, specifically for billing scenarios when only one unit of a timed therapy service remains to be billed (the majority of all billing scenarios) and the ''two remaining unit'' cases described above. As shown in Table 28, this policy requires the application of the CQ/CO modifier when the PTA/OTA provides at least 8 minutes or more and the PT/OT provides less than 8 minutes of the service; or, when both the PT/OT and the PTA/OTA provide less than 8 minutes of the same service.

TABLE 28: Billing Scenario Examples Where CQ/CO Modifier Applies

	Billing Scenario	Stakeholders' Rules
Scenario 1	PT/OT (6 minutes) + PTA/OTA (8 minutes) - for a total of 14 minutes.	The PTA/OTA provided 8 minutes or more and the PT/OT provided less than 8 minutes; therefore, the *de minimis* standard is exceeded. Bill with the CQ/CO modifier.
Scenario 2	PT (5 minutes) + PTA/OTA (5 minutes) - for a total of 10 minutes.	Both the PT/OT and the PTA/OTA provided less than 8 minutes; so the *de minimis* standard is exceeded. Bill with the CQ/CO modifier

Under this modification, the CQ/CO modifier would not apply when the PT/OT furnishes 8 minutes or more, or both the PT/OT and the PTA/OTA furnish 8 minutes or more, of a timed service. This ''midpoint rule'' policy was suggested to us by the therapy stakeholders. We agree that since, in this circumstance, the PT/OT provided enough minutes of the service on their own to bill the last unit of the service, the additional minutes of service performed by the PTA/OTA are not material, and thus, should be disregarded, as shown in the examples in Table 29.

TABLE 29: Billing Scenario Examples Where the "Midpoint Rule" Applies

	Billing Scenario	Therapy Stakeholder Midpoint Rule
Scenario 1	PT (8 minutes) + PTA/OTA (7 minutes) — for a total of 15 minutes.	The PT/OT bills without the CQ/CO modifier because they provided enough minutes on their own (8 minutes or more) without the PTA's/OTA's time to bill the one unit. Disregard PTA/OTA minutes.
Scenario 2	PT (11 minutes) + PTA/OTA (11 minutes) - for a total of 22 minutes.	The PT/OT bills without the CQ/CO modifier because they provided enough minutes on their own (8 minutes or more) without the PTA's/OTA's time to bill the one unit. Disregard PTA/OTA minutes.

With these policy adjustments, the CQ/CO modifiers apply when the PTA/OTA provides all the minutes of a timed service, and to some services (as illustrated in Table 28) when the PTA/OTA and PT/OT each, independent of the other, furnish portions of the same timed service. The CQ/CO modifiers also apply if the portion of an untimed code furnished by the PTA/OTA exceeds the de minimis standard. The CQ/CO modifiers do not apply when the PTA/OTA and the PT/OT furnish different services. Time spent by the PT/OT and PTA/OTA providing services together is considered time spent by the PT/OT for purposes of applying the de minimis standard. Finally, we proposed to modify our policy so that the CQ/CO modifiers would not apply when the PT/OT provides enough minutes of the service on their own to bill for the last unit of a timed service, (more minutes than the midpoint or 8 minutes of a 15-minute timed code) regardless of any additional minutes for the service provided by the PTA/OTA.

Examples of Billing Scenarios using the CQ/CO modifiers when the de minimis standard applies, and the proposed policy for the last billed unit of a service:

Example #A

PTA—10 minutes of 97110
PT—5 minutes of 97110
Total = 15 minutes—qualifies to bill one 15-minute unit (8 minute to 22 minutes).

Analysis: Bill one unit of 97110 with the CQ modifier because the PTA provided 8 minutes or more and the PT provided less than 8 minutes. The de minimis standard applies in these cases.

Example #B

PTA—5 minutes of 97110
PT—6 minutes of 97110
Total = 11 minutes—qualifies to bill one 15-minute unit (8 minute through 22 minutes).

Analysis: Bill one unit of 97110 with the CQ modifier because the PTA and the PT both provided less than 8 minutes. In this case, the PT provided 6 minutes and the PTA furnished 5 minutes independent of each other. The de minimis standard applies in these cases.

Example #C

PTA–22 minutes of 97110
PT—23 minutes of 97110
Total = 45 minutes—qualifies to bill three 15-minute units (38 minutes through 52 minutes).

Analysis:

• Apply Step One of the general policy rules and bill one unit of 97110 with the CQ modifier because the PTA provided 15 full minutes with 7 minutes remaining.

• Apply Step One to the PT's 23 minutes and bill one unit without the assistant modifier with 8 minutes remaining.

• The third unit of 97110 is billed without the assistant modifier because the therapist provided enough minutes (8 or more minutes) without the PTAs minutes to bill the final unit.

Example #D—Also See the Below Regulatory Proposal Using This 'Two Remaining Unit' Example

PT—12 minutes of 97110
PTA—14 minutes of 97110
PT—20 minutes of 97140
Total = 46 minutes—qualifies to bill three units (38 minutes through 52 minutes)

Analysis:

• Apply Step One of the general policy rules and bill one unit of 97140 without the CQ modifier because the PT provided 15 full minutes of one unit with 5 minutes remaining.

• Two units remain to be billed and the PT and the PTA each provided between 9 and 14 minutes independent of one another with a total time between 23 and 28 minutes—in these ''two remaining unit'' scenarios, one unit is billed with the CQ modifier for the PTA and the other unit is billed without it for the PT.

• The PT's 5 remaining minutes of 97140 are counted towards the total timed minutes but are not billable in this scenario.

Example #E

OTA—11 minutes of 97535
OT—11 minutes of 97530
Total = 22 minutes—qualifies to bill one (1) unit (8 minutes through 22 minutes)

Billing Analysis: Since two different services were furnished for an equal number of minutes—the ''tie-breaker'' scenario applies. Either code 97530 by the OT or code 97535 by the OTA can be billed in accordance with a billing example in the MCPM, Chapter 5, section 20.2.C. Either one unit of 97530 is billed without the CO modifier or one unit of 97535 is billed with the CO modifier.

Example #F: Untimed Code—1 Unit Is Billed for All Untimed Codes Including Evaluations, Reevaluations, Supervised Modalities, and Group Therapy

OTA—20 minutes 97150 independent of the OT
OT—20 minutes 97150 independent of the OTA
Total = 40 minutes of Group Therapy = 1 unit of 97150 is billed for each group member

Billing Analysis: One unit of group therapy 97150 is billed with the CO modifier because the OTA provided more than the 10 percent time standard in this example. Either method can be used to determine if the OTA's time exceeded the 10 percent time standard for this clinical scenario, see below:

• *The simple method:* First add the OTA's 20 minutes to the OT's 20 minutes to get 40, then divide by 10 to get 4.0 and add 1 to equal 5 minutes. The OTA's 20 minutes is equal to or greater than 5 minutes so the CO modifier is required on the claim.

• *The percentage method:* Divide the number of minutes that an OTA independently furnished a service by the total number of minutes the service was furnished as a whole—20 divided by 40 equals 0.50. Then multiple by 100 to get 50 percent, which is greater than 10 percent. The CO modifier is applied to 97150.

• *Tie breaker:* The tie breaker does not apply in this scenario because the example does not contain two different timed codes described in 15-minute intervals. For ''tie breaker'' see Example #F above.

As noted above and illustrated in Example #D, there are a finite number of cases where there are two 15-minute units left to bill. In these ''two remaining unit'' cases, the PTA/OTA and the PT/OT each provide between 9 and 14 minutes with a total time of at least 23 minutes through 28 minutes. Under our proposed policy, one unit of the service would be billed with the CQ/CO modifier for the minutes furnished by the PTA/OTA (who furnished between 9 and 14 minutes of the service), and one unit would be billed without the CQ/CO modifier for the service provided by the PT/OT (who also furnished between 9 and 14 minutes of the same service). This is because the PTA/OTA and the PT/OT each independently furnished part of each unit of the same service, and these cases are not addressed by the proposed midpoint rule that would apply when there is only one single unit left to bill. We proposed to amend our regulation to address the scenario where there are two remaining 15-minute units of the same service for which the PTA/OTA and the PT/OT each provided between 9 and 14 minutes with a total time of at least 23 minutes and no more than 28 minutes. In this scenario, we proposed that one unit of the service will be billed with the CQ/CO modifier and the other unit of the service will be billed without

the assistant modifier. We proposed to add this policy to our regulations at §§ 410.59(a)(4)(v) and 410.60(a)(4)(v) for outpatient occupational therapy and physical therapy services, respectively and at § 410.105(d)(3)(iv) for CORF services.

As noted previously, when we finalized the policy to consider each 15-minute unit of a service for purposes of determining whether the *de minimis* standard applies, we neglected to revise our regulations at §§ 410.59, 410.60 and 410.105 to reflect this change. As such, we proposed to amend the regulations at §§ 410.59(a)(4)(iii)(B) and 410.60(a)(4)(iii)(B) for outpatient occupational therapy and physical therapy services, respectively, and at § 410.105(d)(3)(ii) for CORF services to specify that we consider a service to be furnished in part by a PTA or an OTA when the PTA/OTA furnishes a portion of a service, or in the case of a 15-minute timed code, a portion of a unit of a service, separately from the portion of the service or unit of service furnished by the therapist such that the minutes for that portion of a service or a unit of a service furnished by the PTA/OTA exceed 10 percent of the total minutes for that service or unit of a service.

To accommodate the proposed refinement of the *de minimis* policy, we proposed to amend the same regulations at §§ 410.59(a)(4)(iv) and 410.60(a)(4)(iv) for outpatient occupational therapy and physical therapy services, respectively, and at § 410.105(d)(3)(iii) for CORF services to provide that, for the final 15-minute unit billed for a patient for a date of service, when the PT/OT provides more than the midpoint (at least 8 minutes) of a service such that they could bill for the service without any additional minutes being furnished by the PTA/OTA, the service may be billed without a CQ or CO modifier, and any remaining minutes of service furnished by the PTA/OTA are considered immaterial.

Beginning January 1, 2022, therapy services furnished in whole or in part by a PTA or OTA will be identified based on the inclusion by the billing therapy services provider (whether a therapist in private practice or therapy provider) of the CQ or CO modifier, respectively, on claim lines for therapy services, and the payment for those services will be adjusted as required by section 1834(v)(1) of the Act. Per our usual system update process, we plan to issue instructions in a change request to prepare our shared systems and Medicare Administrative Contractors (MACs) to pay the reduced amount for therapy services furnished in whole or in part by a PTA or OTA. We will issue a Medlearn Learning Network® (MLN) article once the CR is released, after the CY 2022 PFS final rule is issued.

When we identified a limited number of cases in which there are two 15-minute units left to bill and the PTA/OTA and the PT/OT each provide between 9 and 14 minutes with a total time of 23 through 28 minutes, where we proposed that one unit is billed with an assistant modifier and one unit is billed without it, we have identified four additional examples of PTA/OTA:PT/OT (or vice versa) time splits that we would like to acknowledge—these instances include 10:14, 11:13, 11;14, and 13:12. The full complement of these time splits are: 9:14, 10:13, 10:14, 11:12, 11:13, 11:14, 12:12, 12:13, 12:14, 13:12, 13:13, 13:14, and 14:14.

We are making a technical correction to the proposed regulation text at § 410.105(d)(3)(iii) that appeared in the CY 2022 PFS proposed rule, to remove an extra parenthesis ''('' as it appeared in ''((ii)'' so that the CORF regulation at § 410.105(d)(3)(iii) correctly reads as ''(iii) Paragraph (d)(3)(ii)''.

We solicited comment on all of our proposals.

We received over 12,000 public comments on our proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters, including the major therapy stakeholders, expressed appreciation that we updated the interpretation of the *de minimis* standard to take into account the ''8-minute rule'' for the final unit billed. One commenter conveyed their belief that this policy is sound and will ensure that therapists and therapy providers are not paid less for providing more care. A few commenters also supported our explanation and proposal to bill one unit of a service with the CQ/CO modifier and one unit without a CQ/CO modifier when the PTA/OTA and the PT/OT each provide between 9 and 14 minutes of a 15-minute timed service with a total time of 23 to 28 minutes where there are two units left to bill.

Response: We appreciate that commenters are supportive that we revised our *de minimis* policy in response to specific requests from the major therapy stakeholders regarding the ''8-minute rule'' for the final unit billed; and, thank the commenter for their remark about the soundness of this policy that permits therapists and therapy providers to furnish proper care without being paid less for the service. We also appreciate that others specifically supported our proposal to further refine our *de minimis* policy for those limited number of cases where there are 2 15-minute units remaining to be billed.

Comment: Many commenters supported and welcomed the refinement to the de minimis standard; however, many others requested that CMS delay implementation of the therapy assistant payment policy until CY 2023 so that: (a) Therapists and therapy assistants would have the time to implement the final policy changes; (b) we have additional time to provide education and technical assistance to providers on what some term as a complex policy; (c) electronic medical record (EMR) vendors have time to program, test, and finalize their systems; and (d) therapists in private practice and therapy providers have time to recover financially from the coronavirus pandemic. We also received several positive comments regarding the implementation of the therapy assistant payment policy, effective January 1, 2022.

In requesting the one-year delay of the 15 percent payment reduction for services furnished in whole or in part by PTAs, one commenter noted that the reduction alone would be a challenge in non-pandemic times, and stated that the total reduction in payment to physical therapists and therapy providers will total nearly 28 percent in the midst of the ongoing pandemic. The commenter described the nearly 28 percent reduction as the cumulative 27.75 percent reduction in payment that includes the 15 percent reduction for services furnished in whole or in part by PTAs, plus the 3.75 percent reduction in Medicare payment, and a 7 percent (on average) reduction in payment due to the MPPR, and the 2 percent Medicare sequester that is scheduled to return in CY 2022. The commenter cited these reductions in combination with the ongoing effects of the PHE for COVID–19 as support to delay the implementation of the 15 percent PTA payment differential until January 1, 2023.

Response: We are not able to change the implementation date as the statute at section 1834(v)(1) of the Act specifies that the payment adjustment for physical therapy and occupational therapy services furnished in whole or in part by PTAs and OTAs begins January 1, 2022. The revision we proposed to incorporate, the ''8-minute rule'' for the final 15-minute unit billed, according to discussions with the major therapy association stakeholders, reflects typical billing for some private insurers. We plan to add billing scenarios to our Therapy Services website located at *https://www.cms.gov/Medicare/Billing/TherapyServices* that

are similar to or the same as the above Billing Scenarios #A through #F we discussed in the proposed rule. We will also include the general rules and steps involved with applying these rules to the various billing scenarios.

Comment: A majority of commenters asked that we provide an exemption of the 15 percent payment differential for rural and underserved areas, where they stated that a disproportionate amount of therapy services are provided by OTAs and PTAs. Some of these commenters noted that physical and occupational therapists, together with their therapy assistants, work as teams to play a critical role in assisting access to care in rural areas where they report a shortage of therapists exist.

One commenter told us that implementing the payment differential for services provided in whole or in part by PTAs and OTAs in January 2022 will further increase existing health disparities in rural areas. The commenter stated that they agree with the two mechanisms that were recommended by congressional members in a May 14, 2021 letter to help mitigate potential harm to rural beneficiaries from the 15 percent payment reduction for PTA/OTA services. Although the letter containing the recommendations from congressional members was not submitted as a comment to our CY 2022 PFS proposed rule, we note that the recommendations are the same as those that the commenter shared directly with us as a public comment to the CY 2020 PFS proposed rule. Those recommendations were for us to use our discretionary authority to help mitigate potential harm to rural beneficiaries from the 15 percent payment reduction for PTA/OTA services through one of two means based on provisions of section 1848 of the Act: (a) Create a class-specific geographic index for physical and occupational therapy services furnished by PTAs and OTAs; or (b) establish incentive payments for RVU data collected from physical and occupational therapists practicing in rural areas.

Response: While we empathize with commenters about a shortage of therapists and other healthcare workers in rural areas, section 1834(v)(1) of the Act does not provide us with statutory authority to exempt rural areas or other underserved areas from the 15 percent payment differential for therapy services provided in whole or in part by PTAs and OTAs. The suggested methods to mitigate the effects of the reduced payment amounts involving section 1848 of the Act cannot be used to supersede the requirements of section 1834(v)(1) of the Act that requires CMS to make the reduced payment for physical and occupational therapy services furnished in whole or in part by PTAs and OTAs in all areas at 85 percent of the otherwise applicable PFS amount. We are hopeful that the revised de minimis standard will improve the access issues in rural areas and underserved communities.

Comment: Many commenters requested that we change the requirement that PTs and OTs provide direct supervision of PTAs and OTAs in the private practice setting, claiming that the requirement is burdensome and inconsistent with CMS supervision requirements in all other settings where general supervision is allowed. Many commenters stated that the direct supervision requirement is more restrictive than the majority of State practice acts for physical and occupational therapists, does not allow therapists to practice within the full scope of their license, and that this impedes employment opportunities for PTAs and OTAs. Commenters also told us that changing the private practice direct supervision requirement to general supervision that allows audio-only contact between the PT/OT and the PTA/OTA, respectively, would also help to ensure continued patient access to needed therapy services, especially in rural and underserved areas where beneficiaries rely on assistant services to access therapy, assist in the ongoing recovery from the COVID–19 pandemic, and provide support for small outpatient therapy businesses that are facing the 15 percent cut to services provided by therapist assistants beginning in CY 2022. Many commenters informed us that they would support permanently allowing direct supervision via audio/video communications that they have appreciated using during the PHE, if we could not change the direct supervision requirement to general; however, they also reminded us to consider that some patients in rural and underserved areas may not have access to broadband, which may not allow patients to receive therapy services in their homes under this requirement.

Response: We did not address supervision requirements for PTAs and OTAs in the CY 2022 PFS proposed rule. As such, it would not be appropriate to modify those requirements in this final rule. We also received other comments raising issues that were well outside the scope of the issues we discussed in the CY 2022 PFS proposed rule, and for that reason, we decline to address those comments here.

While we are still reviewing the comments received in response to our comment solicitation about whether the flexibility we adopted to permit direct supervision through virtual presence should be continued, as discussed in section II.D. of this final rule, we want to acknowledge that the virtual presence definition for direct supervision is effective until the later of the end of the calendar year in which the PHE ends or December 31, 2021. The presence of the supervising practitioner includes virtual presence through audio/video, real-time communications technology (excluding audio-only). This allows the private practice therapist to provide direct supervision of therapy assistants through virtual presence via real-time audio/video communications technology (excluding audio-only).

Comment: Several commenters requested that we confirm the order of claims processing for therapy services billed with a CQ or CO modifier. Some questioned whether the 15 percent reduction is taken before or after the therapy MPPR. While some commenters thanked us for clarifying in the proposed rule that the 15 percent reduction for PTA/OTA services does not impact the beneficiary's 20 percent coinsurance, two commenters requested that we verify that the 20 percent beneficiary copay was not impacted, as they believed was suggested by the ratesetting formula we used to estimate the volume discount factor of 88 percent for services provided by PTAs and OTAs billed with a CQ or CO modifier that appeared in the PE section of the CY 2022 PFS proposed rule (86 FR 39112).

Response: In the CY 2022 PFS proposed rule (86 FR 39112), we clarified that the 15 percent payment reduction applicable to some PTA/OTA services applies to the 80 percent of the lesser of the actual charge or applicable fee schedule amount and that the remaining 20 percent is the beneficiary copayment. We explained that for therapy services to which the 15 percent reduction applies, payment will be made at 85 percent of the 80 percent of allowed charges, or 68 percent of allowed charges. We confirm that the beneficiary's copayment for a therapy service is deducted right after the application of the MPPR to the PE payment. CMS applies the MPPR to ''always therapy'' codes (as explained below), which occurs right before the 15 percent reduction is applied to 80 percent of the lesser of the actual charge or applicable fee schedule amount for claims with a CQ or CO modifier.

For the majority of therapy claims, the beneficiary copay is less than the 20

percent PFS allowed amount because it is always determined after the application of the therapy MPPR that applies to all ''always therapy'' codes. ''Always therapy'' codes include almost all therapy applicable codes in the Physical Medicine and Rehabilitation section of the 2021 CPT Professional Codebook with the exception of the codes for active wound care management (which are not ''always therapy'' codes). When therapy claims have more than one unit of a service or two or more ''always therapy'' codes, and they also have a CQ or CO modifier for each unit or code, the beneficiary's deductible (where it applies) is calculated first, then the MPPR is applied to the PE payment, and then the 20 percent coinsurance is deducted, as per the usual process. After that, the 15 percent reduction is taken for PTA/OTA services, followed by the 2 percent sequestration that is always last (when applicable).

Comment: We received many comments objecting to our determination (see section II.E.37. of this final rule) that physical therapists are not able to bill for the Remote Therapeutic Monitoring (RTM) codes because services cannot be billed incident to the services of a physical therapist (86 FR 39173 through 39174). The commenters maintain that, when billed by physical therapists, the RTM services would not be considered ''incident to'' as they are when billed by physicians. The commenters urged us to reconsider our interpretation of the RTM codes to permit physical therapists to bill and be paid for these services.

Response: The RTM codes addressed in section II.E.37. of this final rule were intended to be furnished by physical therapists and other practitioners who do not bill for E/M visits. (Please see section II.E.37. of this final rule for full discussion of the RTM codes and their use by therapists.) Payment for these RTM codes is being finalized for CY 2022, and we are now designating the five RTM CPT codes as ''sometimes therapy'' codes. (Please refer to section II.E.37. of this final rule for the discussion on code valuation for these RTM services.) As sometimes therapy codes, the RTM services can be billed outside a therapy plan of care when provided by a physician and certain NPPs, but only when appropriate. While therapists' services must always be provided under therapy plans of care, RTM services that relate to an RTM device that is specific to therapy services, such as the ARIA Physical Therapy device supply in CPT code 98977, must also be furnished under a therapy plan of care when furnished by physicians and NPPs. RTM services must be provided under direct supervision when not directly performed by physicians, NPPs, or therapists; and RTM services delegated by PTs and OTs to PTAs and OTAs, respectively, are subject to the *de minimis* standard.

The RTM codes we are finalizing as described in section II.E.37. of this final rule include two 20-minute codes, which is a different time interval from the existing 15-minute timed therapy codes. To accommodate the two 20-minute CPT codes 98980 and 98981 under our *de minimis* policy, we are making a technical amendment to the regulatory text to recognize this 20-minute time interval (or any other potential time intervals that may arise in the future) as an ''other time interval.'' Specifically, we will add ''or other time interval'' after the ''15-minute'' term in our *de minimis* regulations at §§ 410.59(a)(4)(iii)(B) (for outpatient occupational therapy), 410.60(a)(4)(iii)(B) (for outpatient physical therapy) and 410.105(d)(3)(ii) for CORF physical and occupational therapy services.

We are also providing a billing example to illustrate how the *de minimis* standard would be applied for the RTM treatment management services that describe the interactive communications between the therapist and/or therapy assistant and the patient/caregiver during the calendar month. CPT code 98980 represents the first 20 minutes provided in the month while CPT code 98981 reflects each additional full 20-minute unit, so the midpoint rule is not applicable to these codes.

Billing Scenario #AA: The PT and PTA independently provide a total of 80 minutes of RTM services during the month.

For purposes of billing 98980: The first full 20 minutes were provided by the PT—therefore, CPT code 98980 is billed without a CQ modifier.

For purposes of bulling CPT code 98981, the remaining 60 minutes qualifies for billing three 20-minute units, they were furnished as follows:

PTA—23 minutes of 98981
PT—37 minutes of 98981
Total = 60 minutes of 98981 (qualifies to bill three 20-minute units)

Billing Analysis: The 60 total minutes allows three full 20-minute units of CPT code 98981 to be billed:

- One unit is billed with the CQ modifier for 20 minutes of the 23 minutes provided by the PTA (with 3 minutes leftover).
- One unit is billed without the CQ modifier for the PT's 20 minutes of the 37 minutes—(with 17 minutes left over).
- The final 20-minute unit is billed with a CQ modifier because the PTA's 3 minutes is greater than 10 percent of the 20-minute total—that is, 3 minutes divided by 20 equals 15 percent which is greater than the 10 percent standard of 2 minutes.

The two device codes, CPT codes 98976 and 98977, are not subject to the *de minimis* standard, but, the devices' initial set up and patient education on its use represented by CPT code 98975 is subject to the *de minimis* policy as an untimed code.

Comment: We heard from many commenters on issues of interest to PTs, OTs, and SLPs, most relating to services included on the Medicare telehealth services list that are primarily provided by PTs, OTs, and SLPs (see section II.D. of this final rule). We also received several comments addressing issues other than those related to the reduced payment for services furnished in whole or in part by a PTA/OTA, such as requests to modify the plan of care certification requirement and recognize PTs as eligible to furnish and bill the CPT codes 20560 and 20561 for needle insertion without injection—a prohibition that falls under the Acupuncture NCD (NCD 30.3.3).

Response: These comments are outside of the scope of policies addressed in the CY 2022 PFS proposed rule, and therefore, we decline to address the comments here.

After consideration of public comments, we are implementing the final requirement of the amendments made by section 53107 of the BBA of 2018 to make payment for physical and occupational therapy services furnished in whole or in part by PTAs and OTAs at 85 percent of the otherwise applicable PFS payment amount for dates of service on and after January 1, 2022. We are finalizing our regulations as proposed at §§ 410.59(a)(4)(iii)(B) and 410.60(a)(4)(iii)(B) for outpatient occupational and physical therapy services, respectively, and at § 410.105(d)(3)(iii) for CORF occupational and physical therapy services to specify that the *de minimis* rule is applied to each 15-minute unit of a service, rather than to all the units of a service. We are also finalizing amendments to these sections of the regulations to account for the 20-minute codes for RTM services—specifically we are adding the phrase ''or other timed'' after ''each 15-minute'' and before ''unit'' such the phrase will correctly read as ''to specify that the *de minimis* rule is applied to each 15-minute or other timed unit of a service.'' We are also finalizing our regulations as proposed at §§ 410.59(a)(4)(iv) and

410.60(a)(4)(iv) for outpatient occupational and physical therapy services, respectively, and at § 410.105(d)(3)(ii) for CORF occupational and physical therapy services to note that the *de minimis* rule is not applied when the OT/PT provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the OTA or PTA. We are also finalizing our regulations as proposed at §§ 410.59(a)(4)(v) and 410.60(a)(4)(v) for outpatient occupational and physical therapy services, respectively, and § 410.105(d)(3)(iv) for CORF services to clarify the two remaining unit scenarios, to allow one unit to be billed with a CO/CQ modifier and the other unit to be billed without the CO/CQ modifier when the OTA/PTA and the OT/PT each provide between 9 and 14 minutes, independent of one another, with a total time between 23 and 28 minutes. We plan to add Billing Scenarios to our Therapy Services website located at *https://www.cms.gov/Medicare/Billing/TherapyServices* that are similar to or the same as the above Billing Scenarios #A through #F that we discussed in the proposed rule. We plan to add a *de minimis* example of the 20-minute RTM services defined by CPT codes 98980 and 98981. We will also include the general rules and steps involved with applying the rules to the various billing scenarios.

2. Therapy KX Modifier Threshold Amounts

The KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act (BBA) of 2018. Formerly referred to as therapy caps, these KX modifier thresholds are a permanent provision of the statute, meaning that the statute does not specify an end date. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the Medicare Economic Index (MEI). Specifically, these amounts are calculated by updating the previous year's amount by the MEI for the upcoming calendar year and rounding to the nearest $10.00. Increasing the CY 2021 KX modifier threshold amount of $2,110 by the CY 2022 MEI of 2.1 percent and rounding to the nearest $10.00 results in a CY 2022 KX threshold amount of $2,150 for PT and SLP services combined and $2,150 for OT services.

Section 1833(g)(7)(B) of the Act was also added by section 50202 of the BBA of 2018 and it retains the targeted medical review process, but at a lower threshold amount of $3,000 (until CY 2028 when it is updated by the MEI). Accordingly, for CY 2022, the MR threshold is $3,000 for PT and SLP services combined and $3,000 for OT services. Under the established targeted review process, some, but not all, claims exceeding the MR threshold amount are subject to review. Information on the targeted manual medical review process is available at *https://www.cms.gov/ResearchStatistics-Data-and-Systems/MonitoringPrograms/Medicare-FFSCompliancePrograms/Medical-Review/TherapyCap.html.*

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable MPPR amount for services of CMS-designated ''always therapy'' services.

We apply the same PFS-rate accrual process noted above to outpatient therapy services furnished by critical access hospitals (CAHs), even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014).

When the expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. By using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied.

I. Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Section 122 of Division CC of the Consolidated Appropriations Act (CAA) of 2021, Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. The reduced coinsurance will be phased-in beginning January 1, 2022. Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance.

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, identifies ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' as two of the recognized procedures. During the course of either one of these two procedures, removal of tissue or other matter may become necessary for diagnostic purposes. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include in the definition other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(s)(2)(R) of the Act includes colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes colorectal cancer screening tests within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for a preventive service under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount, when the preventive service is recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. As such, there is no beneficiary coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at § 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance for colorectal cancer screening tests (except for barium

enemas, which are not recommended by the USPSTF with a grade of A or B).[39]

In addition to colorectal cancer screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests (see § 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary and who uses the results of the diagnostic test in the management of the patient's specific medical condition. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the Part B coinsurance (20 or 25 percent depending upon the setting) associated with these services.

We define colorectal cancer screening tests in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current regulations, we exclude from the definition of colorectal screening services, colonoscopies and sigmoidoscopies that begin as screening services, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening tests is based upon longstanding provisions under sections 1834(d)(2)(D) and (d)(3)(D) of the Act dealing with the detection of lesions or growths during procedures (see CY 1998 PFS final rule at 62 FR 59048, 59082 for a more detailed explanation).

Prior to the enactment of section 122 of the CAA, section 1834(d)(2)(D) of the Act provided that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, prior to the recent legislative change, section 1834(d)(3)(D) of the Act provided that if, during the course of a screening colonoscopy, a lesion or growth is detected that results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal. In these situations, Medicare pays for the flexible sigmoidoscopy and colonoscopy tests as diagnostic tests rather than as screening tests and the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), has not applied. As such, beneficiaries currently are responsible for the usual coinsurance that applies to the services (20 or 25 percent of the cost of the services depending upon the setting).

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub L. 111–148, March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Although amendments made by the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, they did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Public commenters encouraged the agency to eliminate the coinsurance in these circumstances; however, the agency found that statute did not provide for elimination of the coinsurance (75 FR 73170 at 73431).

Beneficiaries have continued to contact us noting their concern that a coinsurance percentage applies (20 or 25 percent depending upon the setting) under circumstances where they expected to receive only a colorectal screening test to which coinsurance does not apply. Instead, these beneficiaries received what Medicare considers to be a diagnostic procedure because, for example, polyps were discovered and removed during the procedure. Similarly, physicians have expressed concern about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during a procedure that they had expected to be a screening procedure to which coinsurance does not apply.

Section 122 of the CAA addresses this coinsurance issue by successively reducing, over a period of years, the percentage amount of coinsurance for which the beneficiary is responsible. Ultimately, for services furnished on or after January 1, 2030, the coinsurance will be zero.

To implement the amendments made by section 122 of the CAA, we proposed to modify our regulations to reflect the changes to Medicare statute. As amended, the statute effectively provides that, for services furnished on or after January 1, 2022, a flexible sigmoidoscopy or a colonoscopy can be considered a screening flexible sigmoidoscopy or a screening colonoscopy test even if an additional procedure is furnished to remove tissue or other matter during the screening test. Specifically, section 122(a)(3) of the CAA added a sentence to the end of section 1833(a) of the Act to include as colorectal screening tests described in section 1833(a)(1)(Y) of the Act, a colorectal cancer screening test, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. We noted that only flexible screening sigmoidoscopies and screening colonoscopies are recognized currently as colorectal cancer screening tests that might involve removal of tissue or other matter. This new sentence added under section 1833(a) of the Act uses the same language that was used to amend the statute at section 1833(b)(1) of the Act and to broaden the scope of colorectal cancer screening tests to which a deductible does not apply. Section 122(b)(1) of the CAA then limits application of the 100 percent Medicare payment rate (that is, no beneficiary coinsurance) under section 1833(a)(1)(Y) of the Act for the additional colorectal cancer screening

[39] We refer readers to the CY 2022 OPPS final rule for a detailed discussion of Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Tests in outpatient and ambulatory surgical settings.

tests (those that are not screening tests ''but for'' the new sentence at the end of section 1833(a) of the Act) by making payment for them subject to a new section 1833(dd) of the Act. Section 1833(dd) of the Act provides for a series of increases in the Medicare payment rate percentage for those services over successive periods of years through CY 2029. Thereafter, section 1833(dd) of the Act has no effect, so payment for all colorectal cancer screening tests would be made at 100 percent under section 1833(a)(1)(Y) of the Act.

To codify the amendments made by section 122 of the CAA in our regulations, we proposed to make two modifications to current regulations.

At § 410.37, we proposed to modify our regulation where we define conditions for and limitations on coverage for colorectal cancer screening tests by adding a new paragraph (j). That paragraph would provide that, effective January 1, 2022, when a planned colorectal cancer screening test, that is, screening flexible sigmoidoscopy or screening colonoscopy test, requires a related procedure, including removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter as the screening test, it is considered to be a colorectal cancer screening test.

At § 410.152(l)(5), we also proposed to modify our regulation. Here we describe payment for colorectal cancer screening tests. Effective January 1, 2022, we proposed to provide for an increase in the Medicare payment percentage that is phased in over time. As the Medicare payment percentage increases, the beneficiary coinsurance percentage decreases. We proposed to revise § 410.152(l)(5) to provide that Medicare payment in a specified year is equal to a specified percent of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to the test. The phased in Medicare payment percentages for colorectal cancer screening services described in the proposed regulation at § 410.37(j) (and the corresponding reduction in coinsurance) are as follows:

- 80 percent payment for services furnished during CY 2022 (with coinsurance equal to 20 percent);
- 85 percent payment for services furnished during CY 2023 through CY 2026 (with coinsurance equal to 15 percent);
- 90 percent payment for services furnished during CY 2027 through CY 2029 (with coinsurance equal to 10 percent); and
- 100 percent payment for services furnished from CY 2030 onward (with coinsurance equal to zero percent).

Thus, between CYs 2022 and 2030, the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter will be reduced over time from the current 20 or 25 percent to zero percent beginning CY 2030 and will remain at zero percent thereafter.

We received several public comments on our proposed modifications to the regulations. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters expressed support for our proposals to implement, as required, section 122 of Division CC of the CAA of 2021.

Response: We thank commenters for supporting our proposals to implement the amendments made by section 122 of the CAA.

Comment: One commenter expressed concern about the length of the phase-in period for the reduction in the beneficiary's coinsurance percentage, and asked whether it could be changed to next year.

Response: We proposed to implement the amendments made by section 122 of the CAA. Those amendments clearly specify the applicable coinsurance percentages for each calendar year, and we do not have discretion to modify them.

Comment: A commenter requested that the beneficiary should not be responsible for coinsurance for anesthesia services when a screening flexible sigmoidoscopy or a screening colonoscopy becomes a diagnostic.

Response: In the CY 2015 PFS final rule (79 FR 67730 through 67732), we amended the definition of colorectal cancer screening tests that are colonoscopies at § 410.37(a)(1)(iii) to include anesthesia that was furnished in conjunction with screening colonoscopies. We did not make a corresponding modification to the definition of colorectal cancer screening tests that are flexible sigmoidoscopies at § 410.37(a)(1)(ii). Section 122 of the CAA did not change these regulatory definitions of colorectal cancer screening tests and we did not propose to modify them in the CY 2022 PFS proposed rule. Therefore, we are not making any changes in the regulation with respect to anesthesia with screening flexible sigmoidoscopy in this final rule. However, we will take these public comments into consideration for possible future rulemaking.

Comment: A commenter requested that we allow suppliers to waive the coinsurance even earlier than 2030 if they elect to do so without fear of violating any CMS rules.

Response: Through this rulemaking we are adopting Medicare regulations regarding beneficiary coinsurance that reflect the decreasing beneficiary financial obligations over time as established by statute. Prior to the complete phaseout of Medicare coinsurance amounts for colorectal cancer screening tests in CY 2030, suppliers may waive coinsurance amounts only if they comply with applicable law, including the Federal Anti-Kickback Statute and the civil monetary penalty provision prohibiting inducements to beneficiaries.[40]

Comment: A commenter urged CMS to conduct patient education and outreach about the changes to their coinsurance when a screening becomes a diagnostic.

Response: We agree it is important for Medicare beneficiaries to understand the changes that will affect their coinsurance percentage for certain colorectal cancer screening services and expect to develop articles and update other media to announce and explain the changes.

We received several comments that were outside the scope of the proposals made in the CY 2022 PFS proposed rule. Comments included questions about coverage of bowel preparation products, coverage of non-invasive screening tests that require a follow-up colonoscopy, and cost-sharing for new colorectal screening technologies. Although we are not summarizing and responding to these comments in this final rule, we will take them into consideration for possible future healthcare provider education or rulemaking.

After considering public comments, we are finalizing the proposals made in the CY 2022 PFS proposed rule to implement section 122 of the CAA without modification.

J. Vaccine Administration Services: Medicare Payments for Administering Preventive Vaccines

As we discussed in the CY 2022 PFS proposed rule (86 FR 39220), on January 31, 2020, under section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (the Secretary) determined that a public health emergency (PHE) as a result of confirmed cases of 2019 Novel

[40] For further information see the OIG website at *https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/.*

Coronavirus exists nationwide and has existed since January 27, 2020 (hereafter referred to as the PHE for COVID–19). The Secretary has since renewed this declaration for successive 90-day periods, the latest on October 18, 2021.

The PHE for COVID–19 has reinforced the important and positive impact that preventive vaccines can have on the health of Medicare beneficiaries and the broader public. At the time of publishing this final rule, the PHE for COVID–19 declaration is still in effect and the United States is in the middle of a national effort to vaccinate as many people against COVID–19 as quickly as possible. This national effort has at least temporarily altered the landscape for vaccines and vaccine administration by, for example, encouraging existing providers and suppliers to dramatically expand their vaccination capabilities and by encouraging new (and new types) of providers and suppliers to furnish vaccines.

Over the past several years, stakeholders have expressed concerns about the reduction in Medicare payment rates for the service to administer preventive vaccines covered by Medicare Part B under section 1861(s)(10) of the Act, including the influenza, pneumococcal, and hepatitis B virus (HBV) vaccines. In the last two PFS rulemaking cycles (that is, for CY 2020 and CY 2021), we have attempted to address some of these concerns and these efforts are discussed in more detail below. However, CY 2021 payment rates for administration of these vaccines by suppliers including physicians, NPPs, and mass immunizers remain the same as in CY 2019: A national average rate of $16.94, which is geographically adjusted. In the CY 2022 PFS proposed rule (86 FR 39221), we requested feedback on how we should update the payment rate for administration of these preventive vaccines under Medicare Part B.

1. Medicare Part B Payment for Vaccines

As we discussed in the CY 2022 PFS proposed rule (86 FR 39220 through 39224), under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and its administration for the preventive vaccines specified—the influenza, pneumococcal, HBV, and COVID–19 vaccines. Under sections 1833(a)(1)(B) and (b)(1) of the Act, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations or the services to administer them. In CY 2021, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for a particular vaccine product except where furnished in the settings for which payment is based on reasonable cost, such as a HOPD, RHC, or FQHC. For example, for the 2020–2021 influenza season, payment limits for adult influenza vaccine products range from about $19 to $61 per adult dose. We noted that most other preventive vaccines not specified for Medicare Part B coverage under section 1861(s)(10) of the Act, such as the shingles vaccine, are covered and paid for under Medicare Part D.

Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136) added the COVID–19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. We implemented this change through an interim final rule with comment period (November 4th COVID–19 IFC (85 FR 71145 through 71150)) which established that payments for COVID–19 vaccines and vaccine administration would be made in the same manner as payments for the influenza and pneumococcal vaccines. The IFC specifically amended §§ 414.707(a)(2)(iii) and 414.904(e)(1) to include the COVID–19 vaccine in the list of vaccines with payment limits calculated using 95 percent of the AWP (85 FR 71147). We noted that Medicare does not pay providers and suppliers for the vaccine product when the Federal Government purchases it and gives it to the provider or suppliers for free, as has been the case for all COVID–19 vaccines as of the publication of the proposed rule.

We noted that the vaccine administration services described under section 1861(s)(10) of the Act are not technically valued or paid under the PFS, as they are not included within the statutory definition of physicians' services in section 1848(j)(3) of the Act. Despite this, we have historically based payment rates for the administration of these preventive vaccines by suppliers such as physicians, NPPs, and mass immunizers on an evaluation of the resource costs involved in furnishing the service, which is similar to the methodology that we use to establish payment rates for the PFS. We noted further that we also assign a payment rate for administering these preventive vaccines under the Outpatient Prospective Payment System (OPPS), and those payment rates are for hospitals and home health agencies for preventive vaccine administration. Certain other types of providers and suppliers, such as RHCs, FQHCs and critical access hospitals (CAHs), are paid based on reasonable cost for vaccine administration. We also noted that payments for the administration of the preventive vaccines by suppliers such as physicians, NPPs, and mass immunizers are geographically adjusted based on the provider's wage index.

As discussed in the CY 2021 PFS proposed rule (85 CFR 50162), many stakeholders raised concerns about the reductions in payment rates for the preventive vaccine administration services that had occurred over the past several years. We generally have established payment rates for the three Healthcare Common Procedural Coding System (HCPCS) codes G0008, G0009, and G0010—which describe the services to administer an influenza, pneumococcal and HBV vaccines, respectively, based on a direct crosswalk to the PFS payment rate for CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Because we proposed and finalized reductions in valuation for that code for CY 2018, the payment rate for the vaccine administration codes was concurrently reduced. Further, because the reduction in RVUs for CPT code 96372 was significant enough to be required to be phased in over several years under section 1848(c)(7) of the Act, the reductions in overall valuation for the vaccine administration codes were likewise subject to reductions over several years. As we noted in the CY 2022 PFS proposed rule (86 FR 39222) in Table 21, Table 30 shows the national payment rate for administering these preventive vaccines has declined more than 30 percent since 2015.

TABLE 30: Payment Rates for influenza, pneumococcal and HBV vaccine Administration Services (CY 2015 – CY 2021)

Year	National Payment Rate for G0008, G0009, G0010
2015	$25.51[1]
2016	$25.42
2017	$25.84
2018	$20.88
2019	$16.94
2020	$16.94[2]
2021	$16.94[3]

[1] We note that there were technically two national payment rates in 2015 due to legislation passed mid-year, although the payment amount for G0008, G0009 and G0010 only changed during the year by roughly $0.20.

[2] Frozen to 2019 rate through rulemaking (PFS).

[3] Frozen to 2019 rate through rulemaking (PFS).

We explained that we have attempted to address the reduction in payment rates for these vaccine administration HCPCS codes in the last two PFS rulemaking cycles. In the CY 2020 PFS final rule, we acknowledged that it is in the public interest to ensure appropriate resource costs are reflected in the valuation of the immunization administration services that are used to deliver these vaccines, and noted that we planned to review the valuations for these services in future rulemaking. For CY 2020, we maintained the CY 2019 national payment amount for immunization administration services described by HCPCS codes G0008, G0009 and G0010.

In the CY 2021 PFS proposed rule, we proposed to crosswalk G0008, G0009 and G0010 to CPT code 36000 (*Introduction of needle or intracatheter, vein*) (85 FR 50163). In the proposed rule, we noted that CPT code 36000 is a service with a similar clinical vignette, and that the additional clinical labor, supply, and equipment resources associated with furnishing CPT code 36000 were similar to costs associated with these vaccine administration codes. We also noted that this crosswalk would have resulted in a payment rate for vaccine administration services that is approximately the same as the CY 2017 rate (as noted in Table 30) that was in place prior to the revaluation of CPT code 96372 (the original crosswalk code). In the CY 2021 PFS final rule, we did not finalize the proposed policy, and instead finalized a policy to maintain the CY 2019 payment amount for G0008, G0009 and G0010 (85 FR 84628). In the final rule, we also noted that we continued to seek additional information that specifically identifies the resource costs and inputs that should be considered to establish payment for vaccine administration services on a long-term basis.

As noted above, section 3713 of the CARES Act added the COVID–19 vaccine and its administration to the preventive vaccines covered under Medicare Part B under section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. We noted in the CY 2022 PFS proposed rule (86 FR 39222) that section 3713 of the CARES Act allows us to implement the amendments made by that section through ''program instruction or otherwise.'' In implementing section 3713 of the CARES Act in the November 4th COVID–19 IFC (85 FR 71147), we indicated that we would establish specific coding and payment rates for the COVID–19 vaccine and its administration through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website.

In December 2020, we publicly posted the applicable CPT codes for the Pfizer-BioNTech and Moderna COVID–19 vaccines and initial Medicare payment rates for administration of these vaccines upon the FDA's authorization of these vaccines. We announced an initial Medicare payment rate for COVID–19 vaccine administration of $28.39 to administer single-dose vaccines. For a COVID–19 vaccine requiring a series of two or more doses—for example, for both the Pfizer-BioNTech and Moderna products—we announced a payment rate for administration of the initial dose(s) of $16.94, which was based on the Medicare payment rate for administering the other preventive vaccines under section 1861(s)(10) of the Act. We also announced a payment rate for administering the second dose of $28.39, which was based on the payment rate that was proposed, but not finalized, for administration of the other preventive vaccines under section 1861(s)(10) of the Act in the CY 2021 PFS proposed rule, discussed in more detail above.

On March 15, 2021, we announced an increase in the payment rate for administering a COVID–19 vaccine to $40 per dose, effective for doses administered on or after March 15, 2021, which means the payment rate is $40 to administer a single dose product, and $40 each to administer the first and second dose in a two-dose regime ($80 total).

TABLE 31: Established Payment Rates for COVID-19 Vaccine Administration Services

CPT Code	Procedure Name	National Payment Amount For Physicians on or After March 15, 2021	National Payment Amount for Physicians Before March 15, 2021
0001A	Pfizer-Biontech Covid-19 Vaccine Administration – First Dose	$40.00	$16.94
0002A	Pfizer-Biontech Covid-19 Vaccine Administration – Second Dose	$40.00	$28.39
0011A	Moderna Covid-19 Vaccine Administration – First Dose	$40.00	$16.94
0012A	Moderna Covid-19 Vaccine Administration – Second Dose	$40.00	$28.39
0031A	Janssen/J&J Covid-19 Vaccine Administration	$40.00	$28.39

As discussed above, payment rates for suppliers such as physicians, NPPs, and mass immunizers for administering the Part B covered preventive vaccines (other than for COVID–19) have generally been based on a direct crosswalk to CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). The service described by this crosswalk code is paid under the PFS, and Medicare's process to value codes under the PFS relies in part on recommended resource inputs provided by the AMA RUC and steps to translate those recommended inputs into national RVUs.

In 2020, the RUC resubmitted its 2009 valuation recommendation for vaccine administration services described by CPT codes, including CPT codes 90460 (*Administration of first vaccine or toxoid component through 18 years of age with counseling*), 90471 (*Administration of 1 vaccine*), and 90473 (*Administration of 1 nasal or oral vaccine*). The AMA RUC also recently provided valuation recommendations for the CPT codes that describe the service to administer the COVID–19 vaccines.

As noted earlier, we also assign a payment rate for administering preventive vaccines under the OPPS by assigning each service to an ambulatory payment classification (APC) based on clinical and resource cost similarity to other services assigned to the APC. Geometric mean costs, which are generally used in establishing the prospective OPPS payments for each APC, are calculated using historical claims and cost report information. In CY 2021, CMS assigned HCPCS codes G0008, G0009 and G0010 to APC 5691 (*level 1 drug administration*), which has a national payment rate of $40 for CY 2021.

In the CY 2022 PFS proposed rule (86 FR 39223), we explained that our practice of setting payment rates for preventive vaccine administration services described by HCPCS codes G0008, G0009 and G0010 for physicians, NPPs, and mass immunizers by using the PFS approach (for example, a crosswalk to an existing CPT code) means that costs incorporated into the rate primarily reflect costs of furnishing the service in a physician office setting. It also means that the payment rate can be affected by other aspects of the PFS rate-setting methodology, such as the allocation of indirect PE, and broader changes to PFS codes and rates, including the multi-year phase-in of significant reductions in RVUs discussed earlier. We noted that we have not historically collected or used information from other providers and suppliers, including pharmacies which are commonly enrolled as mass immunizers to furnish vaccines and vaccine administration services, for purposes of establishing a rate for these codes.

We requested feedback from stakeholders that would support the development of an accurate and stable payment rate for administration of the preventive vaccines described in section 1861(s)(10) of the Act for physicians, NPPs, mass immunizers and certain other providers and suppliers. We invited commenters to submit their detailed feedback to the following questions and requests that we believe may assist us in establishing payment rates for these services that could be appropriate for use on a long-term basis.

- What are the different types of providers and suppliers that furnish preventive vaccines, and have these types of providers/suppliers changed as a result of the PHE for COVID–19? (We noted that our claims data reflect the type of Medicare enrollment for those billing for the vaccine administration, but we are particularly interested in understanding additional, specific characteristics of the providers and suppliers that may not be distinguishable under the more general Medicare enrollment data.) Do different providers and suppliers furnish different aspects of the vaccine administration for the same beneficiary?
- What are the differences in incurred costs of furnishing influenza, pneumococcal and HBV vaccines compared to furnishing COVID–19 vaccines? Are there differences in the costs (per dose or otherwise) of furnishing a one-dose vaccine product vs. a two-dose vaccine product? Also, are there differences in cost of administering preventive vaccines furnished under the Part D benefit, such as the shingles vaccines, compared to those furnished under Part B?
- What are the resource costs that physicians, NPPs, mass immunizers and certain other suppliers incur when furnishing vaccines safely and effectively? Specifically, what are the costs related to staffing/labor, infrastructure, patient onboarding/enrollment, vaccine storage and handling, vaccine procurement and coordination, supplies, CDC and State reporting requirements, patient counseling about safety and efficacy, and other costs we may not have considered? We also sought information on specific resource costs per vaccine dose within each cost category, if that is available.
- What are the impacts of the PHE for COVID–19 on resource costs incurred by vaccination providers, and do stakeholders envision that these impacts will continue after the PHE has ended? Following the end of the PHE, do you expect that the same types of vaccination providers and suppliers will continue to administer vaccines, or do you envision that this will change (if so,

how, and what would be the primary factors driving the change)?

• How should Medicare assess costs associated with furnishing these preventive vaccines outside of the physician office setting, such as in pharmacies, mass immunization sites, mobile vaccine clinics or other locations? In addition, as we noted in the CY 2022 PFS proposed rule (86 FR 39224), we understand that there could be administrative burden associated with the routine collection of cost data to support more accurate rate-setting for suppliers that are vaccinating patients. Are there other ways to update and validate costs for a broader range of entities using existing data?

• Payment rates for vaccine administration currently vary by setting. For HCPCS codes G0008, G0009 and G0010, the CY 2021 national average payment rate for physicians, practitioners and other suppliers is $16.94, which is geographically adjusted, while for HOPDs it is $40. However, for COVID–19 vaccine administration, Medicare now pays $40 per administration in all settings, unless the vaccine in administered under certain circumstances in the home or residence (as discussed in more detail below). Should Medicare continue to pay differently for non-COVID–19 preventive vaccines furnished in certain settings or under certain conditions? If not, what factors contribute to higher costs for administration of non-COVID–19 vaccines that are not currently reflected in the Medicare payment rates?

• Should CMS use a different process to update the payment rates for administration of the preventive vaccines described in section 1861(s)(10) of the Act on an annual basis?

• In the last few years we have also crosswalked vaccine administration CPT codes 90460 (*Administration of first vaccine or toxoid component through 18 years of age with counseling*), 90461 (*Administration of vaccine or toxoid component through 18 years of age with counseling*), 90471 (*Administration of 1 vaccine*), 90472 (*Administration of vaccine*), 90473 (*Administration of 1 nasal or oral vaccine*), and 90474 (*Administration of nasal or oral vaccine*) to the same rate used by G0008, G0009 and G0010. How should Medicare address payment rates for these CPT codes under the PFS?

• Are there major differences between what Medicare pays physicians, NPPs and mass immunizers for non-COVID–19 preventive vaccine administration and what commercial insurers pay? To the extent possible, we also sought comments on the specific rates used by other insurers.

We received feedback from a wide variety of stakeholders in response to our comment solicitation on payment rates for the administration of COVID–19 vaccines and other preventive vaccines covered under the Medicare Part B vaccine benefit. Commenters overwhelmingly emphasized the importance of vaccination in achieving positive health outcomes for Medicare beneficiaries and the broader American public. At the same time, they observed that immunization rates overall continue to fall short of national objectives, and that troubling disparities exist with respect to vaccination among racial and ethnic minorities. Commenters also confirmed that many different types of healthcare providers have contributed to the vaccination effort in the United States, and provided detailed feedback on the challenges and resource costs experienced by these vaccine providers, especially in the context of the COVID–19 public health emergency. In what follows, we summarize the comments that we received on these topics, and explain how they have informed the policies we are adopting in this final rule.

Comment: The comments we received are a testament to the complex landscape of vaccination that has emerged in the wake of the COVID–19 pandemic. We received feedback from representatives of many different types of healthcare providers who stated that they significantly increased their vaccination capabilities in an effort to immunize as many Americans as possible against COVID–19. These include primary care physicians, NPs, pharmacies, urgent care centers, podiatrists, community health centers, Urban Indian Organizations, and schools of nursing. Commenters cited Federal financial assistance and flexibilities, in particular the March 2020 Declaration under the Public Readiness and Emergency Preparedness (PREP) Act (Division C of Pub. L. 109–148), as factors that have enabled a broader scope of healthcare providers to participate in the COVID–19 vaccination effort. In addition, commenters noted that healthcare providers such as hospitals, pharmacies and FQHCs have sought to expand the reach of their vaccination campaigns by establishing mobile and outreach clinics, as well as operating mass immunization sites in their communities.

We also received numerous responses to our request for feedback on the specific types of expenses incurred by healthcare providers of COVID–19 and other preventive vaccines, including the ways in which these expenses have evolved as a result of the COVID–19 PHE. Many commenters indicated that the costs of administering the COVID–19 vaccines are higher than those associated with other preventive vaccines, citing factors such as the needs for ultra-cold storage, manual filling of syringes, scheduling for subsequent doses, post-injection monitoring, stocking of EPI pens, distribution of CDC fact sheets, disposal and logging of wasted doses, and State and Federal reporting obligations, which in turn have required hiring of additional staff and various software and IT enhancements. With respect to the specific impacts of the pandemic on resource costs, commenters cited the need for personal protective equipment, increased sanitization measures, community outreach efforts, and high patient volumes combined with staffing shortages. One commenter added that costs and administrative burdens have increased because patients do not want to go to provider locations to risk other illnesses. In addition, several commenters pointed specifically to misinformation and vaccine hesitancy as factors that have impeded the national immunization effort, and recommended that payment rates should take into consideration the time required to counsel and educate patients, including in the event that a patient ends up declining the vaccine. A few commenters indicated that they expect the effects of the pandemic to persist into CY 2022 and beyond, and that we should therefore maintain the $40 payment rate for COVID–19 vaccines for the foreseeable future.

Finally, commenters also provided feedback on the expenses associated with setting up outreach clinics and mass immunization sites, which require significant upfront infrastructure investments, as well as back-end costs to break down these operations when they are concluded. Specific expenses associated with such ventures include tents, generators, portable restrooms, relocation of computers and other equipment, security services, and staffing. Some commenters recommended that the payment rate for mass community vaccination events organized by FQHCs be increased from $40 to at least $120 per dose to reflect these additional costs incurred by FQHCs.

One commenter representing pharmacists stated that cost reporting would be the best approach to valuing vaccine administration at pharmacies, and that the current crosswalk to the PFS does not accurately reflect the costs incurred by pharmacies in furnishing

these services. The commenter cited costs including vaccine packaging and storage, ancillary supplies such as syringes and gloves, patient outreach and counseling, staffing and training, reporting requirements, seasonal fluctuations in patient volume, and reporting requirements. In response to our inquiry about the differences in costs of administering preventive vaccines furnished under the Part B and Part D benefits, a couple of commenters noted that the Part B claims submission process is more complex and labor-intensive than the process under Part D and results in greater costs for pharmacies.

Given the various expenses outlined above, commenters generally applauded CMS for establishing a payment rate for COVID–19 vaccines of $40 per dose as of March 15, 2021, with several commenters noting that this amount accurately reflects the resource costs involved in COVID–19 vaccine administration. On the other hand, a majority of commenters also expressed concern regarding the payment rate for other Part B preventive vaccines, that is, influenza, pneumococcal, and HBV vaccines—which, as noted above, currently stands at $16.94. Commenters stated that this amount does not take full account of the expenses associated with administering these vaccines, and that, as a result, many healthcare providers, especially smaller, independent practices and those in underserved areas, might be discouraged from offering vaccines to their patients. Indeed, many commenters cited adequate reimbursement as one of the principal factors that contribute to higher immunization rates, and several cited a recent survey in which 80 percent of respondents indicated that increasing vaccine administration payment rates would help overcome vaccination barriers and costs created by the pandemic.[41] A couple of commenters added that Medicare payment rates impact the rates paid by Medicaid and private payers, with one commenter asserting that some regional and private payers pay as little as half of the Medicare rate. One commenter therefore commended CMS for taking efforts to ensure appropriate, predictable and stable payment for vaccines and their administration as a key lever to improving immunization rates among Medicare beneficiaries. Another commenter added that contracting influenza concurrently with COVID–19 may increase the risk of adverse health outcomes, and recommended increasing payment rates for influenza vaccines for this reason.

Commenters generally recommended that payment rates for the influenza, pneumococcal and HBV vaccines should be updated and that payment for the administration of these vaccines and of the COVID–19 vaccines should be determined using consistent methodologies, as discussed below. One group of commenters recommended that CMS pay for these services on the basis of resource-based relative value scale (RBRVS) principles using recommendations submitted by the AMA RUC. In May 2021, the RUC submitted its recommendations for Immunization Administration codes 90460, 90461, 90471, 90472, 90473, 90474, G0008, G0009 and G0010. In particular, the RUC recommended that CMS crosswalk HCPCS codes G0008–10 to CPT code 90471, using inputs that would result in a payment of approximately $21 per dose.

Furthermore, in December 2020, the RUC submitted recommendations for CPT codes 0001A, 0002A, 0011A, 0012A, and 0031A (the first and second doses of the Pfizer-BioNTech and Moderna COVID–19 vaccines and the first dose of the Janssen vaccine, respectively). Specifically, the RUC recommended crosswalking these codes to CPT code 90460, which would result in a payment of approximately $30 for the vaccine administration codes, and additionally recommended that for the duration of the PHE CMS approve payment of approximately $10 for new CPT code 99072 (*Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease*) to reflect the additional PEs associated with administration of the COVID–19 vaccines during the PHE. The RUC submitted similar recommendations for the third doses of the Pfizer and Moderna vaccines in August 2021. Thus, using the RUC recommendations would result in a payment for COVID–19 vaccine administration of approximately $35–$40 per dose during the PHE, and approximately $25–$30 after the PHE is terminated.

Another group of commenters recommended decoupling payment for preventive vaccine administration from the crosswalk to a code valued under the PFS. These commenters generally supported a site-neutral payment of $40 per dose for administration of all Part B preventive vaccines, in line with the current payment rate for COVID–19 vaccine administration and with the payment rate for administration of all preventive vaccines under the OPPS. Several commenters who supported this recommendation stated that equal payment for COVID–19 and other preventive vaccines would be appropriate, since the work involved in administering the different types of vaccines is essentially the same. A few commenters also stated that costs associated with vaccine administration do not vary significantly across different sites of service, with some adding that a site-neutral payment would help address inequities across healthcare provider settings and maximize access to the vaccines. Additionally, a few commenters stated that, if CMS does not decouple payment for vaccine administration from the PFS and adopt a payment rate of $40 per dose as discussed above, then an acceptable alternative would be to value these services by means of a crosswalk to CPT code 36000 (*Introduction of needle or intracatheter, vein*), as originally proposed in the CY 2021 PFS proposed rule. As explained in the CY 2021 PFS proposed rule (85 FR 50163), CPT code 36000 is a service with a similar clinical vignette, and the additional clinical labor, supply, and equipment resources associated with furnishing CPT code 36000 are similar to costs associated with these vaccine administration codes. This proposal, which was not finalized, would have resulted in a payment for Part B vaccine administration services of approximately $28.39 per dose.

One commenter suggested that CMS base payment for vaccine administration services on average rates paid by commercial payers or on the 2015 Medicare rate adjusted for inflation to 2022. Another commenter provided data indicating that rates set by commercial payers for CPT code 90471 (*Immunization, initial*) and CPT code 90472 (*Immunization administration, each additional vaccine*) are about 41 percent and 23 percent higher than rates set by Medicare, respectively.

Response: We appreciate the feedback received from the wide range of providers and suppliers that furnish preventive vaccinations. We agree with commenters on the need to establish stable payment rates that take into account the costs associated with administering the preventive vaccines included in the Part B vaccine benefit. In particular, we agree that the payment

[41] Belowich, E., Pratt, K., Fifer, S., Solis, P., & Hughes IV, R. (2020, December 9). Increased Reimbursement May Help Overcome Barriers To Administration Of Seasonal And Routine Vaccines | Health Affairs. Health Affairs. *https://www.healthaffairs.org/do/10.1377/hblog20201208.111539/full/.*

rates for administration of the influenza, pneumococcal and hepatitis B vaccines are too low and need to be adjusted to reflect the costs incurred by healthcare providers. Furthermore, we agree with commenters who stated that we should decouple payment for these vaccine administration services from the crosswalk to the PFS and treat them independently. We took a number of factors into consideration in developing our final policy.

First, we considered the impact of the pandemic on the costs associated with vaccine administration, as well as the specific costs associated with administration of the COVID–19 vaccines. We generally agree with the commenters who stated that the service to administer these vaccines is essentially the same and does not vary significantly across different types of healthcare providers. At the same time, we recognize that the PHE has posed and continues to pose unique challenges for vaccination providers, particularly with respect to the administration of vaccines for COVID–19. For example, we anticipate that healthcare providers will continue to experience unusual costs associated with staffing, scheduling, and reporting requirements as increasing numbers of patients receive additional doses and boosters of the COVID–19 vaccines in the near future, and as health care providers adapt their vaccine delivery infrastructure accordingly. After the PHE, however, we anticipate that these costs will go down as patient volumes stabilize and as healthcare providers incorporate tasks such as scheduling and reporting into their routine clinical practice. In addition, we note that healthcare providers will have already made certain capital investments associated with the COVID–19 vaccines, such as ultra-cold storage freezers and software upgrades, during the course of the PHE, and thus after the PHE such investments will no longer represent a significant additional cost over and above the costs of administering other preventive vaccines. At the same time, we recognize that the formal termination of the PHE will not necessarily coincide with an immediate return to pre-pandemic circumstances, and that some of the additional costs mentioned above may persist while conditions normalize. For these reasons, we believe that it is appropriate to establish a single, consistent payment rate for the administration of all Part B preventive vaccines following the end of the calendar year in which the PHE expires. That is, effective January 1 of the year following the year in which the PHE ends, the $40 payment rate for administration of the COVID–19 vaccines will be adjusted to equal the payment rate for the administration of other Part B preventive vaccines.

We also considered the empirical data sources available to us for establishing an appropriate vaccine-neutral payment. On the one hand, we considered the recommendations submitted by the AMA RUC, which, as noted above, would result in payment rates of approximately $21 for administration of the influenza, pneumococcal and hepatitis B vaccines, and approximately $25–$30 for administration of the COVID–19 vaccine following the end of the PHE. On the other hand, we considered the payment rate for vaccine administration services established using the APC methodology under the hospital OPPS, which currently stands at approximately $40. Finally, we considered the recommendation made by commenters who stated that we should base the payment rate on a crosswalk to CPT code 36000, which would result in a payment rate of approximately $30 after adjusting the CY 2021 rate of $28.39 for inflation. Based on these data and on the feedback we received from commenters, we believe that $30 is the most appropriate payment rate for administration of Part B preventive vaccines. Specifically, this amount is approximately equivalent to the CY 2021 valuation of CPT code 36000 adjusted for inflation to CY 2022, and also near the upper range of the approximate payment rates that would result if we adopted the RUC recommendations for administration of the COVID–19 vaccines.

Based on the history and status of payment for preventive vaccine administration discussed above and given the concerns gathered through the comment solicitation we believe that we need to act expeditiously to update payment rates for the administration of preventive vaccines paid under Medicare Part B, effective January 1, 2022. In addition, we believe that the timing is appropriate for establishing a predictable payment rate for preventive vaccine administration since the PHE has ignited a hypervigilance for infectious diseases.

In setting the payment rate for administration of preventive vaccines, we carefully considered how to move forward with what we believe is the appropriate payment mechanism that would align with the goal of vaccinating as many Medicare beneficiaries as possible each year in an effort to prevent illnesses that are known to lead to negative outcomes. For example, we considered the value of establishing a site-neutral payment rate versus recognition that cost structures are different between an office, hospital, or temporary remote COVID–19 vaccination administration site. We concluded that establishing payment rates that are intended to address the unique costs experienced across the wide variety of providers and suppliers that administer vaccinations would require the development of an unnecessarily complex payment methodology and potentially delay implementation.

We also recognize the value of a site-neutral payment rate, especially with regard to vaccine administration, since the procedure itself is practically the same across settings. However, we are unable to establish a single Medicare program payment rate that is site-neutral since there are several settings in which different Medicare payment methodologies dictate different payment rates for vaccine administration under Part B. Payment rates for administration of preventive vaccines by suppliers such as physicians, NPPs, and mass immunizers historically have been based on an evaluation of the resource costs involved in furnishing the service, which is analogous to the methodology that we use to establish payment rates under the PFS. We also assign a payment rate under the OPPS for administration of preventive vaccines by hospitals. Certain other types of providers and suppliers, such as RHCs, FQHCs and CAHs, are paid on a reasonable cost basis for vaccine administration.

We believe we have gathered sufficient resource cost data that can be used to set an appropriate payment rate for suppliers such as physicians, NPPs, and mass immunizers, who administer the majority of preventive vaccines to Medicare beneficiaries. In addition, we believe a stable vaccine-neutral payment rate is appropriate in this space so providers and suppliers that furnish preventive vaccinations can rely on predictable payments for this service, which we anticipate would allow them to forecast their business plans and engage in activities that could continue to build and sustain robust vaccination programs. As we discuss above, we recognize there are cost differentials that exist with regard to the COVID–19 vaccine versus the other preventive vaccines at the time of this final rule and that those may continue to exist into and potentially throughout CY 2022. Therefore, beginning for services furnished in CY 2022, we are finalizing a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine covered

under the Medicare Part B preventive vaccine benefit at section 1861(s)(10) of the Act.

The AMA RUC develops recommended valuations for services by contemplating the typical case and then deciding how many minutes the typical case takes and what supplies are typically used. The RUC developed specific estimates for COVID–19 vaccine administration and for pediatric and other immunizations, but not for the Part B preventive vaccines. The RUC recommendations would produce a payment for COVID–19 vaccine administration of approximately $35–$40 per dose during the PHE, and approximately $25–$30 after the PHE is terminated. The best cost data we have available comes from the hospital outpatient setting, which, as mentioned above, suggests a cost of approximately $40 for administration of a preventive vaccine. However, most immunizers will not have a cost structure similar to an acute care hospital. As such, we believe it is appropriate to finalize a payment rate that approximates the RUC's estimates of the costs involved in the typical case of COVID–19 vaccine administration after the PHE, (that is, $30).

In addition, as explained above, we will maintain the current payment rate of $40 per dose for the administration of the COVID–19 vaccines through the end of the calendar year in which the PHE ends; effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID–19 vaccine administration will be set at a rate that aligns with the per dose payment rate for administration of other Part B preventive vaccines. We recognize that it is difficult to predict when resource costs relating to COVID–19 vaccination will align with those for other vaccinations after the PHE ends, as we believe the scale of this PHE is unique in recent Medicare payment history. We will continue to actively monitor vaccination utilization and may consider refinements in the future.

We note that the administration of the preventive vaccines described under section 1861(s)(10) of the Act is not included within the statutory definition of physicians' services, that the payment rates finalized above are independent of the PFS, and that these payment rates will be updated as necessary independently of the valuation of any specific codes under the PFS. We believe that the payment rates finalized above accurately reflect the resource costs involved in the administration of Part B preventive vaccines, and that a payment differential limited to the duration of the PHE recognizes the additional costs involved in the administration of the COVID–19 vaccines in the context of the pandemic.

Comment: Some commenters, while supporting payment rates based on AMA RUC recommendations for CY 2022, encouraged CMS to consider whether it would be more effective and sustainable to develop a payment methodology for vaccine administration that considers the value of preventive vaccinations instead of only considering the cost of furnishing these services, and whether such an approach might boost vaccination rates among Medicare beneficiaries. Commenters who advocated for this approach stated that cost-based reimbursement has been ineffective, whereas moving away from a cost-based methodology would give vaccine providers more flexibility to furnish additional counseling services or implement innovative clinical workflows to optimize vaccination among their patients.

Response: We thank the commenters for their suggestion. We plan to monitor immunization rates among Medicare beneficiaries after the payment rates for vaccine administration services finalized in this final rule go into effect, and will continue to engage with members of the public on potential refinements to our policies.

As we stated above, we believe we have gathered sufficient resource cost data to set a payment rate for vaccine providers such as physicians, NPPs, and mass immunizers, who administer the majority of preventive vaccines to Medicare beneficiaries. Therefore, beginning January 1, 2022, these providers and suppliers will be paid $30 for the administration of an influenza, pneumococcal or HBV vaccine under the Medicare Part B vaccine benefit. In addition, through the end of the year in which the COVID–19 PHE ends, we will maintain the current payment rate of $40 per dose for the administration of the COVID–19 vaccines; following the end of the year in which the PHE ends, the payment rate for COVID–19 vaccine administration will be set at a rate that aligns with the rate for other preventive vaccines.

Comment: A couple of commenters provided feedback in response to our inquiry about the process to update the payment rates for administration of preventive vaccines on an annual basis. One commenter suggested that incremental updates should be made to the payment rate each year. Another commenter stated that annual updates to the vaccine administration payment rates based on OPPS claims data would be a reliable and data-based method for updating the payment rate and would prevent the issues that have occurred in the past with the crosswalk to CPT code 96372.

Response: We thank the commenters for their suggestions. We continue to seek feedback on an appropriate mechanism for updating these payments on a yearly basis by, for example, applying an annual inflation factor, for example the MEI, to the payment rate in order to reflect increases in costs faced by providers and suppliers that furnish the service, and plan to address updating the payment rate for Part B preventive vaccine administration in future rulemaking.

Comment: We received feedback from several commenters who emphasized the role of primary care physicians in vaccinating Medicare beneficiaries and the general public. The commenters cited a study indicating that primary care practices provide over half of all vaccine administration services for Medicare beneficiaries,[42] and noted that these healthcare professionals are an important resource for addressing vaccine hesitancy and encouraging patients to receive vaccinations. On the other hand, commenters expressed concern that inadequate payment rates may discourage small family practices with limited resources from offering vaccines, and that patients may be less likely to follow through on their physician's advice to receive a vaccine if it is not immediately available onsite.

Several commenters emphasized the role of pharmacists in providing both routine seasonal vaccines and vaccines against COVID–19, and anticipated that pharmacies will continue to play a leading role in immunization efforts after the PHE is over and COVID–19 becomes endemic. Commenters pointed to the widespread presence of pharmacies in local communities across the country, with one commenter asserting that pharmacists are the most accessible healthcare professionals, interacting regularly with patients and providing education and recommendations that may have a positive impact on a person's decision to receive a vaccine.

Response: We appreciate the contributions that primary care physicians and pharmacists make in the national immunization effort, including their role in educating patients on the issue of vaccines. We believe that the payment rates for vaccine administration services finalized in this

[42] Wilkinson, E., Jetty, A., Petterson, S., Jabbarpour, Y., & Westfall, J. M. (2021). Primary Care's Historic Role in Vaccination and Potential Role in COVID 19 Immunization Programs. Annals of Family Medicine, 19 (4), 351. 355. *https://doi.org/10.1370/AFM.2679*.

final rule more accurately reflect the costs incurred by primary care physicians, pharmacists and other healthcare providers in furnishing vaccines.

Comment: We also received comments related to payment to FQHCs for COVID–19 vaccine administration services, vaccination efforts among American Indian/Alaska Native (AI/AN) populations and payment for vaccine administration to Indian health care providers, suggestions on ways to promote effective and equitable distribution of preventive vaccines, and potential barriers to access that may prevent beneficiaries from receiving vaccines covered under the Medicare Part D benefit.

Response: We appreciate the commenters' feedback. However, we did not discuss or include proposals on these issues in the CY 2022 PFS proposed rule. As such, these comments are outside the scope of this rulemaking, but we will take these comments into consideration for the future.

2. Payment for COVID–19 Vaccine Administration in the Home

As we discussed in the CY 2022 PFS proposed rule (86 FR 39224), effective June 8, 2021, we announced a new add-on payment with a national rate of $35.50 when a COVID–19 vaccine is administered in the home.[43] Under this policy, providers and suppliers that administer a COVID–19 vaccine in the home under certain circumstances can bill Medicare for one of the existing COVID–19 vaccine administration CPT codes (0001A, 0002A, 0011A, 0012A, 0031A) along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). Providers and suppliers administering a COVID–19 vaccine in the home will be paid a national average payment $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home, and both payments are geographically adjusted).

In establishing the additional payment for COVID–19 vaccine administration in the home, we also established certain conditions for the add-on payment described by HCPCS code M0201. More specifically, for purposes of this additional payment for administration of the COVID–19 vaccine in the home, we established that Medicare will make this payment when either of these situations applies:

- The patient has difficulty leaving the home to get the vaccine, which could mean any of these:

(1) They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;

(2) They have a condition that makes them more susceptible to contracting a pandemic disease like COVID–19; or

(3) They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort;

- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving. We also specified that payment is made for HCPCS code M0201 if the sole purpose of the visit is to administer the COVID–19 vaccine. However, Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.

For purposes of this add-on payment for in-home COVID–19 vaccine administration, we announced that a home can be a private residence, temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter), an apartment in an apartment complex or a unit in an assisted living facility or group home, or a patient's home that is made provider-based to a hospital during the PHE for COVID–19. As such, a home may be a domiciliary or rest home, meaning a facility, which provides room, board, and other personal assistance services (for example, an assisted living facility).

We also announced that the following locations are not considered to be the patient's home for purposes of the add-on payment for COVID–19 vaccine administration: Communal spaces of a multi-unit living arrangement; hospitals; Medicare SNFs, and Medicaid NFs, regardless of whether they are the patient's permanent residence; assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program. In the CY 2022 PFS proposed rule (86 FR 39224), we clarified that an institution is not considered to be a patient's home if the institution meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and skilled nursing facilities (SNFs), as well as most nursing facilities under Medicaid.[44]

Additionally, we established that assisted living facilities participating in the CDC Pharmacy Partnership for Long-Term Care Program partnership would not be eligible for this higher payment for COVID–19 vaccine administration in the home when their residents were vaccinated through this program.

In addition, we established that the COVID–19 vaccine administration service must be furnished inside an individual's home. For this purpose, an individual unit in a multi-dwelling building is considered a home. For example, an individual apartment in an apartment complex or an individual bedroom inside an assisted living facility or group home is considered a home. We established that communal spaces of, or related to, congregate living arrangements (such as a communal area of an apartment or condominium complex, assisted living facility, group home) were not considered a home for purposes of this add-on payment because multiple people could be vaccinated and monitored either simultaneously or in tandem in such communal spaces.

As noted in the code descriptor for HCPCS code M0201, this code could be billed only once per individual home per date of service. In situations where more than one Medicare beneficiary lives in the same individual home, the additional payment for COVID–19 vaccine administration in the home was limited to one time in that home on that day, while any additional COVID–19 vaccine administration services for other individuals in that same home would be paid at the generally applicable rate of approximately $40 without the additional in-home add-on payment amount.

We established the payment amount for HCPCS code M0201 for in-home vaccination to reflect the additional costs associated with administering the vaccine in the home, such as upfront administration costs like scheduling, the additional clinical time needed for post administration monitoring of a single patient, and public health reporting requirements. To identify an appropriate payment rate for HCPCS code M0201, we used the home health low utilization payment adjustment add-on factor for skilled nursing as a proxy for the increased resource costs, above those reflected in the base payment rate for COVID–19 vaccine administration, involved in arranging

[43] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[44] 42 CFR 409.42(a).

and furnishing COVID–19 vaccine administration services in the home. For home health services, we make a low utilization payment adjustment (LUPA) when, during a 30-day period of home health care (or prior to January 1, 2020, a 60-day episode of home health care) a patient receives minimal services (less visits than a predetermined threshold) and the home health agency is paid per visit rather than the full 30-day (previously 60-day) bundled payment amount (see 42 CFR 484.230). As stated in the CY 2008 HH PPS proposed rule, after the HH PPS went into effect we received comments and correspondence stating that the LUPA per-visit payment rates do not adequately account for the front-loading of costs in an episode. Commenters suggested that because of the small number of visits in a LUPA episode, HHAs have little opportunity to spread the costs of lengthy initial visits over a full episode (72 FR 25424). As such, under the Medicare home health payment system, LUPA add-on payments are made to account for the upfront fixed costs and prolonged visit lengths in a LUPA period/episode compared to those for non-LUPA periods/episodes. We believe the LUPA add-on factor for skilled nursing is an appropriate proxy for the upfront fixed costs and prolonged visit lengths that exemplify and constitute the increased resource costs involved in arranging and furnishing COVID–19 vaccine administration services in the home.

The CY 2021 LUPA add-on factor for skilled nursing is 1.8451, and we applied this to the base rate for COVID–19 vaccine administration of $40 per dose (effective March 15, 2021). This calculation results in a total proxy payment rate for in-home COVID–19 vaccine administration of approximately $74. Subtracting the $40 base rate for COVID–19 vaccine administration, which applies across most other settings, results in an additional proxy payment rate of roughly $34. To expedite access to this service and ensure consistency in payment rates for HCPCS code M0201 between health care professionals, other suppliers, and institutional providers, we established a payment rate that corresponds to the proxy we calculated based on the LUPA add-on factor using a reference to another proxy payment rate under the hospital OPPS. Specifically, we looked to APC payment amounts under the hospital OPPS that were similar to the $34 proxy amount and could be implemented with speed under the COVID–19 vaccine benefit (which relies on both institutional and professional claims processing systems). We identified New Technology APC 1494 under the hospital OPPS with a national payment rate of $35.50 as an appropriate reference payment amount for this service for most providers and suppliers, and established that amount as the national payment rate for HCPCS code M0201. That is, the national payment rate for HCPCS code M0201 is $35.50 for all providers and suppliers not paid reasonable cost. Although we announced a payment rate of approximately $35 on June 8, 2021, in order to accelerate implementation of the new payment for claims processing purposes, it was expedient to choose a proxy payment rate that was already in place under the OPPS.

In announcing the add-on payment for in-home COVID–19 vaccine administration, we noted that we established these policies on a ''preliminary basis to ensure access to COVID–19 vaccines during the public health emergency'' and that ''we continue to evaluate the needs of Medicare patients and these policies, and will address them in the future, as needed.'' [45]

On August 24, 2021, after the publication of the CY 2022 PFS proposed rule, we announced a number of changes to our policies. Effective August 24, 2021, communal spaces of a multi-unit or communal living arrangement, as well as assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program, can qualify as a Medicare patient's home for purposes of the additional in-home payment amount. Furthermore, effective August 24, 2021, Medicare pays the additional payment amount for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location.[46]

We used the proposed rule as a way to collect feedback on our policies and potential future changes.

- We sought feedback on our requirements, including the definition of the ''home'' and the types of clinical and non-clinical circumstances that make it difficult for a beneficiary to receive a COVID–19 vaccine outside the home. Do these requirements strike the appropriate balance of ensuring access to vaccines for vulnerable beneficiaries while also protecting against potential fraud? Should we maintain these requirements during the PHE as-is, and if not, what changes should we consider? Outside of the circumstances of the PHE that create a need for beneficiaries to be vaccinated as quickly and broadly as possible, under what circumstances do health care providers, suppliers, or others find particular need to vaccinate people at home rather than periodically in association with routine in-person visits?
- As noted, we established an add-on payment of $35.50, which is based on applying the LUPA add-on factor for skilled nursing to the national $40 payment rate for the base service as a proxy to reflect the additional resources involved in furnishing services in the home setting. What are the costs associated with furnishing COVID–19 vaccines in the home, and how do these costs differ from costs of furnishing vaccines in traditional locations, such as a physician's office or mass immunization site?
- What other steps should we take related to program integrity and beneficiary protection with this new add-on payment for administering the COVID–19 vaccine in the home? What documentation should providers and suppliers that furnish vaccines in the home be required to maintain and/or provide?

As we noted in the CY 2022 PFS proposed rule (86 FR 39225), this add-on payment of $35.50 only applies when providers or suppliers furnish the COVID–19 vaccine in the home, and is not billable when providers and suppliers furnish a different preventive vaccine (influenza, pneumococcal, HBV) in the home. Furthermore, we explained that we believe the additional payment is only appropriate for COVID–19 vaccines due to the unique circumstances of the PHE, as well as the upfront fixed costs and prolonged visit lengths that exemplify and constitute the increased resource costs involved in arranging and furnishing COVID–19 vaccine administration services in the home. However, we sought feedback on whether the same barriers that could prevent a beneficiary from obtaining a COVID–19 vaccine would also prevent them from obtaining other preventive vaccines, whether Medicare should make a similar add-on vaccine administration payment in those circumstances, and whether the costs to furnish other preventive vaccines in the home would be consistent with the costs to furnish the COVID–19 vaccine.

Comment: We received numerous comments in support of our policy to provide an additional payment in the

[45] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[46] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

amount of $35.50 when a COVID–19 vaccine is administered in the home under certain circumstances. Commenters overwhelmingly recommended that we continue making the additional payment beyond the end of the PHE, and many commenters also supported extending the payment to other preventive vaccines, either permanently or until the end of the pandemic. In support of this policy, commenters emphasized the importance of increasing vaccination rates and making the vaccines available to vulnerable homebound beneficiaries, who face barriers including chronic illness, financial and social precarity, and lack of access to digital resources. Several commenters stated that the same circumstances that currently prevent a beneficiary from leaving their home to receive a COVID–19 vaccine apply to other preventive vaccines as well and will continue beyond the end of the PHE. With respect to the specific resource costs involved in providing vaccine services in the home, commenters cited travel, vaccine storage and handling requirements, scheduling challenges, security, and sanitization; some commenters observed that similar costs apply to the administration of both the COVID–19 and other preventive vaccines in a beneficiary's home. A few commenters agreed that the Home Health LUPA is a reasonable proxy for the additional resource costs involved with administering COVID–19 vaccines in the home, while others asserted that the current payment amount of $35.50 is too low.

Response: We agree with the feedback that we received regarding the need to incentivize providers to administer COVID–19 vaccines in the home during the PHE, and especially with commenters who cited the need to protect beneficiaries who would be at increased risk of contracting COVID–19 and developing a serious illness if exposed. We also thank suppliers such as family physicians who have gone to great lengths to vaccine hard-to-reach populations under the difficult circumstances of the pandemic.

Given the commenters' concurrence with the added costs and compelling needs that led CMS to adopt the in-home add-on payment, we believe this policy is an appropriate one. In addition, since we do not expect those needs or costs to diminish immediately with the end of the PHE, we believe it would be appropriate to leave the in-home add-on payment rate in place through the end of the CY in which the PHE ends. For example, we anticipate that additional booster doses will be needed. In addition, we believe that that this policy would set clear expectations for vaccine providers and suppliers and allow for a more gradual transition to a permanent payment policy.

Therefore, we are finalizing our policy to continue making the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home under certain circumstances until the end of the year in which the PHE expires. We believe that this extension will maximize access to COVID–19 vaccines for vulnerable homebound beneficiaries during the gradual return to normal conditions following the formal termination of the PHE. At the same time, it will afford CMS the opportunity to monitor vaccine uptake data. We also note that a policy to continue this payment in place through the end of the year in which the PHE ends is in keeping with our policies outlined elsewhere regarding the payment rate of $40 for COVID–19 vaccine administration, as well as the coverage and payment of COVID–19 monoclonal antibody therapies for COVID–19 under the Part B vaccine benefit.

We note that for purposes of this add-on payment for in-home COVID–19 vaccine administration, we are maintaining the policy that a home can be a private residence, temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter), an apartment in an apartment complex or a unit in an assisted living facility or group home, or a patient's home that is made provider-based to a hospital during the PHE for COVID–19; however, an institution is not considered to be a patient's home if the institution meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and SNFs, as well as most nursing facilities under Medicaid.

We are grateful for the additional feedback we received from commenters who advocated maintaining the additional payment for in-home COVID–19 vaccination beyond the PHE and extending it to other preventive vaccines, and we will continue to engage with stakeholders on this topic.

Comment: Several commenters expressed concern that our policies regarding eligibility for the additional in-home payment are too restrictive, and encouraged CMS to consider incorporating flexibilities that would make this payment available under a greater variety of circumstances. Among the restrictions cited most frequently by commenters was our policy that Medicare does not pay the additional payment if another Medicare service is provided in the same home on the same date. For example, one commenter observed that home providers are not eligible to receive the additional payment if they offer the vaccine during an E/M visit or in conjunction with an influenza vaccine.

Another commenter stated that it is important for CMS to consider the unique cultural dynamics in households in Indian Country and provide flexibility to consider the family size composition and intergenerational living arrangements that are common in AI/AN communities; specifically, the commenter urged CMS to provide the additional payment when services are furnished to other family members in the same household. Commenters also cited restrictions on the number of vaccine administration services that may be furnished during a single visit and in a single home unit or communal space, as well as on the types of providers that are eligible to receive the additional payment. In addition, one commenter requested that CMS classify mobile vaccination as a patient's ''home'' to reflect the increased costs of safely vaccinating patients in this setting.

Response: We thank the commenters and will take their feedback into consideration if we contemplate any future changes to our policy concerning COVID–19 vaccine administration in the home.

Comment: One commenter urged CMS to offer explicit guidance on how the concept of ''home'' should be documented in individual patient medical records to reflect the various circumstances supported by COVID–19 vaccination payment policies as outlined on the CMS website.[47] The commenter also requested that CMS clarify whether the 10-patient limit applies to the capacity of the living facility or whether it is based on the number of patients given vaccination on a date of service.

Response: We have not established any specific medical record documentation requirements for the additional in-home COVID–19 vaccination payment. We have issued guidance explaining the circumstances under which the payment is available; and vaccine providers should ensure that the medical record documentation is sufficient support payment. We note that the documentation should additionally support the beneficiary's appropriateness for home vaccination as

[47] *https://www.cms.gov/medicare/covid-19/coding-covid-19-vaccine-shots.*

indicated in the CMS Coronavirus vaccination toolkit.[48]

In response to the second part of the commenter's question, we are clarifying that, effective August 24, 2021, Medicare pays for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location, but only when fewer than 10 Medicare patients receive a COVID–19 vaccine dose on the same day at the same group living location. When 10 or more Medicare patients receive a COVID–19 vaccine dose at a group living location on the same day, the additional payment can only be billed once per home (whether the home is an individual living unit or a communal space). We are further clarifying that the limit applies to the number of patients who receive a COVID–19 vaccine dose on the same day, regardless of the total number of patients residing at the location or the total capacity of the facility. For example, if 8 Medicare patients all reside in a location that houses 100 patients total, and those 8 Medicare patients receive a COVID–19 vaccine dose on the same day at that location, then, effective August 24, 2021, Medicare pays approximately $497.50 (5 × $35.50 for the in-home vaccine administration, plus 8 × $40 for each dose of the COVID–19 vaccine). On the other hand, if 12 Medicare patients all reside in a location that houses 100 patients total, and those 12 Medicare patients receive a COVID–19 vaccine dose on the same day at that location, then, effective August 24, 2021, Medicare pays approximately $515.50 (12 × $40 for each dose of COVID–19 vaccine, and 1 × $35.50 for one in-home vaccine administration—only one home add-on payment is billable in this circumstance because 10 or more Medicare patients were vaccinated at the same group living location on the same date).

Comment: One commenter stated that most COVID–19 vaccinations in the home have been administered by community pharmacists, and requested retroactive payment for pharmacists and other providers who administered the vaccine in communal spaces and other previously ineligible locations prior to the new flexibilities effective as of August 24, 2021.

Response: The additional flexibilities effective on August 24, 2021, were introduced, among other reasons, in order to enable a greater number of healthcare providers to furnish vaccine services to Medicare beneficiaries in their homes. We are grateful to community pharmacists and other healthcare providers who furnished these services in communal spaces and other ineligible locations prior to August 24, 2021, but we are not adopting the commenter's suggestion to make additional payments to providers retroactively.

3. Monoclonal Antibodies Used To Treat COVID–19

As we discussed in the CY 2022 PFS proposed rule (86 FR 39226), on November 9, 2020, the FDA issued an Emergency Use Authorization (EUA) for bamlanivimab monotherapy.[49] On November 21, 2020 the FDA issued an EUA for casirivimab and imdevimab, which are administered together.[50] On February 9, 2021, the FDA issued an EUA for bamlanivimab and etesevimab, which are administered together and which are also authorized for post-exposure prophylaxis for certain high risk patients.[51] On April 16, 2021, the FDA revoked the EUA for bamlanivimab monotherapy.[52] On May 26, 2021, the FDA issued an EUA for sotrovimab monotherapy.[53] On June 3, 2021, the FDA revised the EUA for casirivimab and imdevimab, which revised the dosing regimen from 2,400 mg (1200 mg of casirivimab and 1 200 mg of imdevimab) to 1 200 mg (600 mg of casirivimab and 600 mg of imdevimab), authorized the addition of a new presentation consisting of a single vial of casirivimab and imdevimab co-formulated in a 1:1 ratio, and also authorized casirivimab and imdevimab to be administered together via subcutaneous injection in certain limited circumstances.[54] On June 24, 2021, the FDA issued an EUA for tocilizumab monotherapy.[55] We explained that under the EUAs, all of these products, except for tocilizumab could be used for certain high-risk patients with mild-to-moderate COVID–19 with the goal of preventing further deterioration and hospitalization. Tocilizumab is authorized for hospitalized patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

When these products were granted EUAs during the PHE for COVID–19, we made the determination to cover and pay for them under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act. When we announced this approach, we also indicated that we would address ''potential refinements to payment for administering monoclonal antibody products to treat COVID–19 through future notice-and-comment rulemaking''.[56]

We make a separate payment for the products (when not given to the provider or supplier for free by the government) and for the service to administer them. We noted that as of June 30, 2021, the monoclonal antibody products authorized by the FDA under an EUA include two products involving drugs administered together, casirivimab and imdevimab and bamlanivimab and etesevimab, sotrovimab monotherapy, and tocilizumab monotherapy. All four products may be administered through intravenous (IV) infusion, and casirivimab and imdevimab may be administered via subcutaneous injection in certain limited circumstances under the updated June 3rd EUA.

Initially, we established a national payment rate of $309.10 for the service to administer (through IV infusion only at the time) these products, which was based on one hour of infusion and post-infusion monitoring in the hospital outpatient setting. We noted that while these products are typically infused over a period of roughly one hour, the EUA for casirivimab and imdevimab allows the product to be infused over a shorter time-period, such as 20 minutes, when appropriate. We noted that, as of June 15, 2021, the EUAs require at least one hour of post-infusion monitoring for all of the products available. On May 6, 2021, we increased the payment rate for administration of these products to $450.00 and established a separate payment rate of $750.00 when a monoclonal antibody product used to treat COVID–19 is administered in a home or residence.[57]

As we further explained in the CY 2022 PFS proposed rule (86 FR 39226), the decision to cover and pay for monoclonal antibody products used to treat COVID–19 under the COVID–19 vaccine benefit prioritized access to

[48] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[49] *https://www.fda.gov/media/143602/download.*

[50] *https://www.fda.gov/media/143891/download.*

[51] *https://www.fda.gov/media/145801/download.*

[52] *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab.*

[53] *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-monoclonal-antibody-treatment-covid-19.*

[54] *https://www.regeneron.com/downloads/treatment-covid19-eua-fda-letter.pdf.*

[55] *https://www.fda.gov/media/150319/download.*

[56] *https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion.*

[57] *https://www.cms.gov/newsroom/press-releases/cms-increases-medicare-payment-covid-19-monoclonal-antibody-infusions.*

these products during the COVID–19 pandemic by allowing almost all Medicare enrolled providers and suppliers, as permitted by State law and consistent with the terms of the EUA, to furnish and bill for administering these products across settings of care. Covering and paying for these services under the COVID–19 vaccine benefit also means that beneficiaries are not responsible for any cost sharing for the product or the service to administer it. We noted that Medicare considers other monoclonal antibody products—that is, monoclonal antibody products used in the treatment of other health conditions—''biologicals'' and pays for them based on the methodology in section 1847A of the Act when they are furnished in physician offices, ambulatory infusion clinics and under a similar methodology under the hospital OPPS. We also noted that, for these care settings, we typically rely on the applicable AMA CPT codes to describe and pay for drug administration services performed by providers and suppliers.

As noted above, bamlanivimab monotherapy and casirivimab and imdevimab, administered together, were authorized in late 2020. At that time, we made the determination to cover and pay for them under the vaccine benefit in section 1861(s)(10) of the Act, and this decision prioritized beneficiary access for purposes of addressing the PHE for COVID–19. Since that time, the EUA for bamlanivimab monotherapy has been revoked, the EUA for casirivimab and imdevimab administered together has been revised to include a new presentation, a new dosing regimen, and a new route of administration (in certain limited circumstances) and post-exposure prophylaxis for certain high-risk patients, sotrovimab monotherapy has been authorized and tocilizumab monotherapy has been authorized. In the CY 2022 PFS proposed rule (86 FR 39226) we stated that it was also becoming clear that, as more products enter the market, the Federal Government might not purchase them for distribution to providers and suppliers for free, as is the case with sotrovimab monotherapy and tocilizumab monotherapy. We note that subsequent to the issuance of the CY 2022 PFS proposed rule, the Federal Government has purchased sotrovimab and will be directing the distribution of the product beginning mid-October, 2021.

Given these fast-moving changes, we solicited feedback on our approach to coverage and payment for COVID–19 monoclonal antibody products under the COVID–19 vaccine benefit. We explained that we are considering whether we should align payment and coverage for these products with our approach for other monoclonal antibody products following the end of the PHE. We further explained that we believe the context in which these products are furnished to beneficiaries after the end of the PHE may more closely resemble the circumstances under which similar drugs and biologics are ordinarily furnished, specifically to a more targeted patient population outside of a pandemic. Outside the context of the PHE, we believe treating these products like other drugs and biologics paid under section 1847A of the Act may better align Medicare coverage and payment policies for COVID–19 monoclonal antibody products with other monoclonal antibody products, which are purchased by providers and suppliers through similar channels and administered using similar modalities. As noted above, coverage and payment for COVID–19 monoclonal antibodies under the COVID–19 vaccine benefit has meant that Medicare beneficiaries are not responsible for any cost-sharing, which is typically 20 percent of the allowed amount in most settings. We noted that if Medicare were to pay for COVID–19 monoclonal antibody products under the methodologies in 1847A of the Act, it would mean that beneficiary co-insurance would apply, similar to the way it applies to other drugs and biologics that are not paid for under a preventive vaccine benefit.

We also noted that tocilizumab—typically sold under the brand name Actemra®—was previously approved by the FDA for several indications.[58] As a result, during the PHE for COVID–19, Medicare has separate coding and payment rules for tocilizumab when it is furnished to patients with COVID–19 and in a manner consistent with the terms of the EUA, and for when tocilizumab is used for other clinical purposes. This may be confusing for hospital providers and we believe that treating these monoclonal antibody products like other drugs and biologics paid under section 1847A of the Act may help clarify these inconsistencies. We invited feedback on these issues.

We also invited additional feedback on the resource costs to administer COVID–19 monoclonal antibody products, such as costs associated with infrastructure, clinical labor, and equipment, including personal protective equipment. We recognize that administering monoclonal antibodies used to treat COVID–19 may be complex due the need to interact with beneficiaries that have active infections and manage the potential for spreading disease. We requested information on how the costs to furnish monoclonal antibodies used to treat COVID–19 compare with infusions of other complex biologics, and how the costs to furnish these products may be different when these products are administered in the home.

Comment: Commenters offered diverging opinions in response to our request for information on the coverage of monoclonal antibodies for the treatment of COVID–19 under the Medicare Part B vaccine benefit. Several commenters urged CMS to extend payment for COVID–19 monoclonal antibodies as vaccines beyond the end of the PHE. A few commenters cited continuing uncertainty regarding the pandemic and the emergence of new variants as reasons why CMS should defer any changes to its current policy to future rulemaking cycles, while others emphasized the importance of maintaining beneficiary access to these treatments, especially among minority communities. In addition, several commenters pointed to the development of monoclonal antibodies used for pre-exposure prophylaxis against COVID–19, stating that such products are functionally equivalent to vaccines and should therefore be covered under the COVID–19 statutory vaccine benefit in section 1861(s)(10) of the Act. On the other hand, we also received comments supporting a transition to regular Part B payment for COVID–19 monoclonal antibody treatments following the end of the PHE, including payment for the products themselves as biologics under section 1847A of the Act. In particular, several commenters recommended a transition to payment for COVID–19 monoclonal antibody therapies as biologics following the end of the year in which the PHE expires, as long as CMS provides clear guidance about the process and takes steps to mitigate out-of-pocket expenses for Medicare beneficiaries. One commenter recommended an extension beyond the PHE of at least two calendar quarters and urged CMS provide clear guidance to manufacturers on ASP reporting obligations.

With respect to the specific expenses incurred by providers of monoclonal antibodies, commenters observed that the current infusion infrastructure is tailored to non-infectious patients, and indicated that increased costs for administration of COVID–19 monoclonal antibody therapies result primarily from measures necessary to mitigate risk and isolate infectious

[58] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125472s044lbl.pdf.*

patients. Specific resource costs cited by respondents include: Isolation of infectious patients in separate rooms or infusion suites; personal protective equipment for staff; staff training and implementation of new clinical workflows; reporting requirements; and, sometimes, increased pharmacy labor to deal with inconsistent product packaging and labeling.

While several commenters encouraged CMS to extend the additional payment and associated flexibilities for administration of COVID–19 monoclonal antibody therapies in the home beyond the end of the PHE, other commenters recommended against in-home administration of these products, citing concerns over patient safety and the potential for adverse reactions.

Response: We agree with commenters who recommended CMS transition to treating COVID–19 monoclonal antibody therapies as biologicals that are paid using methodologies under section 1847A of the Act following the end of the calendar year in which the PHE expires. In particular, we believe that the public health needs that prompted coverage of these products as vaccines will gradually restabilize following the end of the PHE, and that extending the current payment approach to the end of the year will give healthcare providers adequate time to prepare for the change in payment methodology while continuing to maximize access to beneficiaries, including those who receive these treatments in the home. Similar to the continuation policies we are adopting for the $40 payment rate and the in-home add-on payment for COVID–19 vaccine administration, given the commenters' concurrence with the added costs and compelling needs that led CMS to provide payment and coverage for COVID–19 monoclonal antibody therapies under the Medicare Part B vaccine benefit, we believe this policy is an appropriate one. In addition, since we do not expect those needs or costs to diminish immediately with the end of the PHE, we believe it would be appropriate to continue to provide payment and coverage for COVID–19 monoclonal antibody therapies under the Medicare Part B vaccine benefit in place through the end of the CY in which the PHE ends. We recognize that once the COVID–19 PHE declaration is terminated, EUAs issued under that declaration will no longer remain in effect,[59] which may affect the availability of some products either for the diagnosis, treatment, or prevention of COVID–19, because they will need to have the requisite marketing authorization to remain on the market. To the extent there are products that would no longer have the requisite marketing authorization to remain on the market after a revocation of an EUA, we believe a transition period would be appropriate to allow for adjustments, as needed, to care plans that included such products.

Therefore, we are finalizing a policy to continue to pay for COVID–19 monoclonal antibody therapeutic products as vaccines under section 1861(s)(10) of the Act until the end of the calendar year in which the PHE expires. During this interim time, we will continue to pay providers and suppliers for the products themselves at 95 percent of Average Wholesale Price (AWP) except when they are provided for free by the government; we will also maintain the $450 payment rate for administering a COVID–19 monoclonal antibody in a healthcare setting, as well as the payment rate of $750 for administering a COVID–19 monoclonal antibody therapy in the home. Starting at the beginning of the calendar year following the year in which the PHE ends, we will treat COVID–19 monoclonal antibody therapies as biologics paid under section 1847A of the Act, and discontinue the unique payment rates of $450 and $750 for administering a COVID–19 monoclonal antibody product, which were established to ensure access during the PHE. We note that under section 1847A of the Act, physicians and suppliers furnishing COVID–19 monoclonal antibody therapies typically will be paid based on Average Sales Price (ASP) + 6 percent. In addition, providers and suppliers will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID–19 monoclonal antibodies similar to the way they are paid for administering other complex biological products.

Comment: A few commenters stated that CMS should continue to make enhanced payments for COVID–19 monoclonal antibodies even after transitioning to regular coverage of these services under Medicare Part B as discussed above. One commenter stated that if payment for COVID–19 monoclonal antibodies is aligned with that for other monoclonal antibody products, then additional work and PE costs must be factored in, and CMS must address steep reductions in drug administration services due to clinical labor pricing update proposal, for example by providing an enhanced payment when a COVID–19 diagnosis is present on a claim. Another commenter recommended a $300 COVID–19 therapy modifier to offset what they described as grossly undervalued professional service payments for infusion centers.

Response: We believe that the public health needs that prompted enhanced payments for COVID–19 monoclonal antibodies and administration services will gradually restabilize following the end of the PHE. As described in the previous section, extending the current payment approach to the end of the year in which the PHE ends will give healthcare providers adequate time to prepare for the change in payment methodology while continuing to maximize access to beneficiaries.

Comment: One commenter stated that CMS should adjust the eligibility standards for home-based administration of COVID–19 monoclonal antibodies to align with the more flexible standards that apply when determining eligibility for the additional payment when a COVID–19 vaccine is administered in a beneficiary's home. That is, in order to qualify as homebound for purposes of receiving monoclonal antibody services in the home, a beneficiary would need to meet the requirements set forth in the CMS COVID–19 vaccination toolkit.

Response: We thank the commenter for their feedback and will take it into consideration if we contemplate any future changes to our policy concerning in-home administration of COVID–19 monoclonal antibodies.

Comment: We received several comments pertaining to the role of specific provider types in administering and billing for COVID–19 monoclonal antibodies.

One commenter stated that pharmacists are well-positioned to increase awareness of and expand access to monoclonal antibody therapies, and urged CMS to consider supplemental funding for community pharmacies to develop the infrastructure to administer monoclonal antibodies onsite. Additionally, the commenter stated that a significant barrier to maximizing the use of pharmacists to develop these treatments is inadequate reimbursement for administrative costs and delays in the processing of claims by Medicare; the commenter therefore urged CMS to issue pharmacist/pharmacy specific guidance on pharmacy billing for these therapies outlining specific, rapid turn-around of Medicare reimbursements for MACs that covers the entirety of administration costs in a pharmacy setting.

One commenter emphasized the role of urgent care centers in furnishing

[59] *https://www.fda.gov/media/97321/download.*

monoclonal antibody treatment, and stated that simplification of administrative and reporting requirements would improve urgent care centers' ability to offer these services.

Another commenter urged CMS to establish a protocol allowing long-term care pharmacies (LTCPs) to bill independently for the procurement, preparation and reporting of monoclonal antibody treatment administered by a long-term care facility (LTCF). The commenter stated that splitting this fee is currently allowed by CMS, but the division is conducted as a private, two-party contract between LTCFs and LTCPs, and that providing a mechanism to reimburse each party for their efforts would provide CMS with better data related to the use of monoclonal antibodies to combat COVID–19 and other public health threats.

In addition, one commenter emphasized the role of home infusion pharmacies in providing monoclonal antibody treatment, both in beneficiaries' homes and in pharmacy-owned infusion suites. The commenter observed that, after the PHE, administration of monoclonal antibodies for COVID–19 in the home would not be covered under the standard Part B benefit without additional flexibilities, and therefore, urged CMS to maintain coverage of these products as vaccines until the establishment of a similar benefit that allows a licensed home infusion pharmacy to provide COVID–19 treatments in the home or in a pharmacy-owned and operated infusion suite at the current payment rates for each site of care.

Response: We believe that, following the end of the PHE, the public health needs that prompted coverage and payment of COVID–19 monoclonal antibody therapies (and their administration) under the Part B vaccine benefit will gradually restabilize. As discussed in the previous section, extending the current payment approach to the end of the year in which the PHE ends will give healthcare providers adequate time to prepare for the change in payment methodology while continuing to maximize access to beneficiaries, including those who receive these therapies in the home.

Comment: Several commenters urged CMS to update the FQHC cost report to ensure adequate reimbursement for monoclonal antibody infusions at 100 percent of reasonable cost.

Response: We appreciate the commenters' feedback. However, we did not discuss or include proposals on FQHC cost reports in the CY 2022 PFS proposed rule. As such, these comments are outside the scope of this rulemaking, but we will take these comments into consideration for the future.

4. Summary

We have taken several steps to promote broad and timely access to COVID–19 vaccines, including monoclonal antibody products used to treat COVID–19 paid for as vaccines, during the PHE for COVID–19. We appreciate the feedback we have received from the public on these important issues regarding preventive vaccine administration, vaccine administration in the home, and administration of monoclonal antibody products used to treat COVID–19.

In summary, for CY 2022, we are finalizing the following policies:

Administration of Preventive Vaccines

Effective January 1, 2022, CMS will pay $30 per dose for the administration of the influenza, pneumococcal and hepatitis B virus vaccines. In addition, CMS will maintain the current payment rate of $40 per dose for the administration of the COVID–19 vaccines through the end of the calendar year in which the ongoing PHE ends. Effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID–19 vaccine administration will be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines.

In-Home Administration of COVID–19 Vaccines

CMS will continue the additional payment of $35.50 for COVID–19 vaccine administration in the home under certain circumstances through the end of the calendar year in which the PHE ends.

COVID–19 Monoclonal Antibody Products

CMS will continue to pay for COVID–19 monoclonal antibodies under the Medicare Part B vaccine benefit through the end of the calendar year in which the PHE ends. During this interim time, we will maintain the $450 payment rate for administering a COVID–19 monoclonal antibody in a healthcare setting, as well as the payment rate of $750 for administering a COVID–19 monoclonal antibody therapy in the home. Effective January 1 of the year following the year in which the PHE ends, CMS will pay physicians and other suppliers for COVID–19 monoclonal antibody products as biological products paid under section 1847A of the Act; healthcare providers and practitioners will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID–19 monoclonal antibodies similar to the way they are paid for administering other complex biological products.

Table 32 summarizes the policy changes finalized in this final rule.

TABLE 32: Summary of Medicare Payments for Administering Preventive Vaccines

	Current	Effective Jan. 1, 2022	Effective Jan. 1 of the year following the year in which the PHE expires
Administration of influenza, pneumococcal and HBV vaccines	$16.94/dose	$30/dose	Applicable amount/ dose
Administration of COVID-19 vaccines	$40/dose	$40/dose	Aligned with other preventive vaccine administration
Additional payment when a COVID-19 vaccine is administered in the home setting	$35.50	$35.50	No additional payment
Payment for COVID-19 monoclonal antibody products	95% of AWP except when provided for free by the government	95% of AWP except when provided for free by the government	Section 1847A of the Act
Payment for COVID-19 monoclonal antibody administration	$450 in the healthcare setting; $750 in the home setting	$450 in the healthcare setting; $750 in the home setting	Suppliers and providers paid under the applicable payment system

K. Payment for Medical Nutrition Therapy Services and Related Services

Section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, December 21, 2000) added section 1861(vv)(1) to the Act which provided Medicare coverage under Part B for Medical Nutrition Therapy (MNT) services when performed by registered dietitians and nutrition professionals pursuant to a referral from a physician.

Under section 1842(b)(18)(C) of the Act, registered dietitians and nutrition professionals are included in the list of NPPs that may bill Medicare and be paid directly for their services, effective January 1, 2002. To submit claims for MNT services, the registered dietitian or nutrition professional must enroll as such in accordance with our regulations at 42 CFR 414.64 and 424.510. Like other NPPs listed in section 1842(b)(18)(C) of the Act, registered dietitians and nutrition professionals who are employees or independent contractors of hospitals or physician groups may reassign their rights to receive payment to that hospital or physician group, as appropriate. The Medicare specialty code for ''dietitian/ nutritionist'' is 71.

Under section 1833(a)(1)(T) of the Act, we were originally required to pay for MNT services at 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the PFS for the same services if the services had been furnished by a physician. We established payment regulations for MNT in our regulation at § 414.64 in the CY 2002 PFS final rule (66 FR 55278 through 55281 and 55332).

MNT services are defined as nutritional diagnostic, therapeutic, and counseling services that are furnished by a registered dietitian or nutrition professional for the purpose of managing diabetes or a renal disease. These practitioners use three CPT® codes to bill for MNT assessment and intervention services with the referral of a physician. In cases where there is a second physician referral for MNT for the same patient within a calendar year (for example, based on a change in the patient's condition, diagnosis, or treatment regimen), the furnishing practitioner uses two other HCPCS codes to report these episodes. We have worked with stakeholders over the years to establish values for the services described by the five MNT codes.

The importance of MNT services for managing diabetes or renal disease, as well as the underutilization of the benefit by Medicare beneficiaries were discussed in the proposed rule at section III.I. (86 FR 39259 through 39261). More recently, stakeholders who were concerned about the low utilization rate for the services have requested that CMS make changes geared toward making MNT services more accessible to Medicare beneficiaries. These stakeholders believe the underutilization of MNT services is due to multiple factors. Some of these factors and our proposals to address them are discussed elsewhere in this final rule (see section III.I.), including proposals to remove the requirement that the MNT referral be made by the ''treating physician'' and update the glomerular filtration rate (GFR) eligibility criteria to reflect current medical practice. First, stakeholders recommended that we modify the Medicare Claims Processing Manual (MCPM) to increase the visibility of MNT services by moving the provisions that address these services to appear near the provisions addressing other preventive services. (We note that MNT services are included in the definition of preventive services under section 1861(ddd)(3)(A) of the Act). Second, the stakeholders recommended that we revise our Medicare Benefit Policy Manual to address registered dietitians and nutrition professionals, and the MNT services they furnish, in a way that aligns with the provisions addressing other types of practitioners and the services they furnish.

We established the MNT regulations in the CY 2002 PFS final rule at § 410.130 through § 410.134 and § 414.64. There have since been two significant changes to payment for MNT services, which are discussed in more detail below: (1) We added MNT services to the Medicare telehealth services list and recognized that registered dietitians and nutrition professionals can furnish and bill for these services as distant site practitioners; and (2) section 4104 of the

Affordable Care Act (ACA) amended the statute to remove application of the Medicare Part B deductible and coinsurance for MNT services effective January 1, 2011. In the CY 2006 PFS final rule (70 FR 70155 through 70157), we amended our regulation to add registered dietitians and nutrition professionals to the list of distant site practitioners for telehealth services at § 410.78(b)(2)(viii), and to add the three individual MNT services to the Medicare telehealth services list by adding ''individual medical nutrition therapy'' to § 414.65(a)(1). In the CY 2011 PFS final rule, we also added one of the group MNT codes (97804) to the Medicare telehealth services list (75 FR 73314 through 73315). Although the codes for individual MNT services were recognized as telehealth services beginning in CY 2006, a recent claims query (prior to the PHE for COVID–19) showed low utilization of MNT services via telehealth by registered dietitians and nutrition professionals.

In the CY 2011 PFS final rule, (75 FR 73412 through 73430), we implemented the amendments made by section 4104 of the ACA, which were designed to remove financial barriers that may have prevented beneficiaries from obtaining certain preventive services. Section 4104 of the ACA amended section 1833(a)(1) of the Act by adding a new subparagraph (Y), which provides for Medicare Part B payment at 100 percent for preventive services described in section 1861(ddd)(3)(A) of the Act that are recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and, amended section 1833(b)(1) of the Act to specify that the annual Medicare Part B deductible does not apply to preventive services with a recommended grade of A or B by the USPSTF. Section 1861(ddd)(3) of the Act defines ''preventive services'' and includes MNT services as a preventive service through a cross reference to section 1861(ww)(2) of the Act. Additionally, section 4104 of the ACA amended section 1833(a)(1)(T) of the Act to specify that Medicare Part B payment is made at 100 percent (instead of 80 percent) of the lesser of the actual charge or 85 percent of the PFS payment amount for these services if they are recommended with an A or B rating by the USPSTF, thereby removing beneficiary coinsurance for these services. In the CY 2011 PFS final rule, we listed all preventive services and their recommended ratings from the USPSTF in Table 66 (66 FR 73420 through 73430), noting that all 5 MNT services received a grade of B from the USPSTF; and the last column in the table noted that the coinsurance and deductible are not applicable to these services beginning January 1, 2011. We codified the coinsurance exception for MNT services at § 410.152(l)(7) to indicate that Medicare Part B pays 100 percent of the Medicare payment amount; and codified the exception for the Medicare Part B deductible at § 410.160(b)(11).

At that time, the preventive services coinsurance and deductible changes were implemented through Change Request 7012 (Transmittal 864); however, we neglected to update the payment regulation for MNT services at § 414.64(a). As a result, we proposed in the CY 2022 PFS proposed rule to modify the regulation at § 414.64(a) to clarify that MNT services, with their USPSTF recommended B rating, are paid at 100 percent of the lesser of the actual charges or 85 percent of the PFS amount. In the proposed regulation text at § 414.64(a), we made an inadvertent typographical error, using ''or'' instead of ''of.'' We are correcting the error here in this final rule so that § 414.64(a) provides that payment is made at 80 percent, or 100 percent if the service is recommended by the United States Preventive Services Task Force with a grade of A or B, ''of'' the lessor of the actual charge or 85 percent of the physician fee schedule amount.

Because the registered dietitian and nutrition professional are the only practitioner types listed at section 1842(b)(18)(C) of the Act without a specific regulatory provision addressing them as a type of practitioner and specifying payment policies for their services, we proposed to create a new section at § 410.72 to reflect these practitioners and related payment policies. We proposed to include in the regulation at § 410.72 a cross reference to the regulation at § 410.134 that addresses the qualifications for registered dietitians and nutrition professionals. For covered services described at § 410.72(b), we proposed as a condition of coverage to refer to medical nutrition therapy services as defined at § 410.130, and also to refer to the conditions for coverage of MNT services at § 410.132(a). Section 410.132(a) requires a referral for MNT services from a physician (an M.D. or D.O.), and that MNT services are performed by the registered dietitian or nutrition professional in a face-to-face encounter except when those services are furnished as a telehealth service as provided in § 410.78 of our regulations.

Because registered dietitians and nutrition professionals are also the primary specialty that furnishes diabetes self-management training (DSMT) services, we proposed to include DSMT at § 410.72(b)(2) as an ''other service'' that registered dietitians and nutrition professionals can provide in cases where the registered dietitian or nutrition professional is a certified provider of DSMT services as specified at section 1861(qq)(2)(A) of the Act; and they have submitted necessary documentation to, and are accredited by, a CMS-approved accreditation organization, as specified in § 410.141(e) for DSMT services. We also proposed to address in the regulation at § 410.72(b)(2) the current requirement that, as specified in the regulation at § 410.141(b)(1), DSMT services require a referral from the physician or qualified NPP (as defined in § 410.32(a)(2)) who is treating the beneficiary's diabetes condition. We also proposed to specify in the regulation at § 410.72(b)(3) that MNT and DSMT services cannot be furnished together on the same date of service as detailed in the national coverage determination for MNT services (see *https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=252*); and, that neither MNT nor DSMT services can be furnished incident to the professional services of a physician or other practitioner. For MNT services, we proposed to clarify that MNT services cannot be provided incident to the services of a billing physician. As a distinct, stand-alone benefit under Medicare Part B at section 1861(s)(2)(V) of the Act, MNT services cannot be furnished incident to a physician's professional service that is separately specified at section 1861(s)(2)(A) of the Act. Further, if a physician also meets the qualifications to bill Medicare as a registered dietitian or nutrition professional (although not necessarily enrolled as one), they would have to personally provide any MNT services as explained above, meaning that those services could not be furnished by auxiliary personnel incident to their own professional services. For DSMT services, we also proposed to clarify that DSMT services cannot be provided incident to the services of a billing physician or practitioner. DSMT is a distinct benefit under Medicare Part B, as specified in a stand-alone statutory provision at section 1861(s)(2)(S) of the Act. Approved DSMT entities are separately recognized programs, rather than individuals or practitioners, that provide DSMT services in accordance with their accreditation from a CMS-approved organization under § 410.142, indicating that the entity meets a set of quality standards described in

§ 410.144. Even when the DSMT services are billed by a physician or other practitioner, such as the DSMT certified provider, the physician or other practitioner could not provide DSMT services directly, unless they themselves are also an approved DSMT entity. If a physician or practitioner is an approved entity, the DSMT services must be provided in accordance with the requirements to furnish such services. For these reasons, we proposed to add at § 410.72(b)(3)(ii) that neither MNT nor DSMT may be furnished and billed incident to the professional services of a physician or practitioner, where applicable.

Given the foregoing, we proposed to add at § 410.72(d) that the registered dietitian or nutrition professional can be paid for their professional services only if those services have been personally performed by them. Section 1861(vv) of the Act clearly indicates that MNT services are only provided by registered dietitians and nutrition professionals; and this was reiterated at § 410.134 as established in the CY 2002 PFS final rule (66 FR 55331). In addition, the regulation at § 410.132(a) specifies that MNT services consist of face-to-face nutritional assessments and interventions in accordance with nationally accepted dietary or nutritional protocols. After we issued the CY 2022 PFS proposed rule, we reviewed the proposed regulation text at § 410.72(d) regarding the requirement that professional services of registered dietitians and nutrition professionals must be ''personally performed'' by them. We noted that the term, ''personally performed'' is used in 42 CFR part 410 of the regulations to describe services furnished both directly and incident to the services of other types of practitioners that are authorized by the statute to furnish and bill Medicare for covered services incident to their own professional services. Registered dietitians and nutrition professionals are not authorized by the statute to furnish and bill Medicare for services incident to their professional services. Upon further reflection, we are concerned that the reference to ''personally performed'' in the proposed regulation text at § 410.72(d) could potentially be confusing when applied to services of registered dietitians and nutrition professionals. To avoid any potential confusion, we are clarifying that registered dietitians and nutrition professionals may bill Medicare only for professional services that they furnish directly to the beneficiary. For the same reasons, we are also modifying and finalizing our proposed regulation text to substitute ''directly'' for ''personally'' in § 410.72(d).

In the CY 2022 PFS proposed rule, we included proposed regulation text at § 410.72(g) to specify that MNT and DSMT services may be provided as telehealth services (meeting the requirements in § 410.78) when registered dietitians or nutrition professionals act as distant site practitioners. While we did explain as noted above that registered dietitians and nutrition professionals were added to the list of distant site practitioners for telehealth services in § 410.78 of our regulation in the CY 2006 PFS final rule, we neglected to discuss the proposed regulation text at § 410.72(g) in the preamble to the CY 2022 PFS proposed rule. The proposed regulation text at § 410.72(g) essentially provides a cross-reference to longstanding policy codified in § 410.78 beginning in CY 2006. We received no comments on this proposed regulation text. We also discovered typographical errors in the proposed regulation text at § 410.72(g) after the CY 2022 PFS proposed rule was issued. The DSMT acronym was misspelled as ''DMST'' and we left out the ''s'' at the end of ''telehealth services.'' In this final rule, we are correcting these two errors and otherwise finalizing the regulation text at § 410.72(g) as proposed.

In the CY 2002 PFS final rule (which we cited correctly but inadvertently misidentified in the CY 2022 PFS proposed rule as the CY 2001 PFS final rule), we discussed that registered dietitians and nutrition professionals who are enrolled in Medicare could furnish services in various settings including private practices and outpatient hospitals, but that separate payment for MNT services would not be made when beneficiaries are inpatients in Part A stays in hospitals and SNFs (66 FR 55279). We explained that our payment to hospitals and SNFs includes payment for MNT services. We established these conditions of payment in the regulation at § 414.64(e) (which we inadvertently cited incorrectly in the CY 2022 PFS proposed rule as § 414.64(c)). We proposed to add these conditions of payment to our regulation at § 410.72(c)(1) and (2), to address payment for services of registered dietitians and nutrition professionals when beneficiaries are inpatients of hospitals and SNFs. Also, in the CY 2002 PFS final rule, we finalized, in accordance with section 1861(s)(2)(V)(ii) of the Act, that there is no coverage for MNT services available for beneficiaries who are receiving maintenance dialysis for which payment is made under section 1881 of the Act, that is, services from an end-stage renal disease (ESRD) facility. We codified this policy at § 410.132(b) of our regulations. We proposed to add this rule to our regulation at § 410.72(c)(3) through a cross-reference to § 410.132(b).

In accordance with section 1842(b)(18)(B) of the Act, the registered dietitian or nutrition professional must accept assignment, meaning that they must accept the payment amount Medicare approves as payment in full and collect nothing from the beneficiaries for those services for which Medicare pays 100 percent of the Medicare approved amount or only collect the difference between the Medicare approved amount and the Medicare Part B payment in accordance with § 424.55. We proposed to add at § 410.72(f) that the services of a registered dietitian or nutrition professional are provided on an assignment-related basis. Because Medicare pays 100 percent of the Medicare approved amount for MNT covered services, this means that beneficiaries cannot be billed any amount for MNT covered services. For other services, including DSMT, for which the Medicare Part B coinsurance percentage is 20 percent, a registered dietitian or nutrition professional must not collect amounts in excess of the limits specified in § 424.55 of our regulation, and if they do, they must refund the full amount of the impermissible charge to the beneficiary. Finally, we noted that the proposed regulatory text for § 410.72(f) is consistent with the text in existing regulations for other types of NPPs at §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2). We also considered whether alternate regulatory text that cross-references the assignment requirements in § 424.55 would provide additional clarity. Specifically, we considered whether to specify within § 410.72(f) that the services of a registered dietitian or nutrition professional are provided on an assignment-related basis; the registered dietitian or nutrition professional may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55; and if a beneficiary has made payment for a service in excess of these limits, the registered dietitian or nutrition professional must refund the full amount of the impermissible charge to the beneficiary.

To ensure maximum consistency in our regulations, we stated that if we finalize the alternate regulatory text for § 410.72(f), we would also make corresponding revisions to §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2). We

solicited public comments on the clearest language to describe the assignment requirements, as well as the rest of our proposals.

We received public comments on our proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters appreciated and commended our proposal to clarify and codify payment for MNT services at § 414.64(a) to reflect that MNT services, with their USPSTF recommended B rating, are paid at 100 percent of the PFS amount, rather than 80 percent.

Response: We thank the commenters for their support.

Comment: Some commenters offered support for all the proposed changes to regulations related to the Part B MNT benefit and expressed their agreement with our reasons for proposing the changes. Other commenters expressed support for the proposed regulatory text that includes specific payment policies for registered dietitians and nutrition professionals who are recognized to bill Medicare directly for the MNT services they provide.

Response: CMS appreciates the many commenters' support.

Comment: One commenter asked whether a physician (MD or DO) can ''co-sign'' an MNT referral made by an NPP they are supervising, for example, when the physician and NP or PA are practicing under a collaborative practice agreement as required by State law. The commenter added that NPPs manage and coordinate care for many individuals with diabetes and earlier stages of chronic kidney disease (CKD) in both urban and rural areas—suggesting that it would be appropriate to permit these NPPs to refer patients for MNT. We also received several comments about the possibility of expanding the referral requirement for MNT services to include other physicians such as optometrists and certain NPPs, including PAs and NPs.

Response: As discussed in the proposed rule, section 1861(vv)(1) of the Act expressly requires that the referral for MNT services must be from a physician—an M.D. or D.O. as defined in section 1861(r)(1) of the Act. We interpret this requirement to mean that the MNT referral must come directly from an M.D. or D.O., and not through a ''cosignature'' on a referral from another type of physician or practitioner. Therefore, we are not expanding the referral requirement to include other physicians or practitioners as these commenters requested.

Comment: One commenter requested that we provide clarification for our statement in the proposed rule regarding limitations on payment to registered dietitians and nutrition professionals at § 410.72(c). The commenter specifically asked us to explain our statement that the payment CMS makes to hospitals and SNFs for their Medicare beneficiaries who are inpatients includes payment for MNT services.

Response: We appreciate the commenter's interest in payment for MNT services under the PFS and the opportunity to clarify our statement. In developing the proposed regulation at § 410.72, we included the restrictions on separate payment for MNT as discussed in the CY 2002 PFS final rule and codified at § 414.64(e), which specifies that separate payment for MNT services is made only if the beneficiary is not an inpatient of a hospital, SNF, nursing home or hospice; and is not receiving services in an RHC, FQHC or ESRD facility. We did not propose to revise our policy in this regard; only to reiterate it under the proposed new regulation at § 410.72 that pertains to registered to dietitians and nutrition professionals and the services they furnish.

Comment: We received comments from several organizations that were supportive of our proposals to reduce barriers and improve access to MNT services, but expressed the view that the proposals did not go far enough to achieve those goals. They noted that Medicare Advantage plans often cover MNT for other conditions in addition to the Medicare coverage of MNT for patients with diabetes and CKD, and urged us to expand access to MNT for other conditions as appropriate, including mental health conditions (such as eating disorders).

Response: Currently, section 1861(s)(2)(V) of the Act provides a benefit for MNT services only for beneficiaries with diabetes or a renal disease. The scope of the statutory Medicare Part B benefit for MNT does not allow for expansion to additional diagnoses/conditions.

Comment: We received other comments that were not specific to the discussion and proposals made in the CY 2022 PFS proposed rule. For example, a few commenters requested that we provide additional clarity in the Medicare Claims Processing and Benefit Policy Manuals on coverage and billing procedures for MNT and DSMT services under the PFS in all settings, including hospital clinics, FQHCs, RHCs, and CAHs; and one commenter wanted CMS and Congress to address multiple access barriers to the DSMT benefit.

Response: We thank the commenters for their feedback and will take this information into consideration for the future. We look forward to working with stakeholders to consider and work toward increasing appropriate access to MNT and DSMT services. However, these comments are outside the scope of this rulemaking, and we decline to respond to them here.

We did not receive comments in response to our request for comments on the clearest language to describe the assignment requirements for registered dietitians and nutrition professionals. As noted in the proposed rule and specified at section 1842(b)(18)(B) of the Act, registered dietitians and nutrition professionals are required to provide services on an assignment-related basis. We proposed to add regulation text at the new § 410.72(f) that mirrors the current regulation text to reflect the requirements for payment on an assignment-related basis for other types of NPPs in §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2). We also indicated that we were considering whether to adopt alternate regulation text at § 410.72(f) that would reflect the requirements for payment on an assignment-related basis through a cross-reference to the regulation at § 424.55, and whether that approach would provide greater clarity. Specifically, we said we were considering whether to specify in § 410.72(f) that the services of a registered dietitian or nutrition professional are provided on an assignment-related basis, and the registered dietitian or nutrition professional may not charge a beneficiary in excess of the amounts permitted under § 424.55; and that if a beneficiary has made payment for a service in excess of these limits, the registered dietitian or nutrition professional must refund the full amount of the impermissible charge to the beneficiary. We stated that if we finalized the alternate approach to regulation text for § 410.72(f), to ensure maximum consistency across our regulations, we would make corresponding revisions to the regulations at §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2), and 410.77(d)(2). After further reflection, we believe that alternate text that cross-refers to the assignment requirements at § 424.55 provides greater clarity, and helpfully cross-refers to the current regulation that specifies the requirement for billing on an assignment-related basis. Therefore, we are adopting the alternate approach we described in the proposed rule and finalizing alternate

regulatory text to specify that the registered dietitian's or nutrition professional's services are provided on an assignment-related basis, and the registered dietitian or nutrition professional may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. Additionally, the registered dietitian or nutrition professional must refund the full amount of the impermissible charge to the beneficiary, if a beneficiary has made payment for a service in excess of these limits.

Given that we are finalizing the alternate regulatory text for § 410.72(f), as we noted in describing the alternate approach to the regulation text at § 410.72(f) in our proposed rule, to ensure consistency in our regulations, we are also finalizing conforming revisions to §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2), of our regulations for PAs, NPs, CNSs, and certified nurse mid-wives, respectively.

After consideration of public comments, we are finalizing our proposals, with modifications explained above, to amend the regulation at § 414.64(a) to reflect that MNT services are paid at 100 percent (instead of 80 percent) of 85 percent of the Medicare PFS approved amount without cost sharing; and to add the regulation at § 410.72 to address registered dietitians and nutrition professionals and payment for their services. We are also finalizing revisions to the regulations at §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2) to remove current language addressing the requirements of payment on an assignment-related basis and to instead cross-refer to those requirements as specified in the current regulation at § 424.55.

III. Other Provisions of the Proposed Rule

A. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

As discussed in 42 CFR part 405, subpart X, RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area with a shortage of home health agencies. A Transitional Care Management (TCM) service can also be paid by Medicare as an RHC or FQHC visit. In addition, a Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT program may also be considered an FQHC visit for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to a payment limit for the AIR, and this limit will be determined for each RHC in accordance with section 130 of the Consolidated Appropriations Act, 2021 as described below.

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to an FQHC PPS system in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

2. Payment Methodology for RHCs

a. Background

As we discussed previously, under Medicare Part B, payment to RHCs for services (defined in § 405.2411) furnished to beneficiaries is made on the basis of an all-inclusive payment methodology subject to a maximum payment per-visit (discussed in section III.A.3. of this final rule) and annual reconciliation. Our regulations at § 405.2470 provides that RHCs are required to submit cost reports to allow the Medicare Administrative Contractor (MAC) to determine payment in accordance with 42 CFR part 405, subpart X, and instructions issued by CMS. The statutory payment requirements for RHC services are set forth at section 1833(a)(3) of the Act, (as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [60]), which states that RHCs are paid reasonable costs * * * less the amount a provider may charge as described in clause of section 1866(a)(2)(A) of the Act, but in no case may the payment exceed 80 percent of such costs. The beneficiary is responsible for the Medicare Part B deductible and coinsurance amounts. Section 1866(a)(2)(A)(ii) of the Act and implementing regulations at § 405.2410(b) establish beneficiary coinsurance at an amount not to exceed 20 percent of the clinic's reasonable charges for covered services.

We explain in § 405.2464(a) the AIR is determined by the MAC at the beginning of the cost reporting period. The MAC calculates the AIR that will apply for the upcoming cost reporting period for each RHC by dividing the estimated total allowable costs by estimated total visits for RHC services. The MAC also periodically reviews the AIR throughout the cost reporting period to assure that payments approximate actual allowable costs and visits and may adjust the rate. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services (§ 405.2468).

Medicare payment for RHC services are ultimately determined at cost report settlement. That is, during the annual reconciliation as explained in § 405.2466, MACs determine the total reimbursement amount due the RHC for

[60] *https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf.*

covered services furnished to Medicare beneficiaries based on the reporting period. The total reimbursement amount due is compared with total payments made to the RHC for the reporting period, and the difference constitutes the amount of the reconciliation. If the total reimbursement due to the RHC exceeds the payments made for the reporting period, the MAC makes a lump-sum payment to the RHC to bring total payments into agreement with total reimbursement due the RHC. If the total payments made to an RHC for the reporting period exceed the total reimbursement due the RHC for the period, the MAC arranges with the RHC for repayment.

In the event a new RHC is in its initial reporting period, and the MAC does not have a cost report to set its AIR, the RHC provides the MAC an estimate of what it expects its costs to be for its initial reporting period. In the Provider Reimbursement Manual (Pub. 15–2), chapter 46, section 4600,[61] we explain that for an RHC's initial reporting period, the clinic completes the cost report's worksheets with estimates of costs and visits and other information required by the reports. The MAC uses these estimates to determine an interim rate of payment for the RHC. This interim rate may be adjusted throughout the reporting period. Following the end of the RHC's reporting period, the RHC is required to submit its worksheets, using data based on its actual experience for the reporting period. The AIR for the following year will then be based on the RHC's actual experience.

As discussed in Pub. 100–02, Chapter 13, section 80.2,[62] when RHCs are part of the same organization with more than one RHC, they may elect to file consolidated cost reports rather than individual cost reports. Under this type of reporting, each RHC in the organization need not file individual cost reports. Rather, the group of RHCs may file a single report that accumulates the costs and visits for all RHCs in the organization. In order to qualify for consolidation reporting, all RHCs in the group must be owned, leased, or through any other agreement, controlled by one organization.

[61] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.*

[62] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf.*

3. RHC Payment Limit Per-Visit

a. Background

Prior to the Balanced Budget Act of 1997[63] (BBA), the payment methodology for an RHC depended on whether it was ''provider-based'' or ''independent.'' Specifically, payment to provider-based RHCs for services furnished to Medicare beneficiaries was made on a reasonable cost basis by the provider's MAC in accordance with the regulations at 42 CFR part 413; whereas payment to independent RHCs for services furnished to Medicare beneficiaries was made on the basis of a uniform all-inclusive rate payment methodology in accordance with 42 CFR part 405, subpart X. In addition, payment to independent RHCs also was subject to a maximum payment per visit (also referred to as a ''payment limit per-visit'', ''upper payment limit per-visit'', or ''cap'') as set forth in section 1833(f) of the Act. This national statutory payment limit was set at $46 and was adjusted annually based on the Medicare Economic Index (MEI) described in section 1842(b)(3) of the Act.

Section 1833(f) of the Act was further amended by section 4205(a) of the BBA) (Pub. L. 105–33) to permit an exception to the national statutory payment limit for RHCs based in rural hospitals with less than 50 beds. Our guidance directed Medicare intermediaries to use the bed definition at § 412.105(b) and the rural definition at § 412.62(f)(1) to determine which RHCs are eligible for the exception. The hospital bed definition was based on available bed days and the rural definition was based on the Office of Management and Budget's metropolitan statistical area (MSA) method.

Section 224 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F of Consolidated Appropriations Act of 2001) (BIPA)[64] (Pub. L. 106–554, December 21, 2000) further amended section 1833(f) of the Act by expanding the eligibility criteria for receiving an exception to the national statutory payment limit for RHCs. Specifically, this section of BIPA extended the exemption to RHCs based in small, urban hospitals. Effective July 1, 2001, all hospitals of less than 50 beds were eligible to receive an exception from the per visit payment limit for their RHCs.

As discussed in Change Request 1958, Transmittal A–01–138 issued on December 6, 2001, following the implementation of the BBA provision, CMS announced an alternative bed size definition for very rural, sole community hospitals with seasonal fluctuations in patient census. The MAC reviews the number of beds twice a year to determine whether the provider-based RHC meets the exception, during the Desk Review process and during the interim rate process (that is, determining the RHC's AIR). The provider-based RHC continues to receive the exception until the hospital which they are affiliated with submits a cost report with more than 50 beds. However, in the May 8, 2020 **Federal Register**, in response to the PHE for COVID–19, we published the ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' interim final rule with comment period (85 FR 27550) (May 8, 2020 IFC). In the May 8, 2020 IFC, we implemented, on an interim basis, a change to the period of time used to determine the number of beds in a hospital at § 412.105(b) for purposes of determining which provider-based RHCs are subject to the payment limit (85 FR 27569). That is, for the duration of the PHE, we adopted an interim final policy to use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for application of this policy. As such, RHCs with provider-based status that were exempt from the national statutory payment limit in the period prior to the effective date of the PHE (January 27, 2020) would continue to be exempt from the bed count requirement for the duration of the PHE for the COVID–19 pandemic, as defined at § 400.200, even if the hospital raised its bed count above 50. Once the PHE for COVID–19 ends, hospitals need to lower their bed count to less than 50 beds to utilize an RHC policy that has such a requirement.

b. Section 130 of the Consolidated Appropriations Act, 2021

In the CY 2022 PFS proposed rule (86 FR 39231 through 39232), we discussed section 130 of the Consolidated Appropriations Act, 2021 (CAA 2021) (Pub. L. 116–260, December 27, 2020), which updated section 1833(f) of the Act by restructuring the payment limits for RHCs beginning April 1, 2021. We noted that section 2 of H.R. 1868 (Pub. L. 117–7), enacted April 14, 2021, provided a technical correction to

[63] *https://www.congress.gov/105/plaws/publ33/PLAW-105publ33.pdf.*

[64] *https://www.congress.gov/106/plaws/publ554/PLAW-106publ554.pdf.*

section 1833(f) of the Act. The amendments made by this technical correction take effect as if included in the enactment of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260).

We explained that section 1833(f)(2) of the Act, as added by section 130 of the CAA 2021, states that beginning April 1, 2021, RHCs will begin to receive an increase in their payment limit per visit over an 8-year period, with a prescribed amount for each year from 2021 through 2028. Then, in a subsequent year, at the limit established for the previous year increased by the percentage increase in the MEI applicable to primary care services furnished as of the first of such subsequent year. This provision also subjects all new RHCs (including provider-based RHCs in a hospital with less than 50 beds and enrolled in Medicare after December 31, 2020) to the national statutory payment limit.

The national statutory payment limit for RHCs over an 8-year period is as follows:

- In 2021, after March 31, at $100 per visit;
- In 2022, at $113 per visit;
- In 2023, at $126 per visit;
- In 2024, at $139 per visit;
- In 2025, at $152 per visit;
- In 2026, at $165 per visit;
- In 2027, at $178 per visit; and
- In 2028, at $190 per visit.

In addition, in the CY 2022 PFS proposed rule (86 FR 39231), we stated that beginning April 1, 2021, provider-based RHCs that met the qualifications in section 1833(f)(3)(B) of the Act, as added by section 130 of the CAA 2021 and amended by Public Law 117–7, were entitled to special payment rules, as described in section 1833(f)(3)(B) of the Act. That is, a provider-based RHC must meet the following criteria to have its payment limit established based on its per visit payment amount (or AIR):

- As of December 31, 2020, was in a hospital with less than 50 beds and after December 31, 2020 in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the PHE for COVID–19); and one of the following circumstances:

++ As of December 31, 2020, was enrolled in Medicare (including temporary enrollment during the PHE for COVID–19); or

++ Submitted an application for enrollment in Medicare (or a request for temporary enrollment during the PHE for COVID–19) that was received not later than December 31, 2020.

Specifically, beginning April 1, 2021, for provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be set at an amount equal to the *greater of*: (1) The per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; *or* (2) the national statutory payment limit for RHCs per visit. We stated that the details of the most recent MEI rebasing and revising are discussed in the CY 2011 PFS final rule with comment period (75 FR 73262). The MEI increase for an update year is based on historical data through the second quarter of the prior calendar year. For example, the 2021 update reflects data through the second quarter 2020. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the MEI and other CMS market baskets, *https://ihsmarkit.com/index.html.*

We explained that in a subsequent year (that is, after 2021), the provider-based RHC's payment limit per visit shall be set at an amount equal to the *greater of*: (1) The payment limit per visit established for the previous year, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; *or* (2) the national statutory payment limit for RHCs. We stated that the proposed CY 2022 MEI update was 1.8 percent based on the IGI 1st quarter 2021 forecast of the MEI and productivity adjustment, which reflects historical MEI data through 4th quarter 2020 and historical MFP data through 2019. As is our general practice, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the MEI percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the final CY 2022 MEI update.

Based on the more recent data available for this CY 2022 PFS final rule (that is, IGI's third quarter 2021 forecast of the 2006-based MEI with historical data through the second quarter of 2021 and historical MFP data through 2020), we estimate that the CY 2022 MEI update is 2.1 percent.

In the CY 2022 PFS proposed rule (86 FR 39231), we explained for provider-based RHCs that meet certain requirements, but did not have a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be at an amount equal to the greater of: (1) The per visit payment amount applicable to the provider-based RHC for services furnished in 2021; *or* (2) the national statutory payment limit for RHCs.

In a subsequent year (that is, after 2022), the provider-based RHCs payment limit per visit will be the *greater of*: (1) The payment limit per visit established for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year; *or* (2) the national statutory payment limit for RHCs.

We stated that a provider-based RHC that meets the qualifications of section 1833(f)(3)(B) of the Act, as corrected by Public Law 117–7 will lose this designation if the hospital does not continue to have less than 50 beds, beyond the exemptions provided for the PHE for COVID–19. If this occurs, the provider-based RHC will be subject to the statutory payment limit per visit applicable for such year and not able to regain the specified provider-based payment limit.

Lastly, we stated that provider-based RHCs that are newly enrolled beginning January 1, 2021, and after are subject to the national statutory payment limit applicable for such year for RHCs.

c. Implementation of Section 130 of the Consolidated Appropriations Act, 2021

In the CY 2022 PFS proposed rule (86 FR 39232 through 39233), we stated that prior to this legislation, the CY 2020 national statutory payment limit for RHCs was $86.31. We noted that due to this timing, for calendar year 2021, there are two sets of payment rules for RHCs. That is, for the period before March 31, 2021, independent RHCs and provider-based RHCs that did not meet specified requirements were subject to the payment limit of $87.52 that CMS announced in Change Request 12035, Transmittal 10413 issued on October 29, 2020.[65] Provider-based RHCs that met specified requirements were not subject to a payment limit for the first quarter of calendar year 2021. However, beginning April 1, 2021, in accordance with section 130 of the CAA 2021, all RHCs are now subject to a payment limit. For example, beginning April 1, 2021 through December 31, 2021 the national statutory payment limit for RHCs is $100.00. We explained in the proposed rule that in order to prepare for this change in payment limits during the calendar year, Change Request 12185, Transmittal 10679 was issued on March 16, 2021, to implement an

[65] *https://www.cms.gov/files/document/r10413cp.pdf.*

increase in the RHC statutory payment limit per visit and establish the provider-based RHC payment limits per visit, which went in effect on April 1, 2021. We noted Change Request 12185, Transmittal 10679, was rescinded and replaced by Transmittal 10780 issued on May 4, 2021 to reflect the technical corrections in section 2 of H.R. 1868 (Pub. L. 117–7). We also noted that this provision does not impact the way beneficiary coinsurance is calculated as described in § 405.2410(b)(1).

i. Specified Provider-Based RHCs

In section III.A.3.b. of the CY 2022 PFS proposed rule (86 FR 39232) and section III.A.3.b. of this final rule, we discuss the qualifications specified in section 1833(f)(3)(B) of the Act, as amended by Public Law 117–7, that determine if a provider-based RHC is entitled to the special payment rules described in section 1833(f)(3)(A) of the Act. To determine if an RHC was in a hospital with less than 50 beds as of December 31, 2020, we stated that we would review each provider-based RHC using the existing bed count review process, as described previously, to determine if this criterion is met. In addition, we explained that this process generally includes ongoing review by the MACs two times a year. The beds to be counted for purposes of this criterion are described in § 412.105(b), in accordance with existing policy.

In the CY 2022 PFS proposed rule (86 FR 39232), we discussed our intent to continue with our existing policy and in accordance with section 1833(f)(3)(B)(i) of the Act which states that ''as of December 31, 2020, was in a hospital with less than 50 beds and after such date such hospital continues to have less than 50 beds'' an RHC will retain its specified provider-based status until the hospital which they are affiliated submits a cost report with more than 50 beds. An RHC will no longer retain its specified provider-based status nor be eligible for specified status in the future once the hospital which they are affiliated submits a cost report with more than 50 beds. However, in response to the PHE for COVID–19 and in accordance with section 1833(f)(3)(B)(I) of the Act, we stated that we would apply the policy that allows for increased hospital bed counts, as described in the May 8, 2020 IFC, for purposes of determining this bed count criterion for specified provider-based RHC status. That policy specified that for the duration of the PHE, we would use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count. We noted that the criteria specified in section 1833(f)(3)(B)(i) of the Act specified in a hospital with less than 50 beds, therefore, beginning April 1, 2021, we would apply the bed definition at § 412.105(b) exclusively.

In the CY 2022 PFS proposed rule (86 FR 39232), we discussed section 1833(f)(3)(B)(ii) of the Act, as added by section 2 of Public Law 117–7, which requires that these specified provider-based RHCs as of December 31, 2020 are ''enrolled under section 1866(j) of the Act (including temporary enrollment during such emergency period for such emergency period),'' or ''submitted an application for enrollment under section 1866(j) of the Act (or a request for such a temporary enrollment for such emergency period) that was received not later than December 31, 2020.'' We proposed that the RHC's effective date of enrollment (as established under existing regulations) would be used in our determination as to whether an RHC is enrolled under section 1866(j) of the Act as of December 31, 2020. In addition, with regard to an application for enrollment under section 1866(j) of the Act or a request for temporary enrollment, we proposed to use the date an application or request was received to determine if the RHC met the qualification. We explained that RHCs that established temporary locations for the purpose of responding to the PHE for COVID–19, in accordance with their State pandemic response plan, are permitted to enroll and receive temporary Medicare billing privileges. When the PHE for COVID–19 ends, an RHC that had been temporarily enrolled under the flexibilities described previously must submit a complete CMS–855 enrollment application in order to establish full Medicare billing privileges. Failure to do so will result in the deactivation of the RHC's temporary billing privileges. No payments can be made for services provided while the temporary billing privileges are deactivated. For RHCs enrolled through the temporary enrollment process that will need to submit a complete CMS–855 enrollment application, we proposed, regardless of when the temporarily enrolled RHC is fully enrolled, that the RHC would be entitled to the special payment rules as long as it was temporarily enrolled as of December 31, 2020 or a temporary enrollment request was received by December 31, 2020, and it meets the bed count requirement.

As we stated in the CY 2022 PFS proposed rule (86 FR 39233), section 1833(f)(3)(A) of the Act instructs Medicare to set payment limits per visit for these specified provider-based RHCs under certain payment rules. Specifically, beginning April 1, 2021, a payment limit per visit shall be set at an amount equal to the *greater of*: (1) The per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021 *or*; (2) the statutory payment limit per visit as described in section 1833(f)(2) of the Act. For subsequent years, in accordance with section 1833(f)(3)(A)(ii) of the Act, that payment amount is increased by the percentage increase in the MEI or the statutory payment limit described in section 1833(f)(2) of the Act, whichever is greater.

As we explained in the CY 2022 PFS proposed rule (86 FR 39233), we interpreted the ''per visit payment amount'' to align with the interim rate process the MACs use in determining an RHC's AIR. That is, as explained in § 405.2464(a) the AIR is determined by the MAC using the most recently available cost report. Therefore, with regard to ''services furnished in 2020'' we interpreted this to mean the period at which the services were furnished in 2020 and that costs for those services were reported. We understand that there may be more than one cost report that reports costs for services furnished in calendar year 2020. However, since section 130 of the CAA 2021 states that the ''per visit payment amount'' is to be increased by the CY 2021 MEI, if a provider has a cost reporting period that differs from a calendar year time-period then the MACs should use data based on the relevant cost report period ending in 2020.

Finally, in the CY 2022 PFS proposed rule (86 FR 39233), we acknowledged that certain RHCs file consolidated cost reports. We stated that for specified provider-based RHCs, existing RHCs that are independent, and existing RHCs that are in a hospital with greater than 50 beds, we will continue to use the parent RHCs' cost reports to determine the payment limit per visit (for multi-facility RHC systems), as consolidated cost reporting reduces the reporting burden and cost report preparation time for RHCs. We noted that combining multiple individual RHC cost reports into a consolidated cost report allows RHCs to take advantage of administrative efficiencies and economies of scale that do not exist otherwise.

However, we explained that in accordance with section 1833(f)(2) of the Act, all new provider-based RHCs and independent RHCs enrolled, as of January 1, 2021, shall have a payment limit established at the national

statutory payment limit for RHCs. Therefore, beginning with RHCs enrolled in Medicare as of January 1, 2021, we would no longer allow new RHCs to file consolidated cost reports.

ii. All Other RHCs

In the CY 2022 PFS proposed rule (86 FR 39233), we explained that while there are criteria that allow for specified provider-based RHCs to be eligible for certain payment rules, all other RHCs are subject to payment limits as described in section 1833(f)(2) of the Act. We stated that while there may be new RHCs that are ''in a hospital with less than 50 beds'' and ''enrolled under section 1866(j) [of the Act]'', they will not have met these criteria by December 31, 2020. Thus, any new RHCs will also be subject to the national statutory payment limits as described in section 1833(f)(2) of the Act.

We noted that though the payment limit is described, these RHCs will still have an AIR per visit determined based on their allowable costs for each year going forward. The payment limit that is established will be the maximum amount that an RHC will be paid by Medicare per visit. At the time of reconciliation, if an RHC's costs per visit are above the AIR, they will be paid an amount that reflects these additional costs, not to exceed the payment limit. If an RHC's costs per visit are below the AIR, then CMS would collect any overpayment for that visit. In addition, we noted that to implement this provision beginning April 1, 2021, CMS instructed the MACs to increase the payment limits to $100 per visit.

In the CY 2022 PFS proposed rule (86 FR 39233), we stated that while the payment limit per-visit as set forth in section 1833(f) of the Act was implemented in administrative instructions issued to the MACs in Change Request 12185, we proposed revisions to § 405.2462 to reflect the provisions set forth in section 1833(f)(2) and (3) of the Act. We solicited comment on these revisions and on our proposals regarding the implementation of section 130 of the CAA 2021.

The following is a summary of the comments we received and our responses.

Comment: While commenters supported the increased upper payment limit for independent RHCs, some commenters expressed concern about how the payment limit per visit is established for specified provider-based RHCs. To be appropriately reflective of an individual clinic's true costs, one commenter stated that grandfathered, clinic specific, upper payment limits should be based on the final cost settled amount for cost reporting periods that end in 2020, or 2021 (for grandfathered RHCs that do not have cost reporting period that end in 2020), not an interim rate. If an interim final rate is necessary for the time period before final cost settled rates are adjudicated, the commenter suggested that CMS set interim clinic-specific upper limits only until such time that a final rate is established.

Response: We agree with the commenter and believe that what the commenter describes is aligned with the statute and how we implemented the payment limit per visit for specified provider-based RHCs through Change Request 12185, Transmittal 10780, issued on May 4, 2021. That is, in accordance with section 1833(f)(3)(A) of the Act, specified provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, had their payment limit per visit based on their AIR determined from their final settled cost report ending in 2020 increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021 (CY 2021 MEI of 1.4 percent). However, if the product of these two numbers (AIR established for services furnished in 2020 * 1.014) were less than the national statutory payment limit of $100, their payment limit per visit was established at $100.

With regard to a specified provider-based RHC that does not have an AIR established for services furnished in 2020 and is receiving an interim rate until the MAC accepts and finalizes the RHC's initial cost report, we again agree with the commenter. We believe that what the commenter describes also aligns with the statute and how we implemented the payment limit per visit for these specified provider-based RHCs through Change Request 12185, Transmittal 10780, issued on May 4, 2021. That is, in accordance with section 1833(f)(3)(A) of the Act, specified provider-based RHCs that did not have an AIR established for services furnished in 2020, will have their payment limit per visit established based on their AIR determined by MACs using the RHC's final settled cost report ending in 2021. The interim rate estimate will be reconciled at cost report settlement for the cost reporting period ending in 2021 which is used to establish the RHC's payment limit per visit for services furnished in 2021.

Comment: One commenter noted that while the law and the CY 2022 PFS proposed rule is a significant improvement for independent RHCs, they are concerned that implementing the rule for provider-based RHCs will have devastating consequences for the future of the provider-based RHC program and rural health more broadly. The commenter suggested that CMS monitor impacts of the provider-based RHC upper-payment limit changes on access for rural beneficiaries and encouraged CMS to implement the statute in a manner that limits the impact on current and future provider-based RHCs. The commenter further expressed concern that there are differing interpretations on the updated statute regarding the provision that allows those entities who had submitted their CMS–855A applications by December 31, 2020 to be eligible for grandfather status by the regional MAC. Therefore, the commenter urged CMS to implement the statute in a manner allowing all provider-based RHCs who had submitted an CMS–855A application by December 31, 2020, to be eligible for grandfathered rates.

Another commenter requested that CMS confirm that provider-based RHCs whose enrollment application was received by CMS as of December 31, 2020, will not be required to complete their certification process by the end of 2021 since completing this process can take as long as 6 months under normal circumstances and even longer during the PHE. One commenter requested that CMS expand the definition of ''existing RHCs'' to include hospital-based clinics that can provide proof of material efforts to establish a new RHC before December 31, 2020.

Response: We appreciate the commenter notifying us that they believe that the regional MACs may have differing interpretations of the statute and the accompanying Change Request 12185, Transmittal 10780, issued on May 4, 2021 that CMS issued to implement the provisions required under section 130 of the CAA, 2021. In conjunction with the issuance of this final rule, we expect to issue guidance that clarifies what date is used to determine if a provider-based RHC is entitled to the special payment rules described in section 1833(f)(3)(B)(ii) of the Act. The date CMS receives the application or request is the date used to determine whether the RHC met the qualifications.

Regarding the comment requesting that CMS confirm that provider-based RHCs whose enrollment application was received by CMS as of December 31, 2020 will not be required to complete their certification process by the end of 2021, we confirm there is no requirement on the timing of when the certification process needs to be

complete after the enrollment application is received by CMS.

With regard to the comment requesting that CMS expand the definition of ''existing RHCs'' to include hospital-based clinics that can provide proof of material efforts to establish a new RHC before December 31, 2020, we believe that the statute was clear that to be eligible for special payment consideration, the provider-based RHC needed to be, as of December 31, 2020, enrolled in Medicare (including temporary enrollment during the PHE for COVID–19) or have submitted an application for enrollment in Medicare (or a request for temporary enrollment during the PHE for COVID–19) that was received not later than December 31, 2020. We do not believe that hospital-based clinics that can provide proof of material efforts to establish a new RHC before December 31, 2020 meets that criteria.

With regard to the comment suggesting that CMS monitor the impacts of the provider-based RHC upper-payment limit changes on access for rural beneficiaries, we agree with the commenter and CMS plans to monitor the policy changes for potential health equity impacts, including utilization and access to care for rural beneficiaries.

Comment: One commenter requested that CMS clarify whether a hospital with an existing provider-based RHC may temporarily increase capacity to 50 or more beds in response to any future localized or national PHE without being penalized by losing its existing RHC status. The commenter also requested that CMS reduce the administrative burden on both MACs and hospitals by determining a hospital's bed count once a year, based on that year's Medicare cost report.

Response: We appreciate the commenter's suggestion regarding future PHE flexibilities as it relates to the exception for RHCs based in rural hospitals with less than 50 beds. However, it is out of scope for this proposal. For the duration of the COVID–19 PHE, we adopted an interim final policy to use the number of beds from the cost reporting period prior to the start of the COVID–19 PHE as the official hospital bed count for application of this policy. As such, RHCs with provider-based status that were exempt from the national statutory payment limit in the period prior to the effective date of the COVID–19 PHE (January 27, 2020) would continue to be exempt from the bed count requirement for the duration of the PHE for the COVID–19 pandemic, as defined at § 400.200, even if the hospital raised its bed count above 50. Once the COVID–19 PHE ends, hospitals need to lower their bed count to less than 50 beds to utilize the RHC exception. In addition, protocols are already in place to determine how the MACs establish the bed count. The MAC reviews the number of beds twice a year to determine whether the provider-based RHC meets the exception, during the Desk Review process and during the interim rate process (that is, determining the RHC's AIR).

As described in Chapter 13 of the Medicare Benefit Policy Manual, the MACs review is not an additional burden for the purpose of this rule. We note that it is impossible to predict in advance the extent, severity and impact of a future public health emergency, and not every public health emergency, even a localized one, might require us to provide the bed count flexibility the commenter seeks in order to assure patients' access to services. We recognize that many interim policies and waivers established during the COVID–19 PHE provided needed flexibilities for Medicare providers and suppliers, and we continue to study the effectiveness of these waivers in providing patient access in the event of a future PHE.

Comment: One commenter requested that CMS not retroactively recoup any potential overpayments that may accrue as a result of an audit adjustment of a hospital's initial cost report, but instead incorporate the audit adjustments into the RHCs AIR prospectively for future years.

Response: We do not believe that it would be necessary or appropriate for CMS to incorporate the audit adjustments into the RHCs AIR prospectively for future years. Applying audit adjustments prospectively seems to imply that there should be forgiveness of any errors in the cost report that determines the base rate. RHCs are required to submit a cost report that is correct and in compliance with provisions of the health care services laws and regulations, as are the MACs. If an adjustment is proposed and the provider appeals the adjustment, the appeal would be handled like any other appeal that impacts subsequent years. While appeals have taken some years to resolve, the Provider Reimbursement Review Board (PRRB) has implemented new rules to make it easier to settle some appeals and, thereby, reduce the time to resolve appeal and reduce the backlog of cases.

Comment: One commenter requested that CMS not punish any provider-based RHC who may make updates to their facilities by removing their grandfathered status. A provider-based RHC should be able to update their facility or move facilities without losing their specified provider-based status. Another commenter requested that CMS clarify that if an existing RHC needs to change its address or alter its enrollment application, it will not negate the RHC's existing status, subjecting it to the national statutory payment limit. Another commenter requested that the policies regarding grandfathering status following an RHC change of address or change of ownership be explicitly addressed in CMS guidance, as the statute is clear that these RHCs should maintain their grandfathered status and clinic specific upper payment limit in these scenarios.

Response: If an RHC undergoes a change of ownership (CHOW) and the acquiring owner accepts assignment of the Medicare agreement, all things associated with the agreement carries over to the new owner. This would include the CMS certification number (CCN), any financial obligations/repayments, the ''grandfather'' provision located at 42 CFR 491.5(b), which applies to location requirements, and the qualifications specified in section 1833(f)(3)(B) of the Act, as amended by Public Law 117–7, that determine if a provider-based RHC is entitled to the special payment rules described in section 1833(f)(3)(A) of the Act.

Regarding a change of address, updates to a facility (for example, cosmetic improvements), or altering of a specified provider-based enrollment record, we do not believe that this would impact their eligibility, as long as the RHC continues to meet the location requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval, and has filed an agreement with CMS that meets the requirements in § 405.2402 to provide RHC services under Medicare. We note that RHCs are intended to provide services in rural areas.

Comment: A few commenters suggested that CMS revise the proposal to no longer allow new RHCs to file consolidated reports. One commenter suggested that CMS revise this proposal to only prohibit consolidated cost reports when grandfathered and non-grandfathered RHCs are combined and allow new RHCs to file consolidated cost reports with other RHCs who are also subject to the national statutory payment limit. Another commenter requested that CMS clarify whether a hospital who acquires a new RHC that is subject to the lower national statutory payment limit may still include the RHC on the consolidated cost report as long as the RHC is reported using a separate

cost reporting line number. They stated that this solution will reduce the administrative burden on both hospitals and MACs while achieving CMS' goal of segregating the cost to provide care in existing RHCs from new RHCs.

Response: We appreciate the commenters' feedback on the flexibilities for RHCs to file consolidated cost reports. We were persuaded by the commenters' suggestion to reconsider the benefits that consolidated cost reporting provides for RHCs, such as administrative efficiencies. At the time of the proposed rule, we had not contemplated allowing only new RHCs that are subject to the national statutory payment limit to file consolidated cost reports. However, we agree that there are situations where new RHCs could file consolidated cost reports with other RHCs to reduce their administrative burden. We analyzed potential outcomes based on the different statuses of RHCs. We compared provider-based RHCs that have or will have their payment limit per-visit established based on their applicable AIR to RHCs that have their payment limit per visit based on the national statutory payment limit (that is, existing provider-based RHCs that are in a hospital with greater than 50 beds, independent RHCs, and new RHCs).

We note that flexibility in requiring consolidated cost reports has been a longstanding CMS policy. We have historically allowed multi-facility RHC systems to file consolidated cost reports because often sites under common ownership have integrated functions such as bookkeeping and purchases (for example, medical supplies) in an effort to operate more efficiently. We do not want to inadvertently cause a disruption in the data reporting that is in place for RHCs or cause undue burden for new RHCs that may be a part of a multi-facility RHC system with other new RHCs.

Therefore, new RHCs (that is, enrolled under section 1866(j) of the Act on or after January 1, 2021) are permitted to file consolidated cost reports with:

- New RHCs that are provider-based,
- New RHCs that are independent,
- Existing independent RHCs, and/or
- Existing provider-based RHCs that are in a hospital that has greater than 50 beds.

For reasons stated above, we believe that RHCs that have the same national statutory payment limit should have the flexibility to file a consolidated cost report and each of the types of RHCs listed above will have a payment limit per-visit as described in section 1833(f) of the Act.

We agree with commenters with regard to the types of RHCs that should not be permitted to file consolidated cost reports. Specifically, we will not permit specified provider-based RHCs to file a consolidated cost report with a new RHC. We believe that it would not be appropriate to allow a new RHC that the statute specifies should have a payment limit per-visit set to the national statutory payment limit provided at section 1833(f)(2) of the Act to file a consolidated cost report with an RHC that otherwise has a payment limit per-visit established on their applicable AIR.

Regarding the comment requesting CMS to clarify whether a hospital that acquires a new RHC that is subject to the national statutory payment limit may still include the new RHC on the consolidated cost report, we agree that the hospital cost report provides this ability. That is, hospitals have the ability to identify a group of RHCs as consolidated and identify an individual RHC. More information on identifying provider-based RHCs on the hospital cost report (FORM CMS–2552–10) is available in PRM 15–2, Chapter 40, section 4010.

After consideration of the public comments, we are finalizing our proposal to codify § 405.2462 as proposed to reflect the provisions set forth in section 1833(f)(2) and (3) of the Act.

3. Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients

a. Background

In the Fiscal Year (FY) 2021 Hospice Payment Rate Update final rule (85 FR 47070) we explain that hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Palliative care is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit. The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment.

A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

Section 1861(dd)(3)(B) of the Act defines the term ''attending physician'' to mean, with respect to an individual, the physician, the NP or PA who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

As explained in Pub. 100–02, chapter 9, section 20.1,[66] the attending physician is a doctor of medicine or osteopathy who is legally authorized to practice medicine or surgery by the State in which he or she performs that function, an NP, or PA, and is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care. An NP is defined as a registered nurse who performs such services as legally authorized to perform (in the State in which the services are performed) in accordance with State law (or State regulatory mechanism provided by State law) and who meets training, education, and experience requirements described in § 410.75. A PA is defined as a professional who has graduated from an accredited PA educational program who performs such services as he or she is legally authorized to perform (in the State in which the services are performed) in accordance with State law (or State regulatory mechanism provided by State law) and who meets the training, education, and experience requirements as the Secretary may prescribe. The PA qualifications for eligibility for furnishing services under the Medicare program can be found in the regulations at § 410.74(c).

RHCs and FQHCs are not authorized under the statute to serve in the role of an attending physician. However, a physician, NP, or PA who works for an RHC or FQHC may provide hospice attending physician services during a time when they are not working for the RHC or FQHC (unless prohibited by their RHC or FQHC contract or

[66] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c09.pdf.*

employment agreement). These services would not be considered RHC or FQHC services since they are not being provided by an RHC or FQHC practitioner during RHC or FQHC hours. The physician, NP, or PA would bill for services under Part B using their own provider number/NPI. In addition, any service provided to a hospice beneficiary by an RHC or FQHC practitioner must comply with Medicare prohibitions on commingling. Further information regarding commingling is available in Pub. 100–02, Chapter 13, section 100.[67]

b. Section 132 of the Consolidated Appropriations Act 2021

In the CY 2022 PFS proposed rule (86 FR 39234), we discussed that section 132 of the CAA 2021 amended section 1834(o) of the Act and added a new section 1834(y) to the Act, to provide the authority for both FQHCs and RHCs, respectively, to receive payment for hospice attending physician services. Specifically, when a designated attending physician employed by or working under contract with an FQHC or RHC furnishes hospice attending physician services (as described in section 1812(d)(2)(A)(ii) of the Act) on or after January 1, 2022, the FQHC or RHC is eligible to receive payment under the FQHC PPS or RHC AIR, respectively.

Therefore, beginning January 1, 2022, a physician, NP, or PA who is employed by or working under contract with an RHC or FQHC may provide hospice attending physician services during a time when they are working for the RHC or FQHC. The RHC or FQHC would bill for these services as they would for any other qualified service to be paid the RHC AIR or the FQHC PPS rate, respectively. When the RHC/FQHC furnishes a hospice attending physician service that has a TC, the provider furnishing the TC would go to the hospice for payment as discussed in the Medicare Claims Processing Manual at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c11.pdf.*

We proposed to codify the new statutory provisions as described in section 132 of the CAA 2021 in 42 CFR 405, subpart X, specifically:

- At § 405.2411, Scope of benefits, we are amending § 405.2411(b) to reflect that hospice attending physician services are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, NP, or PA designated by the patient at the time of hospice election as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished.
- At § 405.2446, Scope of services, we are amending § 405.2446(c) to include that FQHC services are covered when they are hospice attending physician services furnished during a hospice election.

We received public comments on the proposal to codify the new statutory provisions as described in section 132 of the CAA 2021. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of our proposal to codify the new statutory provision as described in section 132 of the CAA 2021 in 42 CFR part 405, subpart X. One commenter noted that the new statutory provision would remove an unnecessary barrier to the efficient provision of hospice care for Medicare beneficiaries. Another commenter stated that allowing RHC/FQHC providers to continue to care for their patients who elect the hospice benefit should enhance the quality of care and coordination of care.

A few commenters requested that CMS clarify that hospice patients could change their attending physician to an RHC/FQHC provider after their initial hospice election and expressed concern that the proposed language in § 405.2411(b)(3) limits this payment to RHC/FQHC providers whom patients choose as their attending provider at the time they elect to receive hospice care. Commenters stated that under current Medicare rules, hospice patients are permitted to change their attending provider after they have made their initial election to receive hospice benefits, and that nothing in section 132 of the CAA 2021 would prohibit RHC/FQHC providers from serving as attending providers for patients who select them after making their initial hospice election. Commenters requested that the phrase ''at the time of election'' be removed from the regulatory text. Several commenters requested that CMS align FQHC policies with other Medicare providers and permit patients to change their attending provider after they have made their initial election to receive hospice benefits. Commenters stated that CMS has the authority to provide more flexibility for health center patients to ensure they have the provider of their choice during every step of hospice care.

Response: Regarding the concerns that CMS align policies with other Medicare providers and permit patients to change their attending physician after they have made their initial election to receive hospice benefits, we agree. The regulations at § 418.24(g) provide authority for changing the attending physician, and states ''to change the designated attending physician, the individual (or representative) must file a signed statement with the hospice that states that he or she is changing his or her attending physician.'' Since hospice beneficiaries can change their attending physician at any time during their hospice election and we believe that this would also permit a beneficiary to change from their attending physician designated at their election to an RHC or FQHC practitioner, if they preferred. Therefore, we will remove the phrase ''at the time of election'' stated in our proposed regulation text at § 405.2446(c).

After consideration of the comments received, we are finalizing our proposal to codify the new statutory provision as described in section 132 of the CAA in 42 CFR 405, subpart X with a revision to the proposed regulation text at § 405.2446(c) to provide flexibility since hospice patients are permitted to change their attending provider after they have made their initial election.

Comment: One commenter stated that ''CMS did not specify in the proposed rule which revenue code(s) RHCs can use when billing for these encounters'' and requested that CMS provide clarity.

Response: We would point the commenter to subregulatory guidance published in Transmittal 10907, Change Request 12357 on August 10, 2021. In exploring how to implement this policy, we found that there is a HCPCS modifier, -GV, defined as ''attending physician not employed or paid under arrangement by the patient's hospice provider'' currently in existence and this modifier provides the necessary information for RHCs and FQHCs to bill. Therefore, we believed that a new revenue code was not needed.

Comment: We received one comment that was out of scope for this rule. While supportive of our proposal to codify the new statutory provision as described in section 132 of the CAA 2021 in 42 CFR 405, subpart X, the commenter recommended that CMS authorize PAs employed by a hospice to prescribe medications to Medicare hospice patients, similar to hospice-employed physicians and NPs. The commenter noted that CMS should allow a beneficiary to have the option to select a PA employed by a hospice when the patient does not have a previously established attending physician.

Response: We appreciate the feedback; however, this comment is

[67] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf.*

considered to be out of scope of the proposed rule, and therefore, we are not addressing in this final rule.

4. Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs

a. Background

In the CY 2013 PFS final rule (77 FR 68978 through 68994), we authorized Medicare payment for TCM services furnished by an RHC or FQHC practitioner, effective January 1, 2013, consistent with the effective date of payment for TCM services under the PFS. We adopted two CPT codes (99495 and 99496) to report physician or qualifying NPP care management services for a patient following a discharge from an inpatient hospital or SNF, an outpatient hospital stay for observation or partial hospitalization services, or partial hospitalization in a community mental health center. As a condition for receiving TCM payment, a face-to-face visit was required.

In the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088), we finalized policies for payment of CCM services in RHCs and FQHCs. Payment for CCM services in RHCs and FQHCs was effective beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that were expected to last at least 12 months or until the death of the patient, and that would place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Payment was made for CCM services when CPT code 99490 was billed alone or with other payable services on an RHC or FQHC claim, and the rate was based on the PFS national average non-facility payment rate. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services furnished to an RHC or FQHC patient because CCM describes non-face-to-face services.

In the CY 2018 PFS final rule, (82 FR 53172 through 53180), we finalized a policy permitting payment for CCM, general Behavioral Health Integration (BHI), and the psychiatric collaborative care model (CoCM) services furnished by RHCs or FQHCs on or after January 1, 2018, described by HCPCS codes G0511 and G0512. HCPCS code G0511 is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. HCPCS code G0512 is a psychiatric CoCM code for use by RHCs or FQHCs when at least 70 minutes of initial psychiatric CoCM services or 60 minutes of subsequent psychiatric CoCM services are furnished to a patient in a calendar month. The payment amount for HCPCS code G0511 is set at the average of the three national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS rates. The three codes are CPT code 99490 (20 minutes or more of CCM services), CPT code 99487 (60 minutes or more of complex CCM services), and CPT code 99484 (20 minutes or more of BHI services). The payment amount for HCPCS code G0512 is set at the average of the two national non-facility PFS payment rates for the CoCM codes and is updated annually based on the PFS rates. The two codes are CPT code 99492 (70 minutes or more of initial psychiatric CoCM services) and CPT code 99493 (60 minutes or more of subsequent psychiatric CoCM services).

In the CY 2019 PFS final rule (83 FR 59687), we finalized a policy that effective January 1, 2019, the payment rate for HCPCS code G0511 (General Care Management Services) is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491.

In the CY 2020 PFS final rule with comment period (84 FR 62692), we added HCPCS code G2064 (*30 minutes of PCM services furnished by physicians or NPPs*) and G2065 (*30 minutes or more of PCM services furnished by clinical staff under the direct supervision of a physician or NPP*) as a general care management service and included it in the calculation of HCPCS code G0511. Beginning January 1, 2021, the payment for HCPCS code G0511 is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491, and HCPCS codes G2064 and G2065, and is updated annually based on the PFS rates. Additional information on CCM requirements is available on the CMS Care Management web page [68] and on the CMS RHC [69] and FQHC [70] web pages.

Currently, RHCs and FQHCs may not bill for TCM services for a beneficiary if another practitioner or facility has already billed for CCM services for the same beneficiary during the same time-period.

b. Concurrent Billing for Chronic Care Management Services and TCM Services for RHCs and FQHCs

As discussed in the CY 2022 PFS proposed rule (86 FR 39235), we finalized a policy in the CY 2020 PFS final rule (84 FR 62687) allowing suppliers paid under the PFS to concurrently bill care management codes that were previously restricted from being billed with TCM for services billed under the PFS. This included allowing concurrent billing of TCM with 14 HCPCS codes, as well as CPT codes 99490 and 99491, which describe CCM services furnished under the PFS. However, we did not extend this policy to care management services furnished in RHCs or FQHCs at that time.

Consistent with changes made in the CY 2020 PFS final rule for care management services billed under the PFS, in the CY 2022 PFS proposed rule (86 FR 39235) we proposed to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided that all requirements for billing each code are met. This would include the services described by HCPCS codes G0511 (General Care Management for RHCs and FQHCs only) and G0512 (Psychiatric CoCM code for RHCs and FQHCs only), which both describe a service period of one calendar month. We stated that when medically necessary, these services may complement each other rather than substantially overlapping or duplicating services since TCM services are furnished once within 30 days of a patient's discharge, whereas CCM services require a more comprehensive care management plan, care coordination and ongoing clinical care, and CoCM services describe care management services specifically for behavioral health conditions. We noted that under this proposal, time and effort could not be counted more than once.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided that all requirements for billing each code are met. Commenters agreed that patients receiving TCM services after discharge would benefit from the more comprehensive care management plan developed under CCM, as well as the

[68] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/Care-Management.html.*

[69] *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html.*

[70] *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html.*

behavioral health-specific care management included in the Psychiatric Collaborative Care Management (CoCM) when furnished simultaneously.

Response: We appreciate the commenters' support and feedback on our proposal to allow RHCs and FQHCs to concurrently bill TCM with other care management services.

After consideration of the public comments, we are finalizing our proposal to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided all requirements for billing each code are met.

5. Conforming Technical Changes to 42 CFR 405.2466

In the November 6, 2020 **Federal Register**, we published the ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with request for comment (85 FR 71145 through 71147) (hereinafter referred to as the November 6, 2020 IFC). In the November 6, 2020 IFC, we implemented section 3713 of the CARES Act (Pub. L 116–136, March 27, 2020), which established Medicare Part B coverage and payment for a COVID–19 vaccine and its administration.

As we discussed in that rule (85 FR 71147), section 3713 of the CARES Act added the COVID–19 vaccine and administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. Therefore, the Medicare allowed amount and billing processes for COVID–19 vaccinations are similar to those in place for influenza and pneumococcal vaccinations across provider/supplier settings. The amendments made to section 1861(s)(10)(A) of the Act were effective on the date of enactment, that is, March 27, 2020, and apply to a COVID–19 vaccine beginning on the date that such vaccine is licensed under section 351 of the PHS Act (42 U.S.C. 262). A list of vaccines and their effective dates are updated as they are available and located on the CMS website at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.* Although there were regulations updated to reflect the changes set forth by the CARES Act, we inadvertently did not revise the specific regulation text that applies to RHCs and FQHCs.

Therefore, in the CY 2022 PFS proposed rule (86 FR 39235) consistent with the changes described previously, we proposed to make conforming technical changes to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically:

- At § 405.2466, Annual reconciliation, we proposed to amend paragraph (b)(1)(iv) to include the COVID–19 vaccine in the list of vaccines and their administration that would be paid at 100 percent of Medicare reasonable cost.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)—Telecommunications Technology

1. Revising the Definition of an RHC and FQHC Mental Health Visit

a. Payment Rules for RHC and FQHC Visits and for Medicare Telehealth Services

Section 1861(aa)(1) of the Act defines RHC services as physicians' services and such services and supplies that are furnished as an incident to a physician's professional service, and items and services, as well as certain vaccines and their administration. It also includes services furnished by a PA, NP, clinical psychologist, or clinical social worker and services and supplies furnished as incident to these services as would otherwise be covered if furnished by a physician or incident to a physician's service. In the case of an RHC in an area with a home health agency shortage, part-time or intermittent nursing care and related medical supplies may be furnished by a registered professional nurse or licensed practical nurse to a homebound individual under certain conditions. Section 1861(aa)(3) of the Act defines FQHC services to include the specified RHC services and preventive services, as well as required primary preventive health services.

As previously stated, RHC and FQHC visits are defined as medically-necessary, face-to-face encounters between a patient and an RHC or FQHC practitioner, during which time one or more RHC or FQHC qualifying services are furnished. Services furnished must be within the practitioner's State scope of practice, and only services that require the skill level of the RHC or FQHC practitioner are considered RHC or FQHC visits. The RHC and FQHC payment is based on the costs of all services, except in certain circumstances, such as vaccines and their administration.

RHCs are paid an all-inclusive rate (AIR) for medically-necessary primary health care services, and qualified preventive health services, furnished by an RHC practitioner. Medicare pays 80 percent of the RHC AIR, subject to a payment limit. Services furnished incident to an RHC professional service are included in the AIR and are not billed as a separate visit. The PC of a procedure is usually a covered service, but is not a stand-alone billable visit. The costs of covered services provided incident to a billable visit may be included on the RHC cost report.

FQHCs are paid 80 percent of the lesser of the FQHC's charge or the FQHC PPS payment rate. Except for grandfathered tribal FQHCs, the FQHC PPS payment rate reflects a base rate that is the same for all FQHCs, a geographic adjustment based on the location where services are furnished, and other applicable adjustments. The FQHC PPS rate was established based on the aggregate of FQHC total costs, and is updated yearly by the productivity-adjusted FQHC market basket increase.

Under the PFS, Medicare makes payment to professionals and other suppliers for physician's services, certain diagnostic tests, and some preventive services. Section 1834(m) of the Act specifies for Medicare telehealth services paid under the PFS, the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe ''face-to-face'' services but are furnished using audio/video, real-time communication technology instead of in-person (82 FR 53006). Section 1834(m) of the Act also specifies conditions related to which professionals can be paid by Medicare for their professional services furnished via telehealth (referred to as distant site practitioners) and the originating site (both setting of care and geography) where a beneficiary is located while receiving telehealth services furnished remotely by the physician or practitioner through a telecommunications system. The regulation text at 42 CFR 410.78(f) describes a process for adding or deleting services to the list of Medicare telehealth services through the annual PFS rulemaking process and defines what technology may be used to furnish the service.

Under the statutory authority set out under section 1834(m)(4)(C)(ii) of the Act, RHCs and FQHCs, like hospitals, physician offices, and other sites, are

authorized to serve as originating sites for eligible telehealth services. As defined in section 1834(m)(4)(C)(i) of the Act, the originating site is where the eligible telehealth individual is located at the time the service is furnished via a telecommunications system. As defined in section 1834(m)(4)(A) of the Act, the distant site is where the physician or practitioner is located at the time the service is provided via a telecommunications system. Originating sites are paid an originating site facility fee that is billed using HCPCS code Q3014 and is assigned a rate of $27.02 for CY 2021.

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136, March 27, 2020) directs the Secretary to establish Medicare payment for telehealth services provided by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the public health emergency (PHE) for COVID–19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by the CARES Act, requires that the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site during the PHE for the COVID–19 pandemic. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. CMS established rates based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume. RHCs and FQHCs bill for these Medicare telehealth services using HCPCS code G2025 and the rate for CY 2021 is $99.45. The temporary authority under section 1834(m)(8) of the Act to pay RHCs and FQHCs for furnishing distant site Medicare telehealth services expires when the PHE for the COVID–19 pandemic is terminated. While they will continue to be able to serve as an originating site for Medicare telehealth services, the payment mechanism for the professional services of RHC and FQHC practitioners will be FQHC and RHC payments under the established methodology, that is the RHC AIR or the FQHC PPS.

b. Adoption of Telehealth Technologies for Mental Health Care

While not specific to RHC and FQHC telehealth services provided during the PHE, according to MedPAC's report, Telehealth in Medicare after the Coronavirus Public Health Emergency,[71] there were 8.4 million telehealth services paid under the PFS in April 2020, compared with 102,000 in February 2020. MedPAC also reported that during focus groups held in the summer of 2020, clinicians and beneficiaries supported continued access to telehealth visits with some combination of in-person visits. They cited benefits of telehealth, including improved access to care for those with physical impairments, increased convenience from not traveling to an office, and increased access to specialists outside of a local area. In their annual beneficiary survey, over 90 percent of respondents who had a telehealth visit reported being ''somewhat'' or ''very satisfied'' with their video or audio visit, and nearly two-thirds reported being ''very satisfied.''

Widespread use of telecommunications technology to furnish services during the PHE has illustrated interest within the medical community and among Medicare beneficiaries in furnishing and receiving care through the use of technology beyond the PHE. During the PHE for COVID–19 pandemic, RHCs and FQHCs, much like other provider types, have had to change how they furnish care in order to meet the needs of their patients, and use of the temporary authority to bill Medicare for PFS telehealth services has been widely utilized by RHCs and FQHCs during the PHE. This shift in how care is furnished has prompted us to reevaluate the regulations regarding visit requirements for encounters between an RHC or FQHC patient and an RHC or FQHC practitioner to ensure that they reflect contemporary medical practice.

Recently enacted legislation modified the circumstances under which Medicare makes payment for mental health services furnished via telehealth technology under the PFS following the PHE. Division CC, section 123 of the Consolidated Appropriations Act of 2021 (CAA) (Pub. L. 116–260, December 27, 2020) removed the domestic geographic originating site restrictions and added the home of the individual as a permissible originating site for telehealth services billed under the PFS when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. This change correlates with a growing acceptance of the use of technology in the provision of mental health care. Clinicians furnishing telepsychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (for example, immobilizing depression, anxiety, agoraphobia, and/or time-consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy, and therefore, decrease stigma-related barriers to treatment, potentially bringing care to many more patients in need, as well as enhanced ease of scheduling, decreased rate of no-shows, increased understanding of family and home dynamics, and protection for patients and practitioners with underlying health conditions.[72]

These findings are consistent with our analysis of Medicare claims data that indicate that use of interactive communication technology for mental health care is likely to continue to be in broad use beyond the circumstances of the pandemic. According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth under the PFS during the PHE, use of telehealth for many professional services spiked in utilization around April 2020 and diminished over time; however, utilization was still higher than it was prior to the PHE. In contrast, Medicare claims data suggests that for mental health services both permanently and temporarily added to the Medicare Telehealth list, subsequent to April 2020, the trend is toward maintaining a steady state of usage over time. Given this information, broad acceptance in the public and medical community, and the relatively stable Medicare utilization of services during the entire COVID–19 pandemic, we believe use of interactive communication technology in furnishing mental health care is becoming an established part of medical practice, very likely to persist well after the COVID–19 pandemic, and available across the country under Medicare statute for the range of professionals furnishing mental health care and paid under the PFS.

c. Revising the Definition of an RHC and FQHC Mental Health Visit

In the 2022 PFS proposed rule (86 FR 39237), we stated that beneficiaries receiving mental health services from

[71] *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0.*

[72] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7347331/.*

RHC and FQHC practitioners should have the same access to mental health care delivered via telecommunications technology as beneficiaries receiving services from practitioners paid under the PFS. We believed that disruptions in access to mental health care from trusted practitioners can be particularly problematic for Medicare beneficiaries, especially when it results in fragmented care. However, absent changes in the definition of mental health visits, RHCs and FQHCs would no longer be paid by Medicare for mental health care services delivered via telecommunications technology and would likely resume furnishing solely in-person, face-to-face mental health visits after the PHE, thereby removing the ability for beneficiaries to be able to receive these services from RHC/FQHC practitioners if furnished via interactive communication technology.

Because the definitions of RHC and FQHC services, as specified in sections 1861(aa)(1) and (3) of the Act, respectively, refer specifically to physicians' services, and services that would be physicians' services, but are instead furnished by certain other types of practitioners, we felt it would be consistent to align policies to provide access to services furnished by RHCs and FQHCs similar to PFS services, where appropriate and within statutory requirements. To ensure that beneficiaries could access services furnished by RHCs and FQHCs in a manner similar to mental health services under the PFS after the PHE, we stated that it would be appropriate to consider modifying our regulatory definition of a mental health visit to provide for remote access to RHC and FQHC services. Therefore, to avoid both the inequities in access to modes of care, and to avoid potentially problematic interruptions to care or the negative consequences of fragmented care, for CY 2022, we proposed to revise the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time telecommunications technology, but only when furnishing services for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.

Additionally, similar to the discussion of mental health services furnished under the PFS, as described in section II.D. of this final rule, we believe that mental health telehealth services furnished via audio-only communications technology would increase access to care, especially in areas with poor broadband infrastructure and among patient populations that either are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. Therefore, in order to align with proposals related to use of audio-only telecommunications technology to furnish similar mental health services under the PFS, we proposed to allow RHCs and FQHCs to furnish mental health visits using audio-only interactions in cases where beneficiaries were not capable of, or did not consent to, the use of devices that would permit a two-way, audio/video interaction. We noted that the decision related to a service being furnished via telecommunications technology should be a patient-centered choice and that providers/practitioners should not force or impose services being furnished via telecommunications technology on beneficiaries who prefer to receive the services in-person. Additionally, some patients may have preferred a hybrid whereby some mental health services are in person, but other times they are done using telecommunications technology. We stated that this decision should be based on the clinical judgment of the practitioner, in consideration of patient needs and preferences.

This change would allow RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. This expansion of payable modes of mental health services furnished by RHCs and FQHCs corresponds with the expanded availability for professionals paid for Medicare telehealth services under the PFS authorized by section 123 of the CAA and using the technology available for use for corollary services when paid under the PFS. This revision would not allow RHCs or FQHCs to report visits furnished using asynchronous communications like email exchanges. Rather, RHCs and FQHCs would continue to report and be paid for furnishing medically necessary virtual communications services in accordance with the requirements for HCPCS code G0071 (83 FR 59686). Also, this change would not allow RHCs and FQHCs to report Medicare telehealth services under section 1834(m) of the Act or be paid under the PFS since RHCs and FQHCs are not authorized to serve as distant site practitioners for Medicare telehealth services once the PHE for the COVID–19 pandemic has been terminated. In order to track utilization of mental health visits furnished using communication technology, we proposed that RHCs and FQHCs would append the 95 modifier (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) in instances where the service was furnished using audio-video communication technology or a new service level modifier in cases where the service was furnished audio-only.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many public comments that were supportive of the proposal to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology. Some commenters pointed out that rural residents often face significant barriers to accessing mental health services, which result in significant disparities in care and that patients in rural areas often must travel long distances to receive specialized care such as mental health services. Commenters stated that being able to access these services through local RHCs and FQHCs via telecommunications technology would help to increase the frequency in which rural residents can access mental health services. Some commenters noted that patients without reliable transportation, internet, or the necessary technology will still face difficulties accessing services after the PHE ends.

One commenter stated that allowing RHCs to be reimbursed at the AIR reduces administrative burden and ensures that providing equitable mental health care remains a component of RHC provided care. A few commenters requested that this flexibility be extended to medical visits furnished at RHCs and FQHCs, not just mental health visits. Additionally, MedPAC commented that FQHC and RHC-provided telehealth services should be paid at rates comparable to those under the PFS.

Response: After consideration of the public comments, we are finalizing our proposal to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology and for RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. Since the flexibilities authorized by the CARES Act will expire at the end of the PHE,

we do not believe we currently have the authority to pay RHCs and FQHCs for services that would be paid under the AIR or PPS at the PFS rates outside of the PHE. We note that payment for virtual communications and care management services furnished at RHCs and FQHCs are paid based on PFS rates; however, these services describe non-face-to-face encounters between a patient and an RHC or FQHC practitioner and are paid outside of the AIR or PPS. Therefore, we are finalizing for CY 2022 that RHCs and FQHCs will be paid for mental health visits furnished via telecommunications technology at the same rate they are paid for in-person mental health visits (that is, the AIR or FQHC PPS).

In response to comments that this flexibility be extended to medical visits furnished at RHCs and FQHCs, not just mental health visits, we note that the use of telecommunications technology to furnish medical visits at RHCs and FQHCs was not within the scope of this proposal.

We received public comments on allowing RHCs and FQHCs to furnish mental health visits using audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the inclusion of audio-only communications technology in this proposal and stated that this flexibility especially benefits rural patients with poor broadband structure. Several commenters stated that Medicare beneficiaries receiving services through these facilities should have the same access to mental and behavioral health services as those being treated by providers practicing independently.

Response: After consideration of public comments, we are finalizing our proposal to allow RHCs and FQHCs to furnish mental health visits using audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. We are also finalizing our proposal for RHCs and FQHCs to append the 95 modifier (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) in instances where the service was furnished using audio-video communication technology and to append a new service level modifier in cases where the service was furnished audio-only. This will allow us to track utilization of mental health visits furnished using telecommunication technology at RHCs and FQHCs in order inform future rulemaking.

Additionally, we noted in the proposed rule that section 123 of the CAA also requires that there be an in-person service within 6 months prior to the furnishing of the telehealth service and at intervals thereafter as specified by the Secretary for mental health services furnished via Medicare telehealth under the PFS. We solicited comment on whether we should consider a similar requirement for mental health services furnished by RHCs and FQHCs via telecommunications technology, or whether this requirement may be especially burdensome for beneficiaries receiving treatment at RHCs and FQHCs, particularly in rural areas. In establishing a similar requirement for RHC and FQHC mental health services, we would consider the changes described for Medicare telehealth services described in section II.D. of this final rule that there be an in-person service within 6 months prior to the furnishing of the telecommunications service and that an in-person service (without the use of telecommunications technology) be provided at least every 6 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, which would be documented in the patient's medical record, or whether we should defer to the clinical judgment of the practitioner on how often an in-person visit would be appropriate.

We received public comments on whether we should consider a similar requirement for mental health services furnished by RHCs and FQHCs via telecommunications technology, or whether this requirement may be especially burdensome for beneficiaries receiving treatment at RHCs and FQHCs, particularly in rural areas. The following is a summary of the comments we received and our responses.

Comment: Several commenters were opposed to imposing an in-person service requirement for telehealth mental health visits. A few commenters described that existing evidence does not support the need for such a requirement, which could negatively impact access to care for beneficiaries and recommended CMS defer to the clinical judgment of the practitioner on how often an in-person visit would be appropriate and additionally noting that existing studies suggest low-income patients and those living in rural communities face more transportation barriers compared to other patients, and therefore, it is likely that in-person requirements would more profoundly impede access to care for the populations that RHCs and FQHCs serve. Other commenters encouraged CMS to provide maximum flexibility for FQHCs implementing in-person service requirements for patients receiving mental health services furnished via telecommunications technology. One commenter recommended that CMS provide a robust set of exceptions for patients unable or unwilling to fulfill the once every six months in-person visit requirement.

However, a few commenters supported requiring an in-person visit every 6 months, asserting that these requirements ensure some level of physical proximity between the patient and provider which is valuable in the event of in-person mental health care needs. Some commenters stated that this requirement would protect the integrity of the benefit and aligns with FFS provider in-person requirements and that ensuring that patients in rural areas receive mental health care via telecommunications technology in a location reasonably situated to where they receive in-person care would provide the most comprehensive option in meeting patient needs. Several commenters stated that if CMS had to establish an interval for subsequent in-person visits, it should be at least 12 months, noting that even that would present a hardship for rural patients and patients with disabilities.

Response: We appreciate all the comments received on this topic. We are persuaded by the comments related to ensuring access in the event of in-person needs and alignment with requirements under Medicare FFS. Therefore, we are finalizing that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that in general, there must be an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders. Consistent with policies finalized for mental health services furnished via telehealth under the PFS, the in-person service requirements apply only to telehealth services furnished to a patient receiving the service at home. However, in response to commenters' concerns regarding the requirement that an in-person, non-telehealth visit be furnished every 12 months, we agree with

commenters that there may be specific circumstances when an in-person visit within 12 months of each mental health visit furnished via telecommunications technology may be inadvisable or impracticable for an individual beneficiary. Therefore, we are finalizing a policy that will allow for limited exceptions to the requirement that there be an in-person, non-telehealth service every 12 months based on beneficiary circumstances, in which case the basis for that decision should be documented in the patient's medical record. Specifically, if the patient and practitioner consider the risks and burdens of an in-person service and agree that, on balance, these outweigh the benefits, and the practitioner documents the basis for that decision in the patient's medical record, then the in-person visit requirement is not applicable for that 12-month period. Situations in which the risks and burdens associated with an in-person service may outweigh the benefit could include, but are not limited to, instances when an in-person service is likely to cause disruption in service delivery or has the potential to worsen the patient's condition(s). The risks and burdens associated with an in-person service could also outweigh the benefit if a patient receiving services is in partial or full remission and only requires a maintenance level of care. Other justifications include the clinician's professional judgment that the patient is clinically stable and/or that an in-person visit has the risk of worsening the beneficiary's condition, creating undue hardship on self or family, or if it is determined that the patient is at risk for disengagement with care that has been effective in managing the illness. We note that the 12-month in-person visit requirement is not intended to dictate how often a provider and patient should meet in person; rather, patients and providers should determine the frequency of in-person meetings as driven by clinical needs. This is consistent with the policies for Medicare telehealth services furnished under PFS, as required by section 123 of the CAA and as finalized in Section II.D of this final rule. Given that this requirement may pose more of a challenge for beneficiaries in rural areas, we will monitor the impact of this requirement to determine whether it presents a disruption in access to mental health care in the RHC/FQHC setting.

d. Regulatory Changes

We proposed to revise the regulation at § 405.2463, to revise paragraph (a)(1)(i) to state that a mental health visit is a face-to-face (that is, in person) encounter (or, for mental health visits only, an encounter that meets the requirements under paragraph (b)(3)) between an RHC patient and an RHC practitioner. We proposed to revise paragraph (b)(3) to define a mental health visit as a face-to-face encounter or an encounter where services are furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We also proposed to revise § 405.2469, FQHC supplemental payments, to revise paragraph (d) by adding that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many public comments that were supportive of the proposal to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology.

Response: After consideration of public comments, we are finalizing our proposal to revise the regulation at §§ 405.2463 and 405.2469, as described above. Additionally, at § 405.2463, we are revising paragraph (b)(3) to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders. We are also revising §§ 405.2463(b)(3) and 405.2469(d) to allow an exception for a particular 12-month period when the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record. At § 405.2469, FQHC supplemental payments, we are revising paragraph (d) to describe the same in-person visit requirement referenced above.

C. Federally Qualified Health Centers (FQHCs) Payment for Tribal FQHCs—Comment Solicitation

1. Health Services to American Indians and Alaska Natives (AI/AN)

There is a special government-to-government relationship between the Federal Government and Federally-recognized tribes based on U.S. treaties, laws, Supreme Court decisions, Executive Orders and the U.S. Constitution. This government-to-government relationship forms the basis for Federal health services to American Indians/Alaska Natives (AI/AN) in the U.S. In 1976, the Indian Health Care Improvement Act (IHCIA) (Pub. L. 94–437, September 30, 1976) amended the statute to permit payment by Medicare and Medicaid for services provided to AI/ANs in Indian Health Service (IHS) and tribal health care facilities that meet the applicable requirements. Under this authority, Medicare services to AI/ANs may be furnished by IHS operated facilities and programs and tribally-operated facilities and programs under Title I or Title V of the Indian Self Determination Education Assistance Act, as amended (ISDEAA) (Pub. L 93–638, January 4, 1975). According to the IHS Profile,[73] the IHS healthcare delivery system currently consists of 46 hospitals, with 24 of those hospitals operated by the IHS and 22 of them operated by tribes under the ISDEAA, as well as 492 health centers, 75 operated by IHS and 417 operated by tribes under the ISDEAA.

Payment rates for outpatient medical care (also referred to as outpatient hospital services) furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 248 and 249(b)) (Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHCIA, based on the previous year cost reports from Federal and tribal hospitals. The IHCIA provided the authority for CMS (then HCFA) to pay IHS and tribal facilities for its outpatient hospital services to Medicare eligible patients, using an

[73] *https://www.ihs.gov/newsroom/factsheets/ihsprofile/.*

outpatient per visit rate (also referred to as the Medicare all-inclusive payment rate (AIR).

2. Federally Qualified Health Centers (FQHCs) Prospective Payment System (PPS)

FQHCs were established in 1990 by section 4161 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101–508, November 5, 1990), and were effective beginning on October 1, 1991. They are facilities that furnish services that are typically furnished in an outpatient clinic setting. The statutory requirements that FQHCs must meet to furnish services to Medicare beneficiaries are in section 1861(aa)(4) of the Act. All FQHCs are subject to Medicare regulations at 42 CFR part 405, subpart X, and 42 CFR part 491. Based on these provisions, the following three types of organizations that are eligible to enroll in Medicare as FQHCs:

- Health Center Program grantees: Organizations receiving grants under section 330 of the PHS Act (42 U.S.C. 254b).
- Health Center Program ''lookalikes'': Organizations that have been identified by the Health Resources and Services Administration as meeting the requirements to receive a grant under section 330 of the PHS Act, but which do not receive section 330 grant funding.
- Outpatient health programs or facilities operated by a Tribe or tribal organization under the ISDEAA, or by an urban Indian organization receiving funds under Title V of the IHCIA.

FQHCs are also entities that were treated by the Secretary, for purposes of Medicare Part B, as a comprehensive Federally funded health center as of January 1, 1990 (see section 1861(aa)(4)(C) of the Act). Section 1834 of the Act was amended in 2010 by section 10501(i)(3)(A) of the Affordable Care Act by adding a new subsection (o), ''Development and Implementation of Prospective Payment System'' for FQHCs. Section 1834(o)(1)(A) of the Act requires that the system include a process for appropriately describing the services furnished by FQHCs, and establish payment rates based on such descriptions of services, taking into account the type, intensity, and duration of services furnished by FQHCs. It also stated that the new system may include adjustments (such as geographic adjustments) as determined appropriate by the Secretary. Section 1833(a)(1)(Z) of the Act, as added by the Affordable Care Act, requires that Medicare payment for FQHC services under section 1834(o) of the Act be 80 percent of the lesser of the actual charge or the PPS amount determined under section 1834(o) of the Act.

In accordance with the requirements in the statute, as amended by the Affordable Care Act, beginning on October 1, 2014, payment to FQHCs is based on the lesser of the national encounter-based FQHC PPS rate, or the FQHC's total charges, for primary health services and qualified preventive health services furnished to Medicare beneficiaries. The FQHC PPS rate is adjusted by the FQHC geographic adjustment factor (GAF), which is based on the Geographic Practice Cost Index used under the PFS. The FQHC PPS rate is also adjusted when the FQHC furnishes services to a patient that is new to the FQHC, and when the FQHC furnishes an IPPE or an AWV. Payment to the FQHC for a Medicare visit is the lesser of the FQHC's charges (as established by the G-code), or the PPS rate. The CY 2021 FQHC PPS rate is $176.45.

3. Grandfathered Tribal FQHCs

In the November 16, 2015 **Federal Register**, we published a final rule, entitled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (referred to as CY 2016 PFS final rule). In that rule, we discuss the payment methodology and requirements finalized for grandfathered tribal FQHCs (80 FR 71089 through 71096). We stated that tribal facilities that met the conditions of § 413.65(m) on or before April 7, 2000, and had a change in their status on or after April 7, 2000, from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital, such that the organization no longer met the Medicare Conditions of Participation (CoPs) for Medicare-participating hospitals at § 482.12, the ''governing body'' of the facility could nevertheless seek to become certified as a grandfathered tribal FQHC.

In CY 2016 PFS final rule, we explained that a different structure was needed to maintain access to care for AI/AN populations served by the hospitals and clinics impacted by the provider-based rules at § 413.65, while also ensuring that the tribal clinics are in compliance with our health and safety rules. We recognized that a tribal clinic billing under an IHS hospital's CMS Certification Number (CCN), without any additional administrative or clinical relationship with the IHS hospital, could put that hospital at risk for noncompliance with their CoPs because the clinic had a separate governing body although still provider-based. We explained that the FQHC program provided an alternative structure that met the needs of these tribal clinics and the populations they served, while also ensuring the IHS hospitals were not at risk of being cited for non-compliance with the requirements with their CoPs (80 FR 71090).

As stated in § 405.2462(d)(1) a ''grandfathered tribal FQHC'' is a FQHC that is operated by a tribe or tribal organization under the ISDEAA; was billing as if it were provider-based to an IHS hospital on or before April 7, 2000 and is not currently operating as a provider-based department of an IHS hospital. We refer to these tribal FQHCs as ''grandfathered tribal FQHCs'' to distinguish them from freestanding tribal FQHCs that are currently being paid the lesser of their charges or the adjusted national FQHC PPS rate, and from provider-based tribal clinics that may have begun operations subsequent to April 7, 2000. Currently, there are 7 ''grandfathered tribal FQHCs''.

Under the authority in section 1834(o) of the Act to include adjustments determined appropriate by the Secretary, we revised §§ 405.2462 and 405.2464 to pay these grandfathered tribal FQHCs on the Medicare outpatient per visit rate as set annually by the IHS, that is, the AIR and not the FQHC PPS payment rates (80 FR 71089). Payment rates for outpatient medical care (also referred to as outpatient hospital services) furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 248 and 249(b)) (Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHCIA, based on the previous year cost reports from Federal and tribal hospitals. The outpatient per visit rate is only applicable for those IHS or tribal facilities that meet the definition of a provider-based department as described at § 413.65(m), or a ''grandfathered'' tribal FQHC as described at § 405.2462(d)(1). There is an outpatient per visit AIR for Medicare visits in Alaska and a separate outpatient per visit AIR for Medicare visits in the lower 48 States. For CY 2021, the outpatient per visit rate for Medicare visits in Alaska is $662 and $414 in the lower 48 States (85 FR 86940). There are no grandfathered tribal FQHCs in Alaska because the tribes operate the hospitals, not IHS. We note that IHS does not operate any hospitals or facilities in Hawaii or the territories, and thus, no rates are set in those localities.

As we discussed in CY 2016 PFS final rule, the payment rate is not adjusted by the FQHC GAF; for new patients, annual wellness visits, or initial preventive physical examinations; or annually by the productivity-adjusted FQHC PPS market basket increase, as further adjustments would be unnecessary and/or duplicative of adjustments already made by IHS in deriving the rate. Comparatively, the FQHC PPS rate established by CMS is $176.45. The reimbursement is the lesser of the charges or the IHS AIR rate. We stated as part of the CY 2016 PFS final rule that we would monitor future costs and claims data of these tribal clinics and reconsider options as appropriate.

4. Paying all IHS- and Tribally-Operated Outpatient Clinics the AIR

As we discussed in the CY 2022 PFS proposed rule (86 FR 39239), CMS established a Tribal Technical Advisory Group (TTAG) in 2004 to provide advice and input to CMS on policy and program issues impacting AI/AN populations served by CMS programs. Although not a substitute for formal consultation with Tribal leaders, the TTAG enhances the government-to-government relationship and improves increased understanding between CMS and Tribes. The TTAG has subject specific subcommittees that meet on a regular basis in order to be more effective and perform in-depth analysis of Medicare, Medicaid, CHIP, and the Health Insurance Marketplace policies that have Tribal implications. The TTAG is comprised of 17 representatives: An elected Tribal leader, or an appointed representative from each of the 12 geographic areas of the IHS delivery system and a representative from each of the national Indian organizations headquartered in Washington, DC—the National Indian Health Board, the National Congress of American Indians, and the Tribal Self-Governance Advisory Group. Section 5006(e)(1) of the American Recovery and Reinvestment Act of 2009, which became effective July 1, 2009, mandates that TTAG shall be maintained within CMS and added two new representative's positions: A representative and alternate from a national urban Indian health organization (National Council of Urban Indian Health); and a representative and alternate from the IHS.

In the CY 2022 PFS proposed rule (86 FR 39239), we stated that the TTAG has requested [74] that CMS amend its Medicare regulations to make all IHS and tribally-operated outpatient facilities eligible for payment at the IHS Medicare outpatient per visit rate/AIR. The TTAG explained that outpatient clinics, which are otherwise similar to grandfathered tribal FQHCs, are paid at different rates depending upon whether they meet the requirements as a ''provider based facility,'' a ''grandfathered tribal FQHC,'' a non-grandfathered tribal FQHC, or none of the above. They believe that the rates vary based on the Medicare regulatory definition, rather than the actual costs of the outpatient clinic. There are varying payment differentials among Medicare enrolled providers and suppliers under the authorities of the SSA. For example, ASCs are paid differently than HOPDs; which are paid differently whether they are under the under the outpatient prospective payments system or a located in a critical access hospital.

The TTAG also questioned the need for grandfathered tribal FQHCs to file cost reports. Specifically, the TTAG stated that the FQHC cost reports have no relationship to the IHS Medicare outpatient per visit rate/AIR paid to grandfathered tribal FQHCs, as they use hospital cost reports in setting the rate. Therefore, they stated, the FQHCs should only need to file a cost report to the extent necessary to support payment for non-FQHC services that are reimbursed outside the Medicare outpatient per visit rate/AIR. We noted that under section 1815(a) of the Act, providers participating in the Medicare program are required to submit financial and statistical information to achieve settlement of costs relating to health care services rendered to Medicare beneficiaries. Under the FQHC PPS, Medicare payment for FQHC services is the lesser of the FQHC PPS rate or the charges on the claim. In the establishment of the FQHC PPS, the statute does not exempt FQHCs from submitting cost reports. In addition, Medicare payments for the reasonable costs of the influenza and pneumococcal vaccines and their administration, allowable graduate medical education costs, and bad debts are determined and paid through the cost report. The FQHC market basket also uses information from the FQHC cost report to determine the cost share weights, which reflect the relative costs of input expenses that FQHCs face in order to provide FQHC services. Having a full picture of the costs of providing care by grandfathered FQHCs is important so that CMS can be sure that payments are adequate.

5. Solicitation for Input and Comment

In the CY 2022 PFS proposed rule (86 FR 39240), we expressed appreciation for the TTAG's concerns with ensuring that CMS make appropriate payments among the clinics for similar services and the impact this has on tribal Medicare beneficiaries and ensuring that access to healthcare is available and equitable and we take these concerns seriously, but noted that we had insufficient information necessary to evaluate the costs and benefits of potential changes to these policies. Therefore, we solicited comments on the TTAG's request for CMS to amend its Medicare regulations to make all IHS- and tribally-operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR, regardless of whether they were owned, operated, or leased by IHS.

We solicited information on the kinds of and number of facilities or clinics that could potentially enroll in Medicare as an FQHC, or are already an FQHC paid under the FQHC PPS, and if these clinics are freestanding or provider-based to expand on information provided by the IHS Profile.

We solicited information regarding the relative operating costs of IHS- and tribally-operated outpatient clinics compared to non-tribal FQHCs, stakeholder feedback and supporting evidence to address whether or why payment set at the IHS AIR would be more appropriate than payment rate under the FQHC PPS.

Further, we solicited comment on how the IHS AIR, which is based upon a limited number of hospital cost reports, relates to costs in such clinics and the kinds of services that the clinics furnish.

Finally, we solicited comment on the concerns that the AI/AN community may have on issues regarding access or inequity care in situations where a payment differential exists.

We noted that although we have information on grandfathered tribal FQHCs and the outpatient hospital cost reports, we did not have any information specific to the composition of IHS and tribal facilities. For example, if the facility is not enrolled in Medicare as an FQHC or is not provider based to a hospital, is it a physician practice? It would be helpful to know how the facilities are organized and related. Are there other options for enrolling as different types of providers or suppliers?

As increasing the rate would increase payments from the Medicare Trust

[74] *https://www.nihb.org/tribalhealthreform/wp-content/uploads/2020/06/TTAG-letter-to-CMS-requesting-IHS-rate-for-all-tribal-clinics-06.10.2020.pdf.*

Fund, we also requested comment on the magnitude of that payment change and whether any program integrity concerns would be present with the increased payment.

We also requested comments on FQHC services that are paid through the cost report, like influenza, pneumococcal, and COVID–19 vaccinations and GME and how that impacts the request to not file cost reports.

As stated previously, we believed that having a full picture of the costs of providing care was important to ensure adequate payments.

We also solicited input on other potential uses of the adjustment authority under section 1834(o)(1)(A) of the Act which provides that the FQHC PPS may include adjustments determined appropriate by the Secretary. For example, should we consider TTAG's request on the expansion of the payment policy finalized in the CY 2016 PFS final rule for grandfathered tribal FQHCs to all Tribally-operated outpatient clinics. Alternatively, should we develop a payment adjustment applicable to IHS- and tribally-operated outpatient clinics based on the cost differential reported in their cost reports when compared to non-IHS outpatient clinics, or non-provider-based clinics, if such differentials exist and would be interested in specific comments about appropriate adjustments to the FQHC PPS rate for clinics that are enrolled as FQHCs.

Finally, we requested information on other potential ways to determine whether the costs associated with furnishing services to AI/AN are uniquely greater than other clinics within the confines of the FQHC PPS outlined in section 1834(o)(1) of the Act.

We received several comments on these questions. Below, we provide a summary of the comments we received and our response.

Comment: Commenters stated CMS should exercise its authority to authorize all IHS clinics to bill at the same IHS AIR as a matter of health equity. One commenter noted it is of particular importance in fulfilling the Indian Self-Determination education Assistance Act (ISDEAA) and preventing Tribes from being penalized for having assumed control over their own clinics. Several commenters stated that there is an equity issue when a facility's Medicare designation determines the rate they will be reimbursed as IHS clinics are heavily reliant on third-party reimbursements to fund operations. Commenters also noted that the request for information regarding the make-up, structure, and costs of IHS/Tribal clinics needed to evaluate the costs and benefits of potential changes to Medicare policies was irrelevant to the issue. Commenters did not agree that billing as an FQHC is the only or best solution, especially since so few clinics elect to enroll as an FQHC due to the burden of submitting cost reports, and suggested changes to the tribal provider-based rules at § 413.65(m) and an umbrella rule providing that all outpatient Indian health programs qualify for reimbursement at the AIR regardless of how they are enrolled in Medicare. Commenters also proposed changes that would amend 42 CFR part 405. In addition, one commenter stated that allowing all Indian health clinics to bill at the IHS AIR would have zero impact on program integrity, especially since the IHS AIR is already available to some Tribal clinics.

Response: Although we did not receive specific information on costs or specific types of clinics, we will consider the commenters' requests for CMS to amend its Medicare regulations to make all IHS- and tribally-operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR, regardless of whether they were owned, operated, or leased by IHS. We understand the commenters' concerns and note that commenters do not agree that wholesale enrollment as Medicare FQHCs is the preferred outcome. We would like to continue these discussions to evaluate the impact of the commenters' proposed changes to the current Medicare payment policies and will consider these recommendations for future rulemaking.

D. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B and Determination of ASP for Certain Self-Administered Drug Products

1. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802 and 414.806)

a. Overview and Summary

Section 1927(b)(3)(A)(iii)(I) of the Act requires manufacturers with a Medicaid drug rebate agreement to report Average Sales Price (ASP) data as specified in section 1847A of the Act. Some manufacturers without Medicaid drug rebate agreements voluntarily submit ASP data for their single source drugs or biologicals that are payable under Part B; however, other manufacturers without Medicaid drug rebate agreements do not voluntarily submit such data. Without manufacturer reported ASP data, CMS cannot calculate the ASP payment limit, and consequently, payment is typically based on Wholesale Acquisition Cost (WAC).

Consistent with section 1847A(c)(3) of the Act and our regulations at § 414.804(a)(2), the ASP is net of price concessions. However, consistent with the definition of WAC at section 1847A(c)(6)(B) of the Act, the WAC is not net of price concessions, and thus is nearly always, and sometimes significantly, higher than ASP. Drugs with payment allowances based on WAC may have greater ''spreads'' between acquisition costs and payment than drugs for which there is an ASP-based payment allowance, which, in turn, may: (1) Incent the use of the drug based on its spread rather than on purely clinical considerations; (2) result in increased payments under Medicare Part B; and (3) increase beneficiary cost sharing.

Section 401 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section of this proposed rule, hereinafter is referred to as ''section 401'') amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Section 401(b)(2) also amended section 1847A(c)(6)(A) of the Act to permit the Secretary to exclude repackagers [75] from the definition of ''manufacturer'' for purposes of the ASP reporting requirement in section 1847A(f)(2) of

[75] The FDA has defined ''repackag[ing],'' for purposes of drug establishment registration, as ''the act of taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug.'' 21 CFR 207.1. The FDA has defined ''repack[ager]'' for purposes of drug establishment registration as the person who owns or operates an establishment that repacks a drug or drug package.'' Id. For more information about repackaging, please see FDA guidance documents, including a January 2017 Guidance for Industry titled, ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities,'' available at *https://www.fda.gov/media/90978/download* and the FDA's January 2018 Guidance for Industry titled, ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application,'' available at *https://www.fda.gov/files/drugs/published/Mixing--Diluting-or-Repackaging-Biological-Products-Outside-the-Scope-of-an-Approved-Biologics-License-Application.pdf.*

the Act, if the Secretary determines appropriate.

Section 401(b)(1) also adds provisions to section 1847A of the Act addressing confidentiality, audit and verification provisions; civil money penalties for misrepresentation, late reporting, and reporting of false information; and increasing oversight and enforcement provisions. These provisions largely track the statutory provisions in section 1927(b) of the Act that apply to the reporting of ASP by manufacturers with Medicaid drug rebate agreements. Additionally, section 401(d) requires HHS Office of the Inspector General (OIG) to submit a report on the accuracy of ASP submissions to Congress by January 1, 2023.

Finally, section 401 amended section 1927(b) of the Act to clarify that for Part B ASP reporting, drugs would include items, services, supplies, and products that are payable under Medicare Part B as a drug or biological.

In the CY 2022 PFS proposed rule, we proposed regulatory changes to implement the new reporting requirements at 42 CFR, part 414, subpart J.

b. Reporting Requirements for Manufacturers Without a Medicaid Drug Rebate Agreement

Starting with calendar quarters beginning on January 1, 2022, manufacturers will be required to report ASP for drugs and biologicals payable under Medicare Part B consistent with the statutory requirements of section 1847A(f) of the Act, regardless of whether they have Medicaid drug rebate agreements. Our existing regulations at 42 CFR part 414, subpart J implement the ASP reporting requirements referenced in section 1847A(f)(1) of the Act, that is, the requirements of section 1927(b)(3) of the Act. Thus, the existing regulations at subpart J already set forth requirements for manufacturers with Medicaid drug rebate agreements to report their ASP information (and if required to make payment, WAC) each quarter.

Many manufacturers without Medicaid drug rebate agreements voluntarily submit ASP data consistent with these requirements. Whether obligated to report or voluntarily reporting, manufacturers are accustomed to the existing regulatory requirements at subpart J, and indeed, the methodology for reporting ASP reflected in these regulations does not currently distinguish between manufacturers with Medicaid drug rebate agreements and those without these agreements.

Because new section 1847A(f)(2) of the Act, as noted previously, largely parallels section 1927(b)(3) of the Act, and thus both manufacturers with Medicaid drug rebate agreements, as well as those without such agreements, will be subject to requirements already reflected in the existing regulations at subpart J, we did not believe it was necessary to propose substantial changes to the regulation text. For these reasons, our proposal to amend the regulations to reflect the new requirements of section 1847A(f)(2) of the Act sought to preserve the status quo to the extent possible.

c. Definitions

As noted previously, the new section 1847A(f)(2) of the Act, as added by section 401(a), requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022 for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Section 401 also made a conforming amendment to the ASP reporting requirements applicable to manufacturers with Medicaid drug rebate agreements at section 1927(b)(3)(A)(iii) of the Act to specify that those reporting requirements also apply to items, services, supplies, and products that are payable under Part B as a drug or biological.

To implement this change, we proposed to amend the definition of the term ''drug'' at § 414.802 to mean a drug or biological, and includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

We received public comments on amending the definition of the term ''drug'' at § 414.802 to mean a drug or biological, and includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological. The following is a summary of the comments we received and our responses.

Comment: Some commenters suggested that CMS provide more clarity or be more specific in the definition of the term ''drug'' to further describe which products, or groups of products, are subject to requirement in section 401.

Response: We disagree that further clarification is needed for this definition. The requirements in section 401 apply to drugs or biologicals described in section 1842(o)(1)(C), (E), or (G) of the Act or section 1881(b)(14)(B) of the Act, including items, services, supplies, or products that are payable under [Medicare Part B] as a drug or biological. That is, if a particular item, service, supply, or product of any kind, is payable as a drug or biological under Part B, then it is subject to the ASP reporting requirements.

Comment: One commenter requested that CMS confirm that radiopharmaceuticals that do not currently report ASPs will be excluded from this proposal. The commenter stated that ASPs are not currently reported for all radiopharmaceuticals, and requiring ASP reporting for all radiopharmaceuticals will require CMS to clarify how ASPs should be calculated under circumstances that are unique to radiopharmaceuticals. For these reasons, the commenter suggested that any proposal that requires ASP reporting for all radiopharmaceuticals should be delayed to allow CMS to provide sufficient information to radiopharmaceutical manufacturers to allow for accurate ASP reporting, and to allow radiopharmaceutical manufacturers to prepare.

Response: Consistent with section 303(h) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 8, 2003), radiopharmaceuticals are not paid under section 1847A of the Act. Section 401 requires manufacturers without Medicaid drug rebate agreements to report ASP to the same extent that manufacturers with Medicaid drug rebate agreements must do. It does not change the scope of drugs and biologicals for which ASP must be reported other than to clarify that the ASP reporting requirements apply to items, services, supplies, and products that are payable under Part B as a drug or biological and are described in section 1842(o)(1)(C), (E) of the Act, or (G) or 1881(b)(14)(B) of the Act.

Comment: One commenter generally expressed support of the proposal to modify the definition of ''drug'' at § 414.802 to include any item, service, supply or product that is payable under Part B as a drug or biological.

Response: We thank the commenter for their feedback.

After consideration of public comments, we are finalizing the definition of the term ''drug'' at § 414.802 as proposed.

Section 1847A(c)(6)(A) of the Act incorporates the definition of manufacturer at section 1927(k)(5) of the Act, except that section 401(b)(2) permits the Secretary to exempt repackagers from the definition of

manufacturer, as determined appropriate, for purposes of section 1847A(f)(2) of the Act. However, no such exemption is provided for manufacturers with Medicaid drug rebate agreements (see the definition of manufacturer at § 447.502). Consequently, the current ASP data reporting includes submissions by repackagers.

In the CY 2022 PFS proposed rule (86 FR 39241 through 39242), we discussed Medicare Payment Advisory Commission's (MedPAC's) assertion in their June 2017 report (available at *http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf*) that many repackagers currently do not report ASP data. We explained that we conducted an analysis to estimate the proportion of repackaged products in our existing ASP data because we believed it could inform our consideration of whether we should propose to exclude repackagers from the definition of manufacturers for purposes of section 1847A(f)(2) of the Act. If our existing ASP data do not contain an appreciable proportion of repackaged products, it may be appropriate to exclude repackagers from the definition of manufacturer for this limited purpose. However, if repackaged products comprise an appreciable proportion of our existing ASP data, we would reasonably anticipate this trend to follow under the new requirements, and in such a scenario, it would not be appropriate to exclude repackagers from the definition of manufacturer for purposes of section 1847A(f)(2) of the Act because excluding their sales could distort the ASP.

To effectuate this analysis, we obtained a list of National Drug Codes (NDCs) of repackaged drugs from the United States Food and Drug Administration (FDA).[76] We also obtained a list of labeler codes for which the manufacturers have Medicaid drug rebate agreements.[77] We then performed a crosswalk both of these to our composite file of ASP data submissions to segregate our composite file of ASP data submissions into four categories:

(1) Repackaged products for which ASP data submissions were required (that is, manufacturers with Medicaid drug rebate agreements);

(2) Repackaged products for which ASP data submissions were voluntary (that is, for manufacturers without Medicaid drug rebate agreements);

(3) Non-repackaged products for which ASP data submissions were required; and

(4) Non-repackaged products for which ASP data submissions were voluntary.

We estimated that, of all 6319 products for which we currently receive ASP data submissions (the sum of categories (1) through (4) above), repackaged products accounted for 271 (4.29 percent) of these products. Additionally, repackaged products accounted for 137 (2.51 percent of) products for which ASP data submissions were required, and 134 (15.23 percent of) products for which ASP data were voluntarily submitted.

Additionally, we conducted another analysis to estimate: (1) The number of new ASP submissions we can expect as a result of the new requirements under section 401; and (2) the proportion of those submissions that involve repackaged products. To effectuate this analysis, we obtained a crosswalk of NDCs and Healthcare Common Procedure Coding System (HCPCS) codes that includes the NDCs and HCPCS codes of items for which ASP reporting is not currently required.[78] We supplemented this crosswalk by adding HCPCS codes with NDCs that are payable under Part B, but not already reflected in the crosswalk.[79] We then identified[80] and removed from the crosswalk all of the products contained in our composite file of ASP data submissions and those HCPCS codes that are non-covered under Medicare Part B. Adding the results of this analysis to the results of categories two and four from the prior analysis (that is, repackaged and non-repackaged products for which ASP submissions were voluntary), we estimated there will be 6,994 total products for which manufacturers will now be required to submit ASP data. We then compared this number to FDA's list of repackaged products in the previous analysis, and found that of the 6,994 products for which manufacturers will be required to submit ASP data, 223 (3.19 percent) are repackaged products. Further, we estimated 6,114 products for which their manufacturers did not previously (voluntarily) submit ASP data and will now be required to do so under the new reporting requirements of section 401. Of these, 89 (1.46 percent) are repackaged products.

These data did not persuade us that it was necessary to exempt repackagers from the new reporting requirements under section 401 at this time. Our current operational process to verify the accuracy of manufacturers' reported ASP data does not distinguish: (1) Products on the basis of repackaging; and (2) manufacturers who are required to report ASP data from those who do so voluntarily.

Each month, we review ASP data submissions at the NDC level (and for products without NDCs, the manufacturer's product code). Previously, we have not required manufacturers to identify which products are repackaged as part of these submissions. Exempting repackagers from the new requirements of section 1847A(f)(2) of the Act would significantly increase our administrative burden because we would have to undergo an additional quality check for each NDC from a different database for which data are submitted as part of our operational process to verify the accuracy of manufacturers' reported ASP data. Moreover, for products without NDCs, our ability to determine if these products are repackaged (without manufacturer attestation) to that effect is significantly limited. Finally, any such attestation would require a data source for us to verify the accuracy of the attestation, and no such data source currently exists.

These additional checks could, in turn, significantly increase the time it takes for us to calculate and display on our website the volume-weighted ASP payment limits. Additionally, we were concerned that exempting repackagers from the new reporting requirements could lead to a gap in ASP reporting, meaning that ASPs could be distorted to the extent that certain sales are carved out of the reporting requirement through the use of repackagers. Consequently, in order to maintain consistency and integrity of the ASP data for those manufacturers with and without Medicaid drug rebate agreements, we did not believe it was appropriate to exclude repackagers from the requirements of section 401 at this time. However, we stated that we may

[76] *https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.* We note that this list only includes prescription drugs approved under a New Drug Application (NDA) or Abbreviated NDA (ANDA) and does not include biological products approved under a Biologics License Application (BLA) or devices.

[77] *https://data.medicaid.gov/Uncategorized/Drug-Manufacturer-Contacts/uex2-n56q/data.* This link has all labeler codes with effective date and termination date, if applicable. If there is a termination date, the code was not active as of that date.

[78] *https://www.dmepdac.com/palmetto/PDACv2.nsf/DID/FFYLYC1WVL* Accessed April 12, 2021, using the April 2021 files.

[79] We note that such products were spread across the second and fourth categories in the prior analysis.

[80] We used the April 2021 Alpha-Numeric HCPCS codes files available at *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.* We selected HCPCS codes with a coverage code of S (column AE), which indicates that the product is non-covered by the Medicare statute.

propose to exempt repackagers in the future, if warranted.

We solicited comment on this approach.

The following is a summary of the comments we received and our responses.

Comment: One commenter suggested that CMS exclude repackagers from the proposed ASP reporting requirements. They stated that requiring all repackagers to report would likely be duplicative and increase the burden on all parties without providing tangible benefit. In addition, they stated that, generally, most reporting requirements are simply not applicable to repackagers, whose business is generally outside of the scope of the proposed requirements. They recommend repackagers who already report ASP data continue to do so, but that CMS not require repackagers, as a group, to be subject to the reporting requirements at this time.

Response: We are not persuaded that repackagers should be excluded at this time. As previously stated in this section, in order to maintain consistency and integrity of the ASP data for those manufacturers with and without Medicaid drug rebate agreements, and for operational reasons, we do not believe it is appropriate to exclude repackagers from the ASP reporting requirements. If warranted, we could revisit this in future rulemaking.

Comment: One commenter concluded that CMS' analysis and proposal not to exclude repackagers without a rebate agreement from reporting ASP data is reasonable. The commenter stated that given that repackagers with a rebate agreement are required to report ASP data, it is reasonable not to exclude repackagers without a rebate agreement from the requirements of section 401. They added that having ASP data from repackagers with and without rebate agreements could also permit future analysis of the effect of repackagers' ASP submissions on Medicare Part B payment rates.

Response: We agree it is reasonable not to exclude repackagers without a Medicaid drug rebate agreement and thank the commenter for their feedback.

After consideration of public comments, we are not excluding repackagers from the definition of manufacturers for purposes of section 1847A(f)(2) of the Act.

In summary, we proposed to modify the definition of drug at § 414.802 to include any item, service, supply or product that is payable under Part B as a drug or biological. We did not propose to exclude repackagers from the definition of manufacturer for purposes of the reporting requirements at section 1847A(f)(2) of the Act and are finalizing the definition of drug at § 414.802 as proposed.

d. Civil Money Penalties

As amended by section 401(b), section 1847A(d)(4)(A) of the Act specifies the penalties associated with misrepresentations in the reporting of the manufacturer's ASP for a drug or biological. Consistent with our existing regulation at § 414.806, if the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied.

New sections 1847A(d)(4)(B) and (C) of the Act, as added by section 401(b), apply civil money penalties for failure to report timely and accurate ASP data for manufacturers without Medicaid drug rebate agreements, consistent with the civil money penalties found at sections 1927(b)(3)(C)(i) and (ii) of the Act for manufacturers with Medicaid drug rebate agreements. Our current regulations at § 414.806 refer to section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, as specifying the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

We proposed to amend § 414.806 to reflect the new provisions specifying penalties for manufacturers without Medicaid drug rebate agreements and to provide some technical changes to streamline the regulations text. Specifically, we proposed to do the following:

- Add paragraph (a), labeled as ''Misrepresentation'', moving the existing regulatory language at § 414.806 specific to misrepresentation to this paragraph;
- Remove the sentence which reads, ''If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied,'' since the previous sentence in the regulations text already references the statutory provision for this language;
- Add paragraph (b), labeled as ''Failure to provide timely information or the submission of false information'';
- Add paragraph (b)(1) to clarify that the existing language at § 414.806 regarding civil money penalties for failure to submit timely information or for the submission of false information applies to manufacturers with a Medicaid drug rebate agreement;
- Remove the phrase ''as amended by section 303(i)(4) of the MMA''; and
- Add paragraph (b)(2) to reflect new sections 1847A(d)(4)(B) and (C) of the Act regarding civil money penalties for failure to submit timely information or for the submission of false information for manufacturers without a Medicaid drug rebate agreement.

We welcomed comments on these proposals.

We received one public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: One commenter stated that it fully supported CMS' proposed revisions to the regulations at § 414.806 to mirror the enforcement provisions of the statute. In addition, the commenter expressed concern that the current civil monetary penalties may not sufficiently ensure that all manufacturers fully comply with the express requirements of the new ASP reporting provisions and suggested that CMS address other enforcement options it may use if manufacturers fail to comply with the ASP reporting requirements. Specifically, the commenter suggested that CMS could pursue action under the False Claims Act (31 U.S.C. 3729–3733), elect to not reimburse certain products of a manufacturer that does not report ASP, or adopt alternative reimbursement schemes for certain products.

Response: We appreciate the commenter's support in finalizing these proposals. We also appreciate the feedback regarding other methods of enforcement; however, these are outside the purview of codifying and implementing section 401.

After consideration of public comments, we are finalizing amendments to § 414.806 as proposed.

e. Summary of All Proposals

In summary, to implement the new reporting requirements for manufacturers without Medicaid drug rebate agreements, we proposed to modify:

- The definition of drug at § 414.802; and
- The regulations describing civil money penalties at § 414.806.

We welcomed comments on these proposals.

We received public comments on these proposals as described in sections (c) and (d) above. We received several comments of general support of section 401 implementation. The following is a

summary of these comments and our responses.

Comment: Several commenters expressed general support of section 401 and its implementation. They commended Congress and CMS for taking the necessary steps to resolve the inconsistent treatment of similarly situated products under the Medicare Part B program and support efforts to require manufacturers to provide CMS with regular and accurate ASP data for drugs and biological products payable under Medicare Part B as a means to ensure accurate payment.

Response: We thank these commenters and appreciate their feedback. We also received several comments that were not specifically related to the proposals. The following is a summary of these comments and our responses.

Comment: We received several comments requesting that CMS publish an ASP payment limit in the ASP Drug Pricing File for all billing and payment codes for which there are products reporting ASP data. These commenters stated that this would create a level field for all manufacturers, prevent overbilling to Medicare due to reimbursement based on WAC prices, decrease beneficiary financial responsibility, and ensure that clinicians select products based on clinical efficacy. Commenters also stated that CMS has lacked transparency by not publishing ASP payment limits for all billing and payment codes for which there are products reporting ASP data. They suggested that billing and payment codes with a published ASP payment limit have an advantage over those that do not and that providers are hesitant to prescribe products that do not appear on the ASP Drug Pricing File. In addition, one commenter suggested that if an ASP payment limit is not published in the ASP Drug Pricing File, then the Medicare payment should be based on invoice pricing only, rather than basing payment on the WAC. Two commenters suggested that CMS should expand the list of published ASP payment limits to include all items separately payable under Part B as done in Addendum B for the hospital outpatient setting.

Response: Section 401 does not address the ASP Drug Pricing File, nor does it specify which products should be published on the file, and the proposed rule did not include any proposals pertaining to the ASP Drug Pricing File. CMS does not publish an ASP payment limit or crosswalk for every product for which ASP data is reported.

Similarly, section 401 does not address MACs' discretion to use WAC-based pricing or invoice pricing to determine payment amounts in the absence of a published ASP payment limit, and the proposed rule did not include any proposals pertaining to this discretion.

Comment: Some commenters recommended that CMS address the proper treatment of lagged price concessions in the ASP for products that are newly reporting ASP and that CMS confirm that manufacturers submitting ASP data for the first time are estimating the price concessions based on the most recent 12-month period for which data is available.

Response: Manufacturers that are newly reporting ASP data to CMS must do so in the same manner as those who are already reporting ASP data.

Specific information about calculating and reporting lagged price concessions is available in the December 1, 2006 **Federal Register** (71 FR 69666), the September 16, 2004 **Federal Register** (69 FR 55763), and the regulation text at § 414.804(a)(3).

Comment: A few commenters requested that CMS consider deferring the implementation of this requirement to provide more specific guidance for manufacturers newly reporting ASP data.

Response: Section 401 requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. CMS does not have the authority to defer the statutory implementation date.

Comment: One commenter suggested that manufacturers should disclose actual material and production costs to regulators, as well as research and development costs contributing to a drug's pricing.

Response: We thank the commenter for their feedback; however, manufacturers' reporting of actual material, production, research, and development costs are outside the scope of this rule.

After consideration of public comments, we are finalizing these proposals as proposed.

2. Determination of ASP for Certain Self-administered Drug Products (§ 414.904)

a. Background

Drugs and biologicals payable under Medicare Part B fall into three general categories: those furnished incident to a physician's services (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(10)(A) and (B) of the Act). Payment limits for most drugs and biologicals separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on. Most drugs payable under Part B are paid under the ''incident to'' benefit under section 1861(s)(2) of the Act, which includes drugs and biologicals not usually self-administered by the patient.

Paragraphs (4)(A) and (6) of sections 1847A(b) of the Act require that the Medicare Part B payment amount for a single-source drug or biological be determined using all of the NDCs assigned to it. Section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as a New Drug Application (NDA) or Biologics License Application (BLA)). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are crosswalked to the same billing and payment code. This means that a self-administered version marketed under the same FDA approval is subject to the ASP reporting requirements and is not excluded from the payment limit calculation, even though Medicare does not make separate Part B payment for it. This is consistent with our longstanding policy on the scope of the ASP reporting

requirements. (Please see our final rule titled, ''Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007,'' published in the December 1, 2006 **Federal Register** (71 FR 69675)). The price of a drug or biological product that may be administered by the patient (that is, self-administered) may differ from versions that are administered incident to a physician's service, which may affect the ASP-based payment limit for drug or biological product's billing and payment code.

The HHS OIG conducted studies [81] [82] of payment-limit calculations for certain drugs paid under section 1847A of the Act. The OIG identified two highly utilized biological products for which there are both Part-B-covered (versions administered incident to a physician's service) and non-covered versions (those identified to be self-administered) for which the NDCs were marketed under the same FDA approval number. OIG's studies found that when the ASPs of the self-administered versions are included in the payment limit calculation, the resulting payment limit is substantially higher than if the ASPs of only the incident-to versions had been included.

The OIG studies concluded that as a result, Medicare payment amounts were inflated, causing the program and its beneficiaries to pay an additional $366 million from 2014 through 2016 and $497 million from 2017 through 2018. They recommended that legislative changes be made to provide CMS the flexibility to determine when certain versions of a drug identified to be self-administered should be included in ASP payment limit calculations.

Section 405 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section, referred to as ''section 405''), amended section 1847A of the Act by redesignating existing subsection (g) as subsection (h) and adding new subsection (g), which describes the Medicare Part B ASP payment-limit adjustment for certain drugs and biological products for which NDCs have been identified by the OIG to be self-administered and not covered under Medicare Part B. The new section 1847A(g)(1) of the Act directs OIG to conduct periodic studies to identify NDCs for drug or biological products that are identified to be self-administered for which payment may not be made under Part B pursuant to section 1861(s)(2) of the Act and that OIG determines should be excluded from the determination of the payment amount under section 1847A of the Act.

New section 1847A(g)(2) of the Act specifies that if the OIG identifies an NDC under section 1847A(g)(1) of the Act, it must inform the Secretary at such times as the Secretary may specify. Then the Secretary shall, to the extent appropriate, apply as the payment limit for the applicable billing and payment code the lesser of: (1) The payment allowance that would be determined under section 1847A of the Act if the NDC for the identified drug or biological product were excluded from the calculation; or (2) the payment limit otherwise determined under section 1847A of the Act without application of section 1847A(g) of the Act. In other words, the Medicare payment limit for a drug or biological product's billing and payment code in these circumstances would be the lesser of the payment limit determined including the NDCs identified to be self-administered and the payment limit determined after excluding the NDCs identified to be self-administered (hereinafter referred to as the ''lesser-of payment methodology'').

Although section 1847A(g)(1) of the Act provides us with discretion in whether to apply the lesser-of methodology to billing and payment codes that include self-administered versions identified by the OIG (because we are directed to apply the methodology to the extent deemed appropriate), new section 1847A(g)(3) of the Act, requires the application of the lesser-of methodology to the two billing and payment codes identified in the OIG's July 2020 report titled, ''Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars,'' (available at *https://oig.hhs.gov/oei/reports/OEI-BL-20-00100.asp*) (hereinafter referred to as ''OIG's July 2020 report'')) beginning July 1, 2021. To meet the implementation date required by this provision, we applied the lesser-of methodology to the payment limit calculations for the billing and payment codes representing Cimzia® (certolizumab pegol) and Orencia® (abatacept), details on these calculations are described in this section. In a memorandum providing supplemental information on the OIG July 2020 report, the OIG provided specific NDCs that the report identified: 00003–2188–11, 00003–2188–51, 00003–2814–11, 00003–2818–11, 50474–0710–79, 50474–0710–81. The lesser-of methodology was applied to these billing and payment codes for the July 2021 ASP Drug Pricing Files and crosswalks along with program instructions in a change request (CR) at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files.*

In the CY 2022 PFS proposed rule (86 FR 39244), we proposed to codify the new requirements of section 1847A(g) of the Act at § 414.904. Our proposals sought to specify when the application of the lesser-of methodology would be appropriate, describe how we would apply the lesser-of payment methodology to billing and payment codes that OIG has identified pursuant to studies described in section 1847A(g)(1) of the Act, and how to codify the approach we used for the *certolizumab pegol* and *abatacept* billing and payment codes.

b. Identification of Billing and Payment Codes to Which the Lesser-of Policy Will Be Applied

As noted previously, section 1847A(g)(1) of the Act directs OIG to conduct periodic studies to identify NDCs for drug or biological products that are self-administered and for which payment is not made under Part B. Section 1847A(g)(2) of the Act specifies that if OIG makes an identification under section 1847A(g)(1) of the Act, OIG informs CMS at such times as we may specify, and in such an event, we apply the lesser-of methodology to the extent deemed appropriate. In the CY 2022 PFS proposed rule (86 FR 39244), we proposed that when the OIG conducts a periodic study, they would inform us at the time the study becomes publicly available. CMS would then obtain the NDCs identified by the OIG study described in section 1847A(g)(1) of the Act. However, if the specific NDCs were not available in the OIG study report, we would request OIG provide documentation of the identified NDCs to CMS.

To allow operational time for assessment and application of the lesser-of methodology, we stated it was reasonable that the application of the lesser-of methodology be reflected beginning in the ASP pricing file two quarters following the OIG study publication. For example, if the OIG study became available to the public in the first quarter of the calendar year, the lesser-of methodology would be applied to the payment limit calculation of the applicable billing and payment code in the third quarter ASP pricing file (in

[81] *https://www.oig.hhs.gov/oei/reports/oei-12-17-00260.pdf,* accessed March 15, 2021.

[82] *https://www.oig.hhs.gov/oei/reports/OEI-BL-20-00100.pdf,* accessed March 15, 2021.

other words, the July ASP pricing file) and each quarter thereafter.

We received public comments on the identification of billing and payment codes to which the lesser-of methodology will be applied. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concern regarding the OIG studies described in new section 1847A(g)(1) of the Act. Specifically, there is concern that neither CMS nor the OIG has specified details about future OIG studies, what criteria the OIG will use to initiate a study, how often such studies will be conducted, or if external stakeholders will be able to request a study. Commenters suggested that CMS offer a timeframe under which the OIG would be expected to produce such reports and work with the OIG to ensure transparency of factors used to determine which NDCs are considered ''self-administered'' and address study methodology. Another commenter urged the OIG to be thoughtful and transparent in the factors that it will use when determining which NDCs are ''self-administered.''

Response: The proposed rule did not include any proposals pertaining to how, when, or under what conditions the OIG would produce study reports as described in section 1847A(g)(1) of the Act. The statute assigns to the OIG, and not to CMS, the determination of self-administration for purposes of these studies, as well as study methodology.

Comment: One commenter expressed concern that CMS does not specifically define the term ''self-administered'' for purposes of the lesser-of methodology. The commenter inquired whether CMS and/or the OIG will refer to contractor self-administered drug (SAD) lists to determine if a drug should be studied and the ''lesser-of'' methodology be applied and, if so, if the drug will have to be on all contractor SAD lists for the drug eligible for an OIG study.

Response: Section 1847A(g)(1) of the Act states the Inspector General shall conduct periodic studies to identify which NDCs for drug or biological products are self-administered and should be excluded from the determination of the payment amount under this section. Such studies shall be based on the same or similar methodologies to the methodologies used in OIG's July 2020 report [83] or in the November 2017 final report of the Inspector General entitled ''Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and its Beneficiaries.'' [84] Methodologies for these studies are described in detail in each report. As noted previously, the statute puts these determinations in the OIG's purview.

c. Calculation of Payment Allowance Using the Lesser-of Payment Methodology

Sections 1847A(g)(2) and (g)(3) of the Act set forth the lesser-of payment methodology for applicable billing and payment codes with NDCs for certain drug or biological products identified by the OIG as self-administered products for which payment may not be made under this part because such products are not covered under section 1861(s)(2) of the Act. In the CY 2022 PFS proposed rule (86 FR 39244), we proposed to codify this methodology, which we currently use for the billing and payment codes that describe *certolizumab pegol* and *abatacept*, and which we also proposed to use for billing and payment codes for which OIG identifies a drug or biological product with NDCs identified to be self-administered as described in section 1847A(g)(1) of the Act.

The ASP payment limit calculation is described in section 1847A(b)(6) of the Act and codified at § 414.904(b)(2)(ii) and (c)(2)(ii), which specifies that for a billing and payment code, the volume-weighted average of the ASPs reported by the manufacturer is determined by:

- Computing the sum of the products (for each NDC assigned to such drug products) of:

++ The manufacturer's ASP determined by the Secretary without dividing such price by the total number of billing units for the NDC for the billing and payment code; and

++ The total number of units sold; and

- Dividing the sum determined under (A) by the sum of by the sum of the products (for each NDC assigned to such drug products) of

++ The total number of units specified sold; and

++ The total number of billing units for the NDC for the billing and payment code.

When applying the lesser-of methodology described in 1847A(g)(2) and (g)(3) of the Act, we proposed to make two calculations as described in section 1847A(b)(6) of the Act: (1) The ASP payment limit for the billing and payment code, excluding the NDCs that have been identified by the OIG study (that is, excluding the ASPs for those NDCs, as well as the units of such NDCs sold in the quarter); and (2) the ASP payment limit for the billing and payment code, including such NDCs' ASPs and units sold. The calculation resulting in the lower payment limit would be used as the payment limit for the applicable billing and payment code for that quarter's ASP pricing files. We proposed to apply the lesser-of methodology to the billing and payment codes containing OIG-identified products each quarter when determining ASP payment limits.

New section 1847A(g) of the Act did not change ASP reporting requirements, and consistent with section 1847A(f)(1) of the Act and, beginning January 1, 2022, section 1847A(f)(2) of the Act, manufacturers must continue to report ASP data for all NDCs of the drug or biological product. Under new section 1847A(g) of the Act, ASP data for all NDCs under the same FDA approval application (for example, NDA or BLA, including any supplements) are required to carry out the lesser-of calculations for the purposes of determining the payment limit for the billing and payment code. Even if the resulting payment limit does not reflect the ASPs or units sold of self-administered versions of a product identified by the OIG, the manufacturer must continue to report those versions' ASPs and units sold to the Secretary.

The implementation of the lesser-of methodology is not expected to be associated with substantial administrative costs and we incorporated the methodology in the current operational process used to determine ASP payment limits each quarter. The OIG found that Medicare and its beneficiaries would have saved a combined $497 million on *certolizumab pegol* and *abatacept* over 2 years (2017 through 2018) if such a methodology had been in place.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

d. Exceptions

In the CY 2022 PFS proposed rule (86 FR 39245), we further proposed that the application of the lesser-of methodology was deemed appropriate in all cases in which OIG identifies a drug or biological product in a periodic study described in section 1847A(g)(1) of the Act and made publicly available, unless the drug or biological product is in short supply.[85] As stated in the OIG's July

[83] *https://oig.hhs.gov/oei/reports/OEI–BL–20–00100.pdf;* accessed September 22, 2021.

[84] *https://www.oig.hhs.gov/oei/reports/oei-12–17–00260.pdf;* accessed September 22, 2021.

[85] Our regulation at § 414.904(d)(3)(ii)(C) in reference to AMP price substitution refers to drugs ''identified by FDA as being in short supply.'' The current AMP price substitution policy for shortages

2020 report, CMS expressed concern about the potential impact on beneficiary access if certain versions identified to be self-administered were excluded from the ASP payment limit calculation. Because of the potential for drug shortages that may affect patient care, beneficiary and provider access, and drug prices for providers, we will consider it not appropriate to apply the lesser-of methodology when a drug is in short supply. Similar to the average manufacturer price (AMP) price substitution provision in section 1847A(d)(3)(C) of the Act (codified in § 414.904(d)(3)), we proposed to add § 414.904(d)(4)(ii) to specify that we would not apply the lesser-of methodology (that is, we would determine the payment allowance including all NDCs of the drug or biological product) if the drug and dosage form(s) represented by the billing and payment code are reported by the Drug Shortage list established under section 506E of the Federal Food, Drug, and Cosmetic Act (FFDCA) (Pub. L. 75–717) at the time that ASP payment limits are being finalized for the next quarter. However, we proposed that this exception to the application of the lesser-of methodology would not apply in the case of the billing and payment codes for *certolizumab pegol* and *abatacept* because section 1847A(g)(3) of the Act does not provide us with the same discretion as section 1847A(g)(2) of the Act. Thus, for these applicable billing and payment codes we will always apply the lesser-of methodology. We recognized that NDCs identified by an OIG study described in section 1847A(g)(1) or (g)(3) of the Act may change. In the event that the manufacturer of an OIG-identified product simply redesignates the NDC for its product, we stated the new NDC also would meet the same criteria defined in the OIG study. In this circumstance, we expected that the product labeling would not contain substantial changes regarding the redesignated NDC. Therefore, we proposed to add § 414.904(d)(4)(iv) to codify the application of the lesser-of methodology such that the manufacturer-reported pricing data associated with redesignated NDCs would be used in the lesser-of methodology in the same way as the original OIG-identified NDC.

Once an OIG study identifies self-administered versions of a drug or biological product, there may be subsequent FDA approvals of other products with the same active ingredient, such as new syringe sizes, new types of injector syringes, generic formulations, biosimilar biological products, or interchangeable biological products. For example, this would include the situation in which the current manufacturer of *certolizumab pegol* or *abatacept* obtains a supplemental FDA approval for a new version of the product. Similarly, this would also include the situation in which another manufacturer gains FDA approval of a product with the same active ingredient as an OIG-identified self-administered version. We stated that we believe that provisions at new section 1847A(g) of the Act would require a new OIG study as described in section 1847A(g)(1) of the Act in order for us to apply the lesser-of methodology to the drug or biological product.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support of the proposal to not apply the lesser-of payment methodology to drugs or biological products for which there is a shortage. The commenter stated that ensuring patient access to needed medicines is critical both for individuals and for our health care system more broadly, and not applying the lesser-of payment methodology to products in short supply should help to improve access.

Response: We appreciate the commenters feedback and agree that not applying the lesser-of methodology to products in short supply will help improve access.

After consideration of public comments, we are finalizing § 414.904(d)(4)(ii) as proposed.

e. Summary

In summary, to implement new section 1847A(g) of the Act, we proposed to:

- Add § 414.904(d)(4) to codify the lesser-of payment methodology and define when the application of the lesser-of methodology would first be reflected in the ASP pricing file following the OIG study publication; and
- Describe the lesser of methodology at § 414.904(d)(4)(iv).
- Describe exceptions to application of the lesser-of methodology at § 414.904(d)(4)(ii).
- Clarify application of the lesser-of methodology for billing and payment code described under section 1847A(g)(3) of the Act at § 414.904(d)(4)(iii).
- Describe the application of the lesser-of methodology to redesignated NDCs of those identified in the OIG studies at § 414.904(d)(4)(v).

We solicited comments on these proposals.

We received other general comments on section 405. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that they oppose the application of the lesser-of methodology to *certolizumab pegol* and *abatacept* billing and payment codes as they may negatively impact patient access to the most appropriate treatment for their disease. They expressed that certain products with separate formulations, such as those administered by subcutaneous versus intravenous routes, are distinct with sufficiently unique indications, risks, and target patient populations. To make an appropriate medical decision, providers follow the standards of medical practice and incorporate the patient's unique medical history.

The commenter disputed the OIG report's assertion that providers are monetarily incentivized to administer *certolizumab pegol* and *abatacept* over other therapies and stated that providers select the most appropriate treatment for their patients without any consideration of financial incentives. The commenter suggested that CMS not implement OIG's recommendation of excluding self-administered formulations of *certolizumab pegol* and *abatacept* from ASP payment limit calculations.

Response: Section 1847A(g)(3) of the Act requires the application of the lesser-of methodology to *certolizumab pegol* and *abatacept* billing and payment codes. This section states that, for NDCs identified by OIG's July 2020 report, the lesser-of methodology shall be applied beginning July 1, 2021. As required by this statutory provision, we have implemented section 1847A(g)(3) of the Act as reflected in the July 2021 ASP Drug Pricing File and quarterly files thereafter (*https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files*).

Comment: One commenter encouraged CMS to abandon the lesser-of methodology in favor of a model that works to provide appropriate reimbursement for all drugs. They suggested that CMS consider the alternative approaches that maintain balanced market incentives for competition among physician-administered drugs with the goal of protecting patient access.

is consistent with the policy discussed here, as we interpret the phrase ''identified by FDA as being in short supply'' at § 414.904(d)(3)(ii)(C) to mean the list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

They stated that there is a need to broaden the current thinking beyond the studied ''loophole'' where the OIG finding is based on two specific drugs where the self-administered versions reported appear to increase the volume-weighted ASP creating a financial incentive for the use of these products while leading to increased cost and limiting access for patients. Likewise, there needs to be consideration that including non-covered NDCs may reduce the volume-weighted ASP leading to disincentives in the marketplace for those drugs and again impacting patient access. Furthermore, they stated that approval of same drug within one NDA or BLA versus multiple NDAs or BLAs should not lead to a different reimbursement paradigm for covered and non-covered drugs.

Response: As stated in the previous response, section 1847A(g)(3) of the Act requires the application of the lesser-of methodology with respect to these drugs and does not give CMS the discretion to decline to apply it.

As explained in the background section, paragraphs (4)(A) and (6) of sections 1847A(b) of the Act require that the Medicare Part B payment amount for a single-source drug or biological be determined using all of the NDCs assigned to it and section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as an NDA or BLA). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological, for payments made under section 1847A of the Act and are crosswalked to the same billing and payment code.

Comment: One commenter expressed general support of the proposal to utilize the lesser-of payment methodology for all self-administered NDCs identified by the future OIG studies. They stated that the lesser-of methodology eliminates the potential for non-covered self-administered forms of a product to inflate Medicare Part B payment rates and results in savings for beneficiaries and taxpayers.

Response: We thank the commenter and appreciate their feedback.

After consideration of public comments, we are finalizing these proposals as proposed.

E. Medicare Part B Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act

1. Background

As we discussed in the CY 2022 PFS proposed rule (86 FR 39245 through 39246), for most drugs that are payable under Medicare Part B, payment-limit amounts are determined using the methodology in section 1847A of the Act. In many cases, the payment-limit amount is based on the ASP plus a statutorily mandated 6 percent add-on. Additionally, small molecule drugs payable under Medicare Part B using the methodology in section 1847A of the Act fall into two broad, mutually exclusive categories: (1) Multiple source drugs, and (2) single source drugs. These terms are defined in sections 1847A(c)(6)(C) and (D) of the Act, respectively.

In most cases, the distinction between multiple source drugs and single source drugs is straightforward. We published program instructions in 2007 (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*) that address how these distinctions are made. However, a subset of drugs that are approved by the FDA under New Drug Applications (NDAs) are approved through the pathway established under section 505(b)(2) of the FFDCA (Pub. L. 75–717, June 25, 1938) (hereinafter referred to as ''section 505(b)(2) drug products''). For section 505(b)(2) drug products, the distinction between multiple source drugs and single source drugs can be less straightforward.

The drug approval pathway established under section 505(b)(2) of the FFDCA (hereinafter referred to as ''the section 505(b)(2) pathway'') provides an avenue for applications that contain full reports of investigations of safety and effectiveness, where at least some of the information needed for an approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a ''right of reference or use'' [86]. An application submitted under the section 505(b)(2) pathway (hereinafter referred to as a ''section 505(b)(2) application'') may rely either on the FDA's findings of safety, effectiveness, or both, for an already-FDA-approved drug product or on published literature, provided that: (1) Such reliance is scientifically justified, and (2) the section 505(b)(2) application complies with applicable statutory and regulatory requirements, including, but not limited to, patent certification, if appropriate. Unlike a generic drug product approved under an Abbreviated New Drug Application (ANDA), a section 505(b)(2) drug product is not required to have the same FDA-approved labeling as the labeling for the already-FDA-approved drug product(s) upon which the section 505(b)(2) application relied. (For more information, see the FDA's May 2019 guidance titled, ''Determining Whether to Submit an ANDA or a 505(b)(2) Application,'' available at *https://www.fda.gov/media/124848/download.*)

We noted that the number of section 505(b)(2) drug products approved each year has been growing, from about 40 per year from 2011 to 2016, to about 60 to 70 per year from 2017 to 2020. Approximately 10 to 20 percent of these section 505(b)(2) drug products are payable under Medicare Part B. Of these, some section 505(b)(2) drug products share substantial portions of the FDA-approved labeling with the approved drug product(s) upon which the section 505(b)(2) application relied, for example prescribing information on safety, efficacy, and pharmacokinetics. In some cases, the section 505(b)(2) drug product even shares substantial portions of labeling with generic drug products that are payable under Part B as multiple source drugs. Medicare Part B claims data from 2020 indicate that spending for some of these section 505(b)(2) drug products (that is, those that could be assigned to a multiple source drug code under the framework described below, but are instead currently assigned to a single source drug code) is substantially greater than that for the corresponding generic drug products assigned to a multiple source drug code. One example is a sterile injectable drug that was first approved as a lyophilized powder for reconstitution in a vial and later was approved through the section 505(b)(2) pathway as a concentrated liquid in a vial. Another example is a drug available as a lyophilized powder for reconstitution in a vial that was then approved through the section 505(b)(2) pathway as a ready-to-use intravenous (IV) solution in a bag. Analysis of 2020

[86] Regulations at 21 CFR 314.3 define ''Right of Reference or Use'' to mean the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an NDA, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

claims data for the separately coded section 505(b)(2) drug product (that is, the ready-to-use IV solution) shows that Medicare spending per service unit was approximately eight times that of the corresponding products in the multiple source drug code. Moreover, in the July 2021 ASP Pricing File (available at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files*), the payment limit for the section 505(b)(2) drug product is 17.2 times the payment limit for the multiple source code, when adjusted for the different dose descriptors of each code. In another example, there were approximately 7.54 million allowed service units, representing approximately $1.38 million of allowed charges, for a multiple source drug code, but for the separately coded section 505(b)(2) drug product, over the same time-period there were approximately 1.08 million allowed service units, representing approximately $2.13 million in allowed charges. Calculating the allowed charges per allowed service unit, each service unit of the section 505(b)(2) drug product cost Medicare 10.78 times that of the corresponding products assigned to the multiple source drug code, costing Medicare an additional $1.93 million. In the July 2021 ASP Pricing File, the payment limit for the section 505(b)(2) drug product is 21.3 times the payment limit for the multiple source code.

In the CY 2022 PFS proposed rule (86 FR 39246) we indicated that based on these observed data points, we plan to perform additional analysis of spending on section 505(b)(2) drug products and potential savings to Medicare and Medicare beneficiaries that may be realized if certain section 505(b)(2) drug products were to be assigned to multiple source drug codes based on the framework described in section III.E.3 of the proposed rule. The framework is also provided below in section III.E.3 of this final rule.

2. CY 2021 Proposal

In the CY 2022 PFS proposed rule (86 FR 39246), we discussed that in the CY 2021 PFS proposed rule, we proposed to codify our long-standing approach to determine whether a section 505(b)(2) drug product is described by an existing multiple source drug code, or if the section 505(b)(2) drug product would be assigned to a single source drug code. In that proposal, we explained generally how information about the section 505(b)(2) drug product's active ingredient(s), drug product name (this refers to nomenclature of the drug product as found in the United States Pharmacopeia—National Formulary (USP–NF) and nomenclature as found in title of the FDA-approved labeling), and description; labeling information; and ordering (prescribing) and clinical use would factor into a determination. Commenters on our proposal in the CY 2021 PFS proposed rule (primarily manufacturers) stated that the proposal conflicted with both the Medicare statute and the FDA's therapeutic equivalence (TE) ratings,[87] [88] and would impair access for patients, underpay providers, and stifle innovation. Several commenters from beneficiary advocate and provider organizations generally repeated the same points, although some commenters expressed support for curbing drug prices, particularly if the proposal did not affect patient access. Several commenters appeared to take a middle ground that conditionally supported the proposals, particularly if more detail could be provided and if effects on patient access were considered. Several commenters supported the proposals without conditions. Several commenters expressed that we should provide more detail about the decision framework and the determination process.

Some commenters on the CY 2021 PFS proposed rule requested that we provide more details about the process by which certain section 505(b)(2) drug products would be assigned to multiple source drug codes. Commenters requested that we include more detail on how factors described in the CY 2021 PFS proposal, (for example, differences in the active ingredient and labeling) may be interpreted and which drug products might be affected. Commenters also requested that we provide the public more time to assess a more detailed proposal, as well as an opportunity, such as through future rulemaking, for public input both on the proposal and on decisions about specific drug products.

Several commenters stated that if we move forward with the CY 2021 proposal, we should exclude products with ''meaningful differences'' from the policy and encouraged us to continue an approach ''that allows for innovation, competition, and ultimately more therapeutic choices for Medicare beneficiaries.'' We noted that we recognize some section 505(b)(2) drug products have clear differences in factors such as safety, efficacy, or pharmacokinetics, which would not result in the assignment of the product to the existing multiple source drug code. We stated that the framework discussed in section III.E.3 of the CY 2022 PFS proposed rule (86 FR 39247) would address situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code, and therefore, would not be assigned to the existing multiple source drug code.

We explained in the CY 2022 PFS proposed rule (86 FR 39247) that in response to commenters' requesting more detail about our proposed approach and to delay finalizing a decision, we did not finalize our proposals in the CY 2021 PFS proposed rule regarding section 505(b)(2) drug products. We stated that the delay would allow time for CMS to further consider this issue. Therefore, as part of our further consideration, we solicited comment on a more detailed framework (hereinafter referred to as ''the framework'') for determining when a section 505(b)(2) drug product is a multiple source drug under section 1847A(c)(6)(C) of the Act.

The framework is consistent with program instruction published in 2007, which addressed how we would assign ''single source drugs'' and ''biological products'' using a multi-step process. However, this program instruction did not expressly address how we would assign multiple source drugs. The program instruction uses the term ''drug'' at the billing and payment code level when discussing single source drugs in the same way that the discussion in this preamble uses the term ''drug'' in reference to multiple source drugs. Development of standards for identifying multiple source drugs (that is, the framework) would add to the 2007 program instruction and provide detail about an approach to Medicare Part B payment for section 505(b)(2) drug products.

We stated that the framework described in section III.E.3 in the CY 2022 PFS proposed rule (86 FR 39247) aims to build off the current CMS policy for assigning drug products to billing and payment codes by describing detailed standards for determining whether a section 505(b)(2) drug product corresponds to an existing multiple source drug code. While we did not propose to adopt the framework, we instead sought comment on the framework to inform future policy making.

[87] As published in the FDA's ''Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations'' available at *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.*

[88] See also 21 CFR 314.3(b) for definitions of ''therapeutic equivalents'' and related terms, as well as *https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.*

3. The Framework

As we described in the CY 2022 PFS proposed rule (86 FR 39247), the framework is a determination process to identify when section 505(b)(2) drug products without an FDA TE rating to an existing drug product payable under Part B correspond to an existing multiple source drug code for the purpose of payment under Medicare Part B. The framework would provide additional detail about the decision-making process and increase transparency about potential determinations resulting from the framework.

The first portion of the framework would compare certain qualities of the section 505(b)(2) drug product with drug products already assigned to an existing multiple source drug code.[89] This includes comparison of the: (1) Active ingredient(s); (2) dosage form (if part of the drug product name); (3) salt form; and (4) other ingredients in the drug product formulation. The drug product assessment could result in a match or non-match designation. Section 505(b)(2) drug products receiving a match designation in the first portion of the framework would continue to a verification step. This step would compare the pharmacokinetic and clinical studies of the section 505(b)(2) drug product's FDA-approved labeling with those of the drug products already assigned to an existing multiple source code. Finally, a determination would be made as to whether the section 505(b)(2) drug product could be assigned to the existing multiple source code.

For full details on the framework, please see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/PFS-Federal-Regulation-Notices.*

We solicited comment on the following:

- The framework and how it aligns with the statutory definitions of single source and multiple source drugs in section 1847A(c)(6)(C) and (D) of the Act, respectively;
- How the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code; and
- The potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders.

We received public comments on the framework, a determination process to identify when section 505(b)(2) drug products without an FDA TE rating to an existing drug product payable under Part B correspond to an existing multiple source drug code for the purpose of payment under Medicare Part B. The following is a summary of the comments we received and our response.

Comment: Overall, we received 27 comments on the framework approach to assigning certain section 505(b)(2) drug products to existing multiple source codes. A majority of commenters were pharmaceutical manufacturers; other commenters included MedPAC, and professional associations representing stakeholder interests.

We received 14 comments on the framework and how it aligns with the statutory definitions of single source and multiple source drugs. Several commenters noted that CMS lacks the statutory basis for the framework. The commenters stated that the framework does not align with the statutory definition for multiple source drug.

We received six comments on how the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code. Some commenters stated that framework does detect meaningful differences between drug products. However, some commenters stated that the framework is not robust enough and does not consider all of the important elements that would make two drug products meaningfully different. Other commenters suggested modifications to the framework.

We received comments on the potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders. Several commenters expressed concern about potential impacts of the framework on manufacturers' use of the section 505(b)(2) pathway. Commenters stated that implementation of the framework approach would slow innovation by discouraging or disincentivizing manufacturers from using the section 505(b)(2) pathway for drug approval. The commenters also stated that payment for section 505(b)(2) drug products as multiple source drugs could result in inadequate reimbursement, and subsequently, may limit access to patients in the physician office setting.

Lastly, we received comments in support of the framework and the assignment of certain section 505(b)(2) drug products to existing multiple source codes. One commenter agreed that drugs approved under the section 505(b)(2) pathway should be considered for definition as a multiple source drug. The commenter stated that defining some section 505(b)(2) drug products as multiple source drugs, and potentially assigning lower payment limit, would generate cost savings. MedPAC reiterated their 2021 PFS comment, which supported CMS codifying its longstanding process for assigning certain section 505(b)(2) drug products into multiple source billing and payment codes. A third commenter expressed concern regarding the price of legacy drugs approved through the section 505(b)(2) pathway.

Response: We thank all the commenters for providing feedback on this comment solicitation regarding the framework and how it aligns with the statutory definitions of single source and multiple source drugs; how the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code; and potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders. We will take these comments into consideration for future rulemaking.

F. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA) amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. We have taken steps to implement this program over several years, and codified the AUC program in our regulations at 42 CFR 414.94. In CY 2020, we began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information, which has been extended through CY 2021.

The CY 2016 PFS final rule with comment period (80 FR 70886) addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In the CY 2016 PFS final rule with comment period, we established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS website at the end of June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act.

The CY 2017 PFS final rule (81 FR 80170) addressed the second component

[89] These assignments are published as part of the ASP NDC–HCPCS Crosswalk Files available at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files.*

of this program, specification of qualified clinical decision support mechanisms (CDSMs). In the CY 2017 PFS final rule, we defined CDSM, identified the requirements CDSMs must meet for qualification, including preliminary qualification for mechanisms documenting how and when each requirement is reasonably expected to be met, and established a process by which CDSMs may become qualified. We also defined applicable payment systems under this program, specified the first list of priority clinical areas, and identified exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. The first list of qualified CDSMs was posted on the CMS website in July 2017.

The CY 2018 PFS final rule (82 FR 53190) addressed the third component of this program, the consultation and reporting requirements. In the CY 2018 PFS final rule, we established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic imaging services. Specifically, for services ordered on and after January 1, 2020, we established that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the Medicare claim. We further specified that the AUC program will begin on January 1, 2020 with a year-long educational and operations testing period during which time AUC consultation information is expected to be reported on claims, but claims would not be denied for failure to include proper AUC consultation information. We also established a voluntary period from July 2018 through the end of 2019 that ordering professionals who are ready to participate in the AUC program may consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals; and furnishing professionals who are ready to do so may report AUC consultation information on the claim at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10481.pdf*.

Additionally, to incentivize early use of qualified CDSMs to consult AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule (hereinafter ''CY 2018 Quality Payment Program final rule''), a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

In the CY 2019 PFS final rule (83 FR 59452), we made further additions and clarifications to the AUC program requirements. We added independent diagnostic testing facility (IDTF) to the definition of applicable settings under § 414.94(b). We also clarified that the furnishing professionals (including provider or supplier entities furnishing advanced diagnostic imaging services in an applicable setting, paid for under an applicable payment system) are required to report AUC consultation information on the claims as specified under § 414.94(k). We established significant hardship exception criteria and process under § 414.94(i)(3) to be specific to the AUC program and independent of other Medicare programs. We specified under § 414.94(j)(2) that when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC consultation with a qualified CDSM. Finally, we announced our intention to use G-codes and modifiers to report AUC consultation information on the Medicare claims. In 2020, in response to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19) (PHE for COVID–19), the educational and operations testing period was extended through CY 2021.

1. Background

AUC present information in a manner that links a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation. For purposes of this program, AUC is a set or library of individual AUC. Each individual criterion is an evidence-based guideline for a particular clinical scenario based on a patient presenting symptoms or condition.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information, but may be more effective when they are integrated into EHRs. Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directed the Secretary to establish a program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional's consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). We did not identify mechanisms for consultation by April 1, 2016. Therefore, we did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term ''provider-led entity'' and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by us, the AUC that are developed, modified or endorsed by the qualified PLE are

considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

In the same rule, we established a timeline and process under § 414.94(c)(2) for PLEs to apply to become qualified. Qualified PLEs are listed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html* (OMB Control Number 0938–1288).

b. Mechanism for AUC Consultation

In the CY 2017 PFS final rule, we addressed the second major component of the Medicare AUC program—the specification of qualified CDSMs for use by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term CDSM and finalizing functionality requirements of mechanisms, upon which qualification is based, as provided in section 1834(q)(3)(B) of the Act and in the CY 2017 PFS final rule. We defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or a mechanism established by the Secretary.

In the CY 2017 PFS final rule, we established a timeline and process in § 414.94(g)(2) for CDSM developers to apply to have their CDSMs qualified. Qualified CDSMs are listed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html* (OMB Control Number 0938–1315).

c. AUC Consultation and Reporting

In the CY 2018 PFS final rule, we addressed the third major component of the Medicare AUC program—consultation with applicable AUC by the ordering professional and reporting of such consultations under section 1834(q)(4) of the Act. We established a January 1, 2020 effective date for the AUC consultation and reporting requirements for this program. We also established a voluntary period during which early adopters could begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period, there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On January 1, 2020, the program began with an educational and operations testing period and during this time, we have continued to pay claims whether or not they correctly include AUC consultation information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020; and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020.

Consistent with section 1834(q)(4)(B) of the Act, we also established that the following information must be reported on Medicare claims for advanced diagnostic imaging services as specified in section 1834(q)(1)(C) of the Act and defined in § 414.94(b), furnished in an applicable setting as defined in section 1834(q)(1)(D) of the Act, paid for under an applicable payment system as defined in section 1834(q)(4)(D) of the Act, and ordered on or after January 1, 2020: (1) The qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional).

Section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements in the case of: A service ordered for an individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship. In the CY 2017 PFS final rule, we adopted a regulation at § 414.94(h)(1)(i) to specify the circumstances under which AUC consultation and reporting requirements are not applicable and in the CY 2019 PFS final rule, we updated the significant hardship exception criteria to be specific to the AUC program and independent of other programs. An ordering professional experiencing any of the following when ordering an advanced diagnostic imaging service is not required to consult AUC using a qualified CDSM, and the claim for the applicable imaging service is not required to include AUC consultation information. Significant hardship exceptions under § 414.94(i)(3) include: Insufficient internet access; EHR or CDSM vendor issues; or extreme and uncontrollable circumstances.

We remind readers that, consistent with section 1834(q)(4)(A) of the Act, ordering professionals must consult AUC for every applicable imaging service furnished in an applicable setting and paid under an applicable payment system unless a statutory exception applies.

Section 1834(q)(4)(D) of the Act specifies the applicable payment systems for which AUC consultation and reporting requirements apply. In the CY 2017 PFS final rule, we defined applicable payment system to reflect the statutory requirements in § 414.94(b) as: (1) The PFS established under section 1848(b) of the Act; (2) the PPS for HOPD services under section 1833(t) of the Act; and (3) the ASC payment system under section 1833(i) of the Act.

Section 1834(q)(1)(D) of the Act specifies the applicable settings in which AUC consultation and reporting requirements apply: A physician's office, a HOPD (including an emergency department), an ASC, and any other ''provider-led outpatient setting determined appropriate by the Secretary.'' In the CY 2017 PFS final rule, we added this definition to § 414.94(b). As noted above, we expanded that definition to add an IDTF in the CY 2019 PFS final rule.

d. Identification of Outliers

The fourth component of the Medicare AUC program is specified in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement that applies for outlier professionals beginning

January 1, 2020, as specified under section 1834(q)(6) of the Act. Because we established a start date of January 1, 2020 for AUC consultation and reporting requirements, we did not identify any outlier ordering professionals by that date. As such, implementation of the prior authorization component is delayed. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

We will use future rulemaking to establish the methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services.

4. Continuing Implementation

a. Clarification of AUC Program Scope

i. Modified Orders

Updates or modifications to orders for advanced diagnostic imaging services may be warranted in certain situations once the beneficiary is under the care of the furnishing professional. Unless they are also serving as the ordering professional, furnishing professionals may not consult AUC on behalf of or in place of the ordering professional. The Medicare Benefit Policy Manual (BPM) (Pub. L. 100–02) addresses situations where the furnishing professional performs imaging services that differ from ordered services in chapter 15, sections 80.6.1–4 (hereafter in this section, ''the BPM''). The BPM on modified orders state that when an interpreting physician determines that a different or additional imaging service not included on the order should be performed, the interpreting physician or testing facility generally may not perform the test until a new order from the treating physician/practitioner has been received. If the treating physician/practitioner cannot be reached to change or obtain a new order, the interpreting physician or testing facility may furnish the additional imaging service under the following circumstances, as documented in the patient's medical record: The treating physician/practitioner could not be reached, the ordered test is performed and an additional diagnostic test is medically necessary because of the abnormal result of that test, delaying performance of the additional test would have an adverse effect on the patient's care, the result of the additional test is communicated to and used by the treating physician/practitioner in the patient's treatment, and the interpreting physician/practitioner documents in the report the reasons for the additional testing.

When the furnishing professional performs additional imaging services not reflected on the order under these circumstances, we do not believe it would be appropriate to consider them to be acting as an ordering professional such that an AUC consultation would be needed. Instead, we believe the furnishing professional in these situations is the interpreting physician/practitioner who is exercising their professional judgment to provide the ordering professional with additional diagnostic test results for use in managing the patient's care. Additionally, they are doing so only because, after performing the ordered test and determining that additional testing is expedient given the results of that test, the ordering professional cannot be reached to request a modified or additional order. Given the conditions under which these additional imaging services are performed, we proposed that when the furnishing professional for an advanced diagnostic imaging service performs one or more additional services under the circumstances described in chapter 15, section 80.6.2–4 of the BPM, neither the ordering professional nor the furnishing professional are required to consult AUC for the additional service(s). In these situations, the AUC consultation information from the original order is to be reported on the claim line for the additional service(s). Where the furnishing professional modifies the order for an advanced diagnostic imaging service without obtaining a new order from the ordering professional, the AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred. Because the BPM states that the interpreting physician or testing facility generally may not perform a modified or new test until a new order from the treating physician/practitioner has been received, we expect situations where AUC consultations do not occur for new or modified orders to be infrequent.

We received public comments on the proposal and discussions related to modified orders above. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that CMS does not provide enough data to substantiate that modified orders are infrequent.

Response: We make this statement at the end of the discussion above and after referring to the existing language in the BPM (Chapter 15, sections 80.6.2–4). The BPM states that when an interpreting physician determines that a different or additional imaging service not included on the order should be performed, the interpreting physician or testing facility generally may not perform the test until a new order from the treating physician/practitioner has been received and, if the treating physician/practitioner cannot be reached to change or obtain a new order, only then may the interpreting physician or testing facility furnish the additional imaging service under certain circumstances. Because the expectation is that, except under narrow circumstances, a new or additional order to be placed by the ordering professional, we expect situations where the ordering professional is completely uninvolved, and thus, where we proposed that another AUC consultation would not be performed, to be infrequent. This is not based on information generated from claims or other data as, to the best of our knowledge, claims for modified orders (additional or replacement) do not include unique, identifying information. If orders are in fact being modified frequently, it would suggest to us that practitioners may not be familiar with the provisions of the BPM regarding modified orders.

Comment: Two commenters stated that the proposal conflicts with a response to public comments in the CY 2018 PFS final rule addressing order modifications. These commenters stated that in the CY 2018 PFS final rule, CMS provided guidance that when furnishing professionals must update or modify the order, the AUC consultation information provided by the ordering professional with the original order should be reflected on the claim. These commenters further stated that EHRs implement functionality that automatically applies AUC information from an original order to the modified order without any verification that the requirements for order modification were met. These commenters requested that CMS allow providers to append

modifier MH (indicating that the imaging service was not subject to the AUC program requirements) when the furnishing professional determines a new or modified order should be performed without first requesting the new or modified order to submitted by the original ordering professional.

Response: We disagree that the above proposal conflicts with the guidance included in the CY 2018 PFS final rule, but rather believe it provides further clarification. These commenters did not reference the CMS response in its entirety which stated that we do not believe it was the intent of section 218(b) of the PAMA to reverse the rules specified in Chapter 15, sections 80.6.2–4 of the Medicare BPM, and we expect furnishing professionals and facilities to continue to adhere to them. After this statement, we then addressed instances when the furnishing professional must update or modify the order and stated that for these situations, the AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred. While the language cited by commenters, when taken out of context of the entire response, appears to instruct practitioners to append the original AUC consultation information to the claim without consideration of ordering professionals submitting an updated order, such interpretation is inconsistent with the whole response which states that we expect furnishing professionals to maintain compliance with the provisions of Chapter 15, sections 80.6.2–4 of the Medicare BPM. As such, the proposals in this year's proposed rule are consistent with prior guidance in rulemaking and existing guidance in the BPM. Additionally, we disagree with the commenter's suggestion that it would be appropriate to append a modifier to claims for such services, indicating that they are not subject to the AUC program requirements. We maintain that when the furnishing professional is unable to reach the ordering professional to obtain a new order and proceeds with additional or different imaging as described in the BPM, the AUC consultation information for the original order is to be appended to the claim for the service(s) ultimately furnished.

Comment: One commenter stated that the proposals for modified orders are confusing and CMS should develop other solutions for how AUC data should be reported on claims for revised/additional advanced diagnostic imaging orders. This commenter further stated that the proposals appear to require furnishing professionals to report erroneous information about the consultation on the claim which could potentially negatively impact the ordering professional when the program moves into the outlier identification and prior authorization component. This commenter requested that CMS clarify how AUC data should be reported on claims for revised/additional imaging orders and how CMS might mitigate negative downstream effects on ordering professionals whose CDSM data were erroneously reported on claims to accommodate this scenario. Another commenter also requested clarification around the applicability and documentation for modified orders.

Response: While we recognize that the claims processing solutions to fully implement the AUC program are imperfect, particularly since our claims processing systems do not have the capability to fully automate claims processing for advanced diagnostic imaging services subject to the AUC program, we believe the proposal specific to modified orders is clear, appropriate and does not in fact require the reporting of erroneous information on the Medicare claim.

First, the proposal is that, in the event a different or additional service is furnished than was originally ordered under the circumstances described in the BPM, the furnishing professional would report on the claim for the imaging service(s) ultimately furnished the AUC information communicated with the original order by the ordering professional. In these situations, no other AUC consultations take place since, under our proposal, the furnishing professional is not originally and does not become the ordering professional. As such, the only AUC consultation information pertinent to the specific patient in question and for the specific clinical scenario in question was obtained when the ordering professional consulted AUC for the original order, and thus this is the only AUC consultation information that could be appended to the claim. In instances where the furnishing professional determines additional or replacement imaging services should be performed and he or she is able to reach the ordering professional for a new order, then the ordering professional will consult AUC for the new order(s) and provide that information with the new order(s) for inclusion on the claim.

Second, these services, when furnished in an applicable setting and paid under an applicable payment system, are not excepted from the AUC program, so appending a modifier to indicate that they are, would be erroneous.

Third, we disagree with the suggestion that this approach would result in negative downstream effects for ordering professionals specific to outlier identification and prior authorization as inclusion of the original consultation information on the claim would meet the requirements for the claim to process and communicate the original consultation information to indicate the level of adherence of the order placed by the ordering professional with AUC. This suggestion raises the question whether the modified order parameters set forth in the Medicare BPM are consistently followed. CMS does not have the authority to establish an exception to the reporting requirements. CMS may consider in subsequent rulemaking whether an additional modifier should be appended to all modified orders (additional and/or revised) for which new orders are not submitted by the original ordering professional to ensure that furnishing professionals are not furnishing advanced diagnostic imaging services unilaterally and without the acknowledgement of the ordering professional. An additional modifier to identify these situations could be useful to mitigate any unintended consequences during the outlier identification and prior authorization component. We note that the AUC program is designed to improve ordering patterns of ordering professionals by further educating them on appropriate use of advanced diagnostic imaging services and this may not be achieved if orders are frequently modified without the involvement of the ordering professional.

Comment: Some commenters expressed general support for the proposal. One commenter expressed agreement with the proposal, in the conditions outlined in the proposed rule, that the ordering professional would not be required to consult AUC for imaging studies that need to be modified once under the care of the furnishing professional. Another commenter specifically expressed support for the proposal to except modified orders from the AUC consultation requirement when a different test is clinically appropriate, additional testing may be needed, and the ordering professional is not available to provide a new order. One commenter stated that furnishing professionals should be able to modify the order without obtaining a new order from the ordering professional and use the original AUC on the claim for

modified orders when a radiologist deems it necessary to change the original exam based on best clinical judgement for decisions regarding contrast/non-contrast or scans on contiguous body parts.

Response: We appreciate the comments and remind readers of the specifications in the BPM discussed above.

After consideration of public comments we are finalizing our proposal without change so that furnishing professionals that modify an order for advanced diagnostic imaging services with a replacement and/or additional imaging service, and are unable to reach the ordering professional for a new order as described in Chapter 15, sections 80.6.2–4 of the Medicare BPM, are to append to the Medicare claim for the service(s) the AUC consultation information provided by the ordering professional specific to the original order.

ii. Extreme and Uncontrollable Circumstances Hardship Exception

In the CY 2019 PFS final rule, we describe extreme and uncontrollable circumstances to include disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems. We also explain these may include areas where events occur that have been designated by FEMA as a major disaster or a public health emergency declared by the Secretary. To further clarify, these circumstances are events that are entirely outside the control of the ordering professional that prevent the ordering professional from consulting AUC through a qualified CDSM. We believe the hardship criteria under this program are similar to other programs such as the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), particularly the flexibility that is given to clinicians to identify what they consider to be extreme and uncontrollable circumstances.

The PHE for COVID–19 has been in effect since January 27, 2020. Stakeholders have described challenges in continuing to prepare for the payment penalty phase of the AUC program due to resource reallocation resulting from the PHE. Some stakeholders have explained that all health technology projects unrelated to the PHE were halted, including projects that impact establishing or updating health IT systems that enable AUC consultation through qualified CDSMs. Stakeholders have also indicated that human resources were reallocated to focus on responding to the PHE. Additionally, we recognize that practitioners have been heavily impacted in their own practice of medicine to respond to the PHE and provide treatment to patients which may have prevented them from focusing on and participating in the educational and operations testing period to prepare for the payment penalty phase. While we are continuing to move forward in implementing the AUC program, we want to assure stakeholders that they may attest to a significant hardship under the AUC program due to extreme and uncontrollable circumstances due to the PHE for COVID–19, and such an attestation may be used as needed by ordering practitioners throughout the PHE. Furthermore, as the AUC program progresses into the payment penalty phase, self-attestation for a significant hardship exception will continue to be available for ordering professionals experiencing extreme and uncontrollable circumstances due to the PHE. We also recognize that ordering professionals may experience significant hardships related to or resulting from the PHE that extend beyond the date the PHE expires and note that AUC program exceptions will continue to be available for such significant hardships as defined at § 414.94(i)(3).

We received public comments on the extreme and uncontrollable significant hardship exception along with comments on other exceptions. The following is a summary of the comments we received and our responses.

Comment: Some commenters agreed with our clarification that the PHE for COVID–19 is a significant hardship and significant hardships due to the PHE may extend beyond the date the PHE expires. Another commenter agreed that the PHE for COVID–19 is a proper circumstance for an extreme and uncontrollable circumstance exception even after the start of the payment penalty phase of the AUC program if the PHE or effects of the PHE impact ordering professionals. Other commenters requested that CMS allow providers to use the extreme and uncontrollable circumstances exemption for at least one year following the start of the payment penalty phase because of the PHE.

Response: We appreciate the support of the commenters. As significant hardship exceptions under the AUC program are self-attested, we did not propose, and decline to specify time frame parameters around experiencing an extreme and uncontrollable circumstances significant hardship due to the PHE for COVID–19.

Comment: One commenter requested that CMS harmonize the hardship exceptions with the Quality Payment Program (QPP) hardship exceptions and allow ordering professionals and furnishing professionals to annually attest to hardship rather than on every claim. One commenter stated that significant hardship exemptions should be included for furnishing professionals.

Response: As discussed in the CY 2019 PFS final rule, the AUC program requires real time reporting of information on the Medicare claims for payment purposes while the QPP is not a real time program, but instead uses data from prior performance years to determine status and potential payment adjustments in future years. We explained in that final rule that this difference along with the statutory differences between the programs necessitates a separate significant hardship exception approach and process for the AUC program. In that final rule, we further discuss that the real time self-attestation process (as opposed to a blanket exception for a predetermined period of time) ensures that clinicians have the ability and flexibility to use the significant hardships allowable under the program. We also noted that applying a blanket exception for a specific period of time for ordering professionals based on a single significant hardship attestation would introduce a level of complexity and burden to the process whereby furnishing professionals would need to keep track of which ordering professionals had attested to a significant hardship and over what applicable period of time every time an order is received and a claim is prepared, submitted and processed. We also note that the statute provides for significant hardships for ordering professionals for whom consultation with AUC would result in a significant hardship but the statute does not provide for significant hardships specific to furnishing professionals.

Comment: One commenter requested that, like QPP, the AUC program include an exception for new physicians for one year and for low volume of Medicare patients.

Response: As discussed in the CY 2019 PFS final rule, we do not have the authority to include exceptions to the AUC program beyond the scope of those specified in section 1834(q)(4)(C) of the Act. As explained in that final rule, we believe that significant hardships are reflective of situations that would impede clinicians from consulting AUC through a CDSM and we do not agree

that ordering professionals in practices with a low volume of Medicare patients would be impeded from consulting AUC. Similarly, we stated that we do not believe being a new physician would cause the act of consulting AUC to be particularly difficult or challenging for ordering professionals.

Comment: Two commenters requested exceptions for providers in value-based care models and two commenters requested exceptions for physicians and practices that are already taking on financial risks in advanced payment models (APMs).

Response: The statute does not except participants in certain types of models or initiatives from the AUC program requirements.

Comment: Several commenters requested CMS address how second opinions are to be handled under the AUC program. One commenter stated that it is important to exempt second opinions of already performed and interpreted imaging studies to prevent additional imaging, ensure timely access for patients and limit barriers to evaluation by subspecialty radiologists. Another commenter specifically requested guidance on whether a consulting professional must also consult AUC and how to indicate that consultation was performed particularly if it does not result in a new order and, when it does result in a new order, whether the consulting professional should order the second imaging service and whether the ordering professional must consult AUC a second time. One commenter specifically requested clarification around how the AUC requirements apply to second opinions and how orders that are placed contra-AUC for legitimate clinical reasons are to be identified.

Response: We believe the AUC consultation and reporting requirements apply to second opinions in the same way they apply to original patient assessments and resulting orders for advanced diagnostic imaging serves. If an additional PC is submitted for an imaging services due to a second opinion, the AUC consultation information specific to the advanced diagnostic imaging services that was furnished (the original order) would be appended to the claim for the PC. If, based upon this second opinion, further tests must be ordered, they would require separate and additional AUC consultation as they are new/additional orders. We note that, as introduced by commenters, second opinions are different from modified orders, so if new or additional orders result from the second opinion review, these would be new, subsequent orders and thus be subject to the AUC program requirements as such. We expect second opinions to proceed as they normally would, but with the inclusion of AUC consultation and subsequent reporting on the Medicare claims for and new or additional orders for advanced diagnostic imaging services. When reporting, the appropriate modifier indicating the outcome of the AUC consultation should be appended to the claim, even if the order ultimately placed would not adhere to the AUC consulted albeit for legitimate clinical reasons.

Comment: Some commenters asked if the AUC requirements apply to imaging ordered pursuant to a clinical trial protocol, what modifier should be appended and how to indicate on the claim that the service was pursuant to a clinical trial. Commenters also requested that imaging services performed as part of a clinical trial be excluded from the AUC program and that a separate HCPCS modifier be established to identify such claims.

Response: As discussed above in section III.F.3.c. of this final rule, section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements and these exceptions are codified in our regulations in § 414.94(h)(1)(i). We disagree that advanced diagnostic imaging services furnished pursuant to or as a part of a clinical trial qualify for an exception as specified in the statute and regulations and described above in section III.F.3.c. of this final rule; therefore, we are unable to exclude or except claims for these imaging services. The AUC consultation information relevant to the imaging service that is ordered should be appended on the claim to accurately communicate information about the consultation. Because these services are subject to the AUC program requirements, we do not see a need to establish a separate modifier to identify these services. We note that claims for many clinical trials covered by Medicare must include the national clinical trial (NCT) identifier number, HCPCS modifiers Q0 (zero) or Q1 (one) and also ICD–10 diagnosis code Z00.6, so there are other ways to track claims submitted as part of clinical trials if necessary.

b. Claims Processing

As we move ahead to implement the payment penalty phase of this program, we must address additional operational and administrative issues. We explain these issues here, and our assessments and proposals for addressing them. We solicited comments on whether additional scenarios require our consideration, and whether the proposed solutions adequately address issues raised by stakeholders. We solicited any additional information stakeholders may offer to assist us in developing claims processing system edits or other measures to ensure that only appropriate claims are subject to AUC claims processing edits. The AUC program will be fully implemented when we have the necessary edits established in the claims processing system and we begin using those edits to deny Medicare claims that fail to report the required AUC consultation information. The identification of claims that are or are not subject to the Medicare AUC Program must be precise to avoid inadvertently denying claims that should be paid. Because implementation of this program establishes edits for advanced diagnostic imaging claims, the inadvertent denial of claims would disproportionately impact radiologists, HOPDs and freestanding imaging centers. Also, as we have noted previously, the AUC program is unique in that the burden of consulting AUC and providing AUC consultation information to the furnishing professional falls on the ordering professional, yet the claims that are denied for failing to report AUC consultation information are for services furnished and billed by the professionals and facilities that furnish advance diagnostic imaging.

Two main Medicare claim types are subject to claims processing edits in the AUC program. These are the CMS–1500 and its electronic equivalent (referred to here as the practitioner claim) submitted by physicians and practitioners, ASCs, and IDTFs, and the UB- 04, also called the CMS–1450, (referred to here as the institutional claim) submitted by HOPDs and on-campus and off-campus provider-based departments. These claim types differ in the data elements they contain; therefore, claims processing edits will not be identical across claim types.

We have already issued partial claims processing instructions (CR11268, Transmittal 2404) [90] to support the educational and operations testing period. We established HCPCS Level III G-codes for furnishing professionals to report which CDSM was consulted on a separate claim line. We also established HCPCS modifiers for furnishing professionals to report adherence, non-adherence and not applicable AUC consultation responses on the same claim line as the advanced diagnostic

[90] *https://www.cms.gov/files/document/r2404otn.pdf.*

imaging HCPCS code. We established additional HCPCS modifiers for furnishing professionals to report situations in which the ordering professional is not required to consult AUC, which are also reported on the same claim line as the advanced diagnostic imaging HCPCS code. Both G-codes and modifiers are applicable to practitioner and institutional claims. We also established a procedure code list that identifies the advanced diagnostic imaging codes that are subject to the AUC program. Based on a review of CY 2020 Medicare claims (noting for readers that during this year the AUC program was only in the education and operations testing phase with no payment penalties), we estimate between 9–10 percent of all claims subject to the AUC program reported information sufficient to be considered compliant with the program. This means that 90–91 percent of claims would not be considered compliant with AUC program requirements because they do not include either the required AUC consultation information (including the ordering professional NPI, G-code identifying the qualified CDSM consulted, and the modifier specifying the appropriateness of the order) or a modifier indicating an applicable exception to the AUC consultation information reporting requirements. In other words, if the claims processing systems edits had been in place for the payment penalty phase, only 9–10 percent of claims subject to the AUC program would have been paid as opposed to being denied or rejected. An additional 6–7 percent of claims subject to the AUC program included some relevant information, which demonstrates an awareness of the AUC program among these billing entities; but the claims did not include all of the necessary AUC consultation information that will ultimately be required for the claim to be paid.

i. Ordering Professional NPI

There are locations on both the practitioner and institutional claim types to report the NPI of the ordering professional. The institutional claim uses the K3 segment and the practitioner claim uses the referring professional field. However, to fully implement the AUC program, we must establish a claims processing edit to require these fields to be populated on all advanced diagnostic imaging claims subject to the AUC program.

In addition, there currently are situations in which multiple advanced diagnostic imaging services ordered by more than one ordering professional may be reported on a single claim. This would not be workable for purposes of reporting AUC consultation information because the referring professional field is reported at the claim-level and not at the claim line- or service-level for professional claims. Therefore, the furnishing professional will need to submit separate claims for the services ordered by each referring or ordering professional. In other words, only one ordering professional can be reported per claim.

We received comments on this discussion. The following is a summary of the comments we received and our responses.

Comment: One commenter, referencing different sections of the 837 professional claim, requested confirmation that practitioner claims are unable to accommodate line-level identification of the ordering professional NPI as discussed above. This commenter stated that while the referring professional is a claim level element in ASC 5010 837 Professional Claim Loop 2310A, there is also a line-item element for referring professional in Loop 2420F. This commenter requested further clarification in terminology used by CMS, noting that there are different fields on the claim forms for ''ordering'' and ''referring'' professionals and whether CMS is placing limitations on the ''ordering professional'' or ''referring professional'' elements and how that dictates claims be split. This commenter requested CMS be completely clear on which fields are to be populated with the NPI of the practitioner that ordered the service and whether services for one beneficiary ordered by more than one practitioner must be split into separate claims.

Response: Upon further review of the 837P form, we agree that the practitioner who orders the advanced diagnostic imaging service can be identified at the line level and we will proceed with implementation accordingly. We expect this means the 837P claims will not be required to be submitted separately for each practitioner who orders advanced diagnostic imaging services (the ''ordering professional'' as defined under the AUC program). We will continue to evaluate which line-item field is most appropriate to populate (the ordering or referring professional fields on the claim).

Comment: One commenter stated that one ordering clinician per claim is not overly burdensome in most situations and another commenter noted that splitting claims is not ideal, but can be done and should not hold up the AUC program. This commenter stated that a significant amount of manual intervention will likely be required. One commenter stated that submitting separate claims to accommodate different ordering professionals will be difficult because their current system groups ordering professional encounters for the same date of service on the same institutional claim. This commenter explained that separate claims will require separate registrations which is more burdensome for registration staff and may dissatisfy patients. Furthermore, this commenter stated that two or more account numbers with the same date of service may increase error for documentation and charging. This commenter asked if Medicare will be able to process two separate ordering professional claims with the same date of service.

Response: As noted in the response above, we believe the 837P claim can identify different practitioners that order advanced diagnostic imaging services at the line level so splitting claims will not be necessary, which will also minimize burden. As we proceed with establishing claims processing instructions for the payment penalty phase of the program, we will continue to explore opportunities to minimize burden.

After consideration of public comments, we will move forward with developing claims processing instructions that allow more than one practitioner that orders advanced diagnostic imaging services to be reported on the practitioner claim.

ii. Critical Access Hospitals

As discussed in the CY 2018 PFS final rule with comment period (82 FR 53192), advanced diagnostic imaging services furnished in an outpatient department of a critical access hospital (CAH) are not subject to the AUC program because, in accordance with section 1833(q)(1)(D) of the Act, a CAH is not an applicable setting under the program. Therefore, we must identify these advanced diagnostic imaging services and allow them to bypass the AUC program claims processing edits. For institutional claims, we intend to apply the AUC program claims processing edits to type of bill 13x, which is used only for outpatient hospital settings. CAHs submit outpatient claims using type of bill 85x, rather than type of bill 13x.

In the CY 2019 PFS final rule (83 FR 59694), we further explained that because section 1834(q)(4)(B) of the Act clearly includes all claims paid under applicable payment systems without exclusion, the claims from both furnishing professionals and facilities must include AUC consultation

information. We revised our regulation at § 414.94(k) to specify that AUC consultation information must be reported on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. Prior to this revision, § 414.94(k) required furnishing professionals to report AUC consultation on the claim, without also specifying that facility claims must include the AUC consultation information. In the CY 2019 PFS final rule, we explained that the AUC consultation information would be included on the practitioner's claim for the PC of the service and on the provider's or supplier's claim for the facility portion or TC of the service. Under § 414.94(k), the requirement to report AUC consultation information on the claim applies to both the PC and TC of the imaging services that are furnished in an applicable setting and paid under an applicable payment system. Section 1834(q)(4)(B) of the Act further specifies that the requirement to report AUC consultation information is specific to claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. We believe that all claims for advanced diagnostic imaging services, both the PC and TC, must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. However, if advanced diagnostic imaging services are not entirely furnished in an applicable setting, we believe that neither the PC nor TC claim should be required to include AUC consultation information. This ensures consistent application of the AUC consultation requirements across claims submitted for advanced diagnostic imaging services even when the PC and TC components of the service are furnished by different furnishing professionals. As such, we proposed that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting will not be subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. If a physician or practitioner submits a claim for the PC of an advanced imaging service for which the TC was performed as an outpatient CAH service, there currently is not a systems-based way for us to recognize that the TC of the service was furnished by a CAH. Place of service codes reported on practitioner claims are not specific enough. We have not yet identified a way to segregate these claims and automatically allow them to bypass AUC program claims processing edits. Therefore, as discussed below, we proposed to establish a separate HCPCS modifier that will be used to identify practitioner claims for advanced diagnostic imaging services that are not subject to the AUC program and that are not otherwise identified using the other AUC program modifiers designated to identify specific situations where the claims are not subject to the AUC program.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the proposal that the PC for an advanced diagnostic imaging service for which the TC was furnished by a CAH would also not require AUC consultation information appended to the claim. One commenter also supported applying this proposal for any other non-applicable sites. One commenter expressed support for excluding services when the TC is not furnished in an applicable setting. One commenter agreed with the proposal to identify these situations using a modifier on the claim.

Response: We appreciate the comments. We prefer to automate the identification of these claims whenever possible and will continue to search for a mechanism. For example, we recently determined that a CAH can be identified in the CCN by a number 1 in third position and a number 3 in the fourth position. We will explore whether we can automate an edit in the claims processing system to identify CAH claims using the CCN.

Comment: Some commenters urged CMS to extend the exemption to ordering professionals that order advanced diagnostic imaging services in CAHs as CAHs have limited resources.

Response: As discussed in section III.F.3.c. of this final rule, section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements and these exceptions are codified in our regulations in § 414.94(h)(1)(i). We disagree that ordering professionals that order advanced diagnostic imaging services in a CAH qualify for an exception as specified in the statute and regulations and described above in section III.F.3.c. of this final rule.

Comment: Two commenters stated that the MH modifier does not describe this situation so a new modifier would need to be created. One of these commenters further noted that using modifier MH for CAH related claims will impact data integrity by combining CAH providers with those that do not provide AUC consultation information.

Response: We appreciate this comment and further discuss modifier MH in section III.F.4.b.viii. of this final rule.

After consideration of public comments, we are finalizing this proposal that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting not be subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. We are also finalizing the proposal to use a modifier to identify practitioner claims for advanced diagnostic imaging services that are not subject to the AUC program, like those submitted for advanced diagnostic imaging services furnished in a CAH, and that are not otherwise identified using the other AUC program modifiers designated to identify specific situations where the claims are not subject to the AUC program. We further discuss this modifier in section III.F.4.b.viii. of this final rule.

iii. Maryland Total Cost of Care Model

Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for which AUC consultation and reporting requirements apply are the PFS, the hospital OPPS and the ASC payment system. We define applicable payment system consistent with statute at § 414.94(b) and, as noted above, require AUC consultation information to be reported on Medicare claims for advanced diagnostic imaging services, both the PC and TC, furnished in an applicable setting and paid under an applicable payment system at § 414.94(k). Section 1834(q)(4)(B) of the Act specifies that the requirement to report AUC consultation information is specific to claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. We believe that all claims for the advanced diagnostic imaging services, both the PC and TC, must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. Therefore, if both the PC and TC for advanced diagnostic imaging services are not paid under an applicable payment system, neither the PC nor TC claim is required to include

AUC consultation information. This ensures consistent application of the AUC consultation requirements across claims submitted for advanced diagnostic imaging services even when the PC and TC components of the service are furnished by different furnishing professionals. Similar to claims for the PC of services for which the TC is furnished outside of an applicable setting, and because both practitioner and institutional claims are subject to the AUC program as discussed above, when the practitioner or institutional claim for the advanced imaging service is not subject to the AUC program (for example, payment is not made under an applicable payment system), the corresponding practitioner or institutional claim for the same imaging service is also not subject to the AUC program.

Stakeholders alerted CMS to concerns about whether advanced diagnostic imaging services furnished in hospitals participating in the Maryland Total Cost of Care Model would be subject to the AUC program. We appreciated that this was brought to our attention and we solicited comments on other models. Advanced diagnostic imaging services furnished in outpatient departments of Maryland hospitals that participate in the Hospital Payment Program within the Maryland Total Cost of Care Model are not subject to the AUC program because these services are not paid under an applicable payment system (Maryland hospitals that receive payments under the Hospital Payment Program within the Maryland Total Cost of Care Model are not paid under the OPPS). Because these services are not subject to the AUC program requirements when furnished in a hospital paid under the Hospital Payment Program within the Maryland Total Cost of Care Model, as opposed to an applicable payment system, we propose that the PCs of these advanced diagnostic imaging services, when billed separately, are also not required to include AUC consultation information. We believe we can identify all institutional claims from a hospital that is paid under the Hospital Payment Program within the Maryland Total Cost of Care Model based on their CMS Certification Number (CCN) and allow those claims to bypass AUC program claims processing edits. We understand that when the TC and PC of advanced diagnostic imaging services are billed separately, the professional claim must identify in box 32 the location where the TC of the imaging service was furnished to the patient. Therefore, we believe we will have the ability to identify situations in which the imaging service was furnished in a hospital that is paid under the Hospital Payment Program within the Maryland Total Cost of Care Model and exclude those claims from being subject to AUC program claims processing edits. We believe this can be accomplished by using the CCN and will continue to work to determine if a list of CCNs can be used as the source of our edits in addition to determining the frequency that the list will be updated.

Note that advanced diagnostic imaging services furnished in applicable settings in the State of Maryland and paid under an applicable payment system are subject to the AUC program—the above discussion applies only to the outpatient departments of hospitals that are paid under the Hospital Payment Program within the Maryland Total Cost of Care Model.

We received comments on the Maryland Total Cost of Care Model related proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed concerns with excluding Maryland outpatient hospital departments under the Maryland Total Cost of Care Model from the AUC program requirements and instead recommended that all Maryland ordering professionals be excluded. The commenter stated that excluding outpatient hospital departments under the model will have negative unintended consequences. These include acting as an incentive for ordering professionals to send Medicare patients to hospitals instead of non-hospital entities like imaging centers and IDTFs creating a major competitive disadvantage for imaging centers, IDTFs and other non-hospital imaging providers in Maryland. The commenter stated that it may disrupt existing referral patters and continuity of care, is likely to increase cost to Medicare and patients through higher out of pocket expenses at high priced hospital facilities, will inconvenience patients through longer travel times, scheduling delays resulting from higher demand for hospital based imaging and limited access due to COVID and related staffing shortages. The commenter requested that if Maryland Total Cost of Care Model participating outpatient departments are excluded from the AUC program, CMS explore ways to restore competitive balance between Maryland outpatient departments and non-hospital imaging providers like giving ordering professionals more flexibility in meeting AUC consultation requirements and/or making AUC a required performance metric under the Maryland model. The commenter further requested CMS clarify if hospital-owned imaging centers, whether on-campus or off-campus, that are paid for advanced diagnostic imaging services according to the PFS or OPPS, regardless of provider tax ID number used for billing, are still subject to the AUC program.

Response: We appreciate this comment and understand the concerns expressed, however we are unable to modify the AUC requirements and applicability in the State of Maryland given the statutory provisions that AUC consultation and reporting is required for advanced diagnostic imaging services furnished in an applicable setting and paid for under an applicable payment system. Since services furnished under the Maryland Total Cost of Care Model are not paid under an applicable payment system, the advanced diagnostic imaging services furnished under the model are not subject to the program requirements. We are unable to create an exception for other locations or providers in Maryland to offset the potential impact of the model on settings or providers that are not included in the model. The AUC program requirements apply to advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system as specified in § 414.94 without exclusion of sites based on ownership or the provider tax ID used for billing.

After consideration of public comments, we will continue to work to set up claims processing edits using the CCN in box 32 to identify advanced diagnostic imaging services furnished under the Maryland Total Cost of Care Model, the claims for which, as discussed above, are not subject to the AUC program requirements.

iv. Inpatients Converted to Outpatients

While uncommon, there are situations in which a beneficiary's hospital inpatient status is changed to outpatient. Certain criteria must be met for this to occur and, if met, condition code 44 (inpatient admission changed to outpatient) is appended to the institutional claim (*https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r299cp.pdf*). We proposed to allow institutional claims with condition code 44 to bypass AUC claims processing edits. We made this proposal because, at the time advanced diagnostic imaging services were ordered and furnished, they were ordered for and furnished to a beneficiary who was in inpatient status. As such, the AUC consultation

requirement would not have applied at that time. We believe that any professional claims would include place of service code 21 (inpatient hospital) since the expectation, until just prior to discharge, would be that the patient is in an inpatient status. We expect less than half of one percent of claims will include condition code 44.

We received comments on our proposal to allow institutional claims with condition code 44 to bypass AUC claims processing edits. The following is a summary of the comments we received and our responses.

Comment: Some commenters agreed with this proposal. Two commenters supported the proposal but noted that not all patients moved from inpatient to outpatient will be captured with condition code 44 so CMS should create an exception for any inpatient order for advanced diagnostic imaging services furnished within a short period after the inpatient discharge and use a new modifier for these instances where inpatient imaging orders are performed in the outpatient setting shortly after discharge. One commenter requested that in addition to excepting ''inpatient to outpatient''/condition code 44 claims, CMS should also except inpatient part A claims that are self-denied or denied by an auditor and then rebilled to part B, usually with a 131 or 121 claim since imaging services were furnished to an inpatient at the time.

Response: We appreciate the comments and disagree that a modifier is needed to capture relevant claims. In section III.F.4.b.ix. of this final rule, we discuss proposals around what type of bill would be subject to the AUC program edits and do not include type of bill 121 which is used for Medicare Part A/B rebillings for services that occurred during the inpatient period. Type of bill 131 is an outpatient bill type and is included in the type of bill to which we proposed, and are finalizing, to limit claims processing edits. As discussed below, we are finalizing this proposal.

After consideration of public comments, we are finalizing the proposal to allow institutional claims with condition code 44 to bypass AUC claims processing edits.

v. Deny or Return Claims That Fail AUC Claims Processing Edits

As discussed above, claims that do not properly include AUC consultation information will not be paid once we fully implement the AUC claims processing edits. We are considering whether claims that do not pass the AUC claims processing edits, and therefore, will not be paid, should be initially returned to the health care provider so they can be corrected and resubmitted, or should be denied so they can be appealed. On one hand, we expect there will be some errors in reporting AUC consultation information on claims, especially early on, and health care providers might find it helpful to have the opportunity to correct claims. However, there may be situations in which the health care provider would prefer the claim be denied so they have an earlier opportunity to appeal. We requested comments to help us better understand which path would be most appropriate once we fully implement the AUC program claims edits. Additionally, we requested comments on whether the payment penalty phase should begin first with returning claims and then transition to denying claims after a period of time, which may be helpful to furnishing professionals and facilities as they become more proficient in submitting claims under the AUC program.

We received public comments on which path would be most appropriate once we fully implement the AUC program claims edits and whether the payment penalty phase should begin first with returning claims and then transition to denying claims after a period of time. The following is a summary of the comments we received and our responses.

Comment: Some commenters recommended that claims be returned for correction instead of being denied. Some of these commenters noted that returning claims affords practitioners the opportunity to correct and resubmit which is a faster, easier and less costly process than denying and appealing. Other commenters suggested claims be returned at least initially for similar reasons. Two of these commenters suggested returning claims for the first year of the payment penalty phase and then transition to denials, one supported transitioning to denials but did not identify a timeframe within which to transition, and two commenters suggested revisiting the approach at some point in the future to determine if it should be revised. One commenter recommended that CMS should allow for correction of claims without complete information on the front-end by indicating the claim cannot be accepted for processing until it contains necessary information. One commenter stated that if CMS decides to deny claims, the denials should be for the line-item if AUC information is not present instead of denying the whole claim. One commenter suggested that instead of deciding whether to deny or return claims, CMS should ensure the program does not result in substantial number of claims submission issues for furnishing provider claims.

Response: We appreciate the recommendations and perspectives shared by commenters and assure commenters that we working to establish claims processing solutions amenable to the practitioners and providers impacted by this program to the best of our ability given the constraints of the claims processing systems and specifications set forth in statute.

Comment: Two commenters requested CMS clearly outline the claim denial process and how it pertains to ordering and furnishing providers. One commenter requested further detail and elaboration of criteria used in claims processing and auditing as soon as possible so institutions can incorporate internal review prior to claims submissions.

Response: We remind readers that the reporting requirements are specific to the furnishing professionals as AUC consultation information is required on the claim for the advanced diagnostic imaging service. Since the ordering professional, unless they are also the furnishing professional, does not submit a claim for the advanced diagnostic imaging service, the claim denial process would not impact them. As we proceed through the process of establishing claims processing systems edits and instructions, we will post those documents on the AUC website: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program*.

After consideration of public comments, we agree that returning claims for correction and resubmission when the payment penalty phase begins would be most appropriate. If needed, we may revisit whether claims denials are appropriate at some point in the future once practitioners become more comfortable with the claims processing requirements.

vi. Medicare as a Secondary Payer

We understand based on feedback from stakeholders that, in some EHRs, the primary payer information is readily available and known to the ordering professional; however, secondary payer information typically is not available. Additionally, it is possible that when Medicare is the secondary payer that no Medicare payment would be made at all after the primary payer makes payment. Medicare is reported as the secondary payer for approximately 1.5 percent of advanced diagnostic imaging services

that are subject to the AUC program. Because the secondary payer information for a patient generally is not available to the ordering professional, and because no Medicare payment may be involved at all when Medicare is the secondary payer, we proposed to exclude claims that identify Medicare as the secondary payer from application of the AUC consultation and reporting requirements. Specifically, we proposed to allow claims that identify Medicare as the secondary payer (using block 1 or the electronic equivalent of the practitioner claims and using FL 50/51 or the electronic equivalent of institutional claims) to bypass the AUC program claims processing edits.

We received public comments on excluding claims that identify Medicare as the secondary payer from application of the AUC consultation and reporting requirements. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to exclude claims that identify Medicare as the secondary payer from the AUC consultation and reporting requirements. Two commenters stated that if this proposal is implemented, it would change how primary and secondary payer information is captured in health information technology (HIT) so HIT systems would need sufficient advance notice to update accordingly. One commenter specified that HIT systems would need a minimum of 18 months to scope, develop, test and implement new requirements.

Response: We appreciate the comments and will work to issue claims processing instructions as expeditiously as possible.

Comment: One commenter asked if Medicare Managed Care claims require AUC consultation information.

Response: The AUC program requirements under our regulations are specific to fee-for-service Medicare, so Medicare Advantage organizations (MAOs) are not required to follow the AUC program requirements, and the requirements do not apply to Medicaid. However, MAOs might require their contracted providers to follow Medicare AUC program procedures, so you would need to contact the MAOs (and any other types of plans) for more information about their requirements specific to AUC.

After consideration of public comments, we are finalizing as proposed to allow claims that identify Medicare as the secondary payer (using block 1 or the electronic equivalent of the practitioner claims and using FL 50/51 or the electronic equivalent of institutional claims) to bypass the AUC program claims processing edits.

vii. Date of Service and Date of Order

We will specify a start date for the AUC program claims processing edits to take effect. Medicare claims include a date of service but do not allow for the date of an imaging order to be recorded. Because we cannot identify the order date for an advanced imaging service based on claims, we proposed that the AUC program claims processing edits for the payment penalty phase will be applicable for advanced imaging services furnished on or after the effective date of the claims edits. For imaging services ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, the furnishing professional would apply the separate HCPCS modifier discussed in section III.F.4.b.ii. (Critical Access Hospitals) of this final rule to indicate that the claim is not subject to the AUC claims processing edits.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters disagreed with this proposal and instead recommended that for services ordered prior to the penalty phase but furnished after it begins, CMS should have a grace period within the penalty phase for these services which would eliminate the burden associated with returning claims. This commenter suggested soft edits to establish the end of the grace period based on a decrease in potential returns. Some commenters supported this proposal and agreed with denoting these claims with a separate modifier.

Response: Because the time over which advanced diagnostic imaging services are ordered for patients with chronic or ongoing conditions necessitating repeat imaging is different for each patient, we disagree that establishing a grace period to account for these situations is a viable option. We believe allowing these claims to instead bypass edits based on the presence of a modifier is more appropriate, particularly since all other advanced diagnostic imaging services will be subject to payment penalties when the payment penalty phase begins. This approach would essentially extend the educational and operations testing period further.

After consideration of public comments, we are finalizing as proposed our proposal to identify claims for imaging services ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, using the separate HCPCS modifier we will create to identify claims that are not subject to AUC claims processing edits.

viii. HCPCS Modifiers

We established two primary sets of HCPCS modifiers for this program. In the proposed rule we erroneously stated that the first set of modifiers, which report whether the imaging service adheres to the AUC consulted (modifier ME), does not adhere to the AUC (modifier MF), or the qualified CDSM does not contain AUC that applies to the order (modifier MG), is to be included on the same claim line as the G-code identifying the CDSM that was consulted. This is incorrect and we are correcting this mistake with the following revised description of modifier placement, consistent with the previously released MLN Matters article 11268. The first set, modifiers ME, MF and MG, is to be included on the same claim line as the CPT code for the advanced diagnostic imaging service. We intend for these modifiers to continue to be used when the program enters the payment penalty phase. Additionally, reporting of these modifiers should be limited to one per qualified CDSM G-code (listed on a separate claim line) since these modifiers are mutually exclusive.

The second set of HCPCS modifiers is available for use when the ordering professional does not consult a qualified CDSM. On these claims, providers would not add a G-code for a CDSM because a consultation did not take place, and the HCPCS modifier would be included on the same line as the procedure code for the advanced diagnostic imaging service that was furnished. These HCPCS modifiers include the three that were created to describe significant hardship exceptions (insufficient internet access (modifier MB), EHR or CDSM vendor issues (modifier MC) and extreme and uncontrollable circumstances (modifier MD)). Additionally, section 1834(q)(4)(C) of the Act includes an exception for services ordered for an individual with an emergency medical condition and modifier MA is available to identify claims for patients with a suspected or confirmed emergency medical condition. This set of codes is mutually exclusive and we expect only one to be reported per procedure code-level claim line.

Modifier QQ was created for use during the voluntary period, before more detailed modifiers and codes were created, to indicate that an ordering professional consulted a qualified CDSM for the service and related AUC consultation information was provided

to the furnishing professional. The descriptor for this code explains that the ordering professional consulted a qualified CDSM for this service and the related information was provided to the furnishing professional. Modifier QQ continues to be available for use through the educational and operations testing period, but we intend to end the use of that modifier and not carry it forward into the payment penalty phase since we have established and will require the use of distinct modifiers to communicate specific AUC consultation information.

Modifier MH was created for use during the educational and operations testing phase to identify claims for which AUC consultation information was not provided to the furnishing professional and furnishing facility. When the AUC program enters the payment penalty phase, we will no longer have a need for this modifier because claims will be required to include AUC consultation information or indicate a reason the information is not required in order to avoid AUC program claims processing edits. Beginning for services furnished on and after the effective date of the AUC program claims processing edits, we proposed to redefine modifier MH to describe situations in which the ordering professional is not required to consult AUC and the claim is not required to report AUC consultation information. For example, we proposed to repurpose modifier MH to be used in the scenarios described in sections III.F.4.b.ii. (Critical Access Hospitals), III.F.4.b.iii (Maryland Total Cost of Care Model) if other options to identify claims are not feasible, and III.F.4.b.vii. (Date of Service and Date of Order) of this final rule as those scenarios would fall outside the scope of the AUC program requirements.

We received comments on the modifier discussion and proposals. The following is a summary of the comments we received and our responses.

Comment: Two commenters requested clarification on where the modifiers are to be placed on the claim. They noted that the proposed rule states that the modifier should be placed on the same line as the G-code denoting which qualified CDSM was consulted, however prior guidance in MLN Matters article 11268 states that the modifier should be placed on the same line as the CPT code for the imaging service.

Response: Thank you for bringing this to our attention and we apologize for the confusion. The description in the proposed rule was incorrect and has been revised in this final rule to be consistent with the previously communicated instructions in MLN Matters article 11268.

Comment: One commenter agreed with the proposed modifier clarifications. Three commenters supported the proposal to end the use of modifier QQ when the payment penalty phase of the program begins.

Response: We appreciate the comments.

Comment: Several commenters requested more clarification around the use of modifier MA. One commenter asked if MA can only be used in the emergency department and another commenter asked if MA applies to EMTALA patients generally or only to patients with certain conditions. One commenter requested more specific information including guidelines for accurate and appropriate use of modifier MA to avoid overuse. Another commenter requested that CMS confirm modifier MA includes suspected or confirmed emergency medical conditions and recommended adding ''suspected or confirmed'' to the regulatory text. One commenter requested that CMS ensure this exception accounts for the time-sensitive evaluation needs of emergency patients.

Response: We have addressed and provided clarification on the emergency services exception, denoted with modifier MA, in notice and comment rulemaking in prior years. The statute and regulations do not limit the use of this exception, and thus modifier MA, to emergency department settings. The exception, as specified in both statute and regulation, is for applicable imaging services for individuals with an emergency medical condition, which the statute defines with a cross reference to section 1867(e)(1) of the Act. The exception may be used consistent with the regulations and additional clarification as discussed in prior rulemaking. Most recently, in the CY 2019 PFS final rule (83 FR 59699), which reiterated clarifications from the CY 2017 PFS final rule, we reminded readers that we agree that exceptions granted for an individual with an emergency medical condition include instances where an emergency medical condition is suspected, but not yet confirmed. We further stated that this may include, for example, instances of severe pain or severe allergic reactions. In these instances, the exception is applicable even if it is determined later that the patient did not in fact have an emergency medical condition. Given the clarifications previously communicated through rulemaking and the existing description for modifier MA, we disagree that the regulatory text for the emergency services exception requires modification or further clarification.

Comment: One commenter asked what modifier is to be used for patients in the emergency department who do not qualify for the emergency services exception, but whose insurance is unknown when treated (as hospitals do not collect insurance information prior to emergency department medical screening), and therefore, a CDSM is not triggered. Another commenter requested that all emergency department visits be excluded since hospitals approach every patient as if they have an emergency medical condition thus requiring AUC consultations for emergency room patients without an emergency medical condition causes confusion and inconsistent practices within the emergency department.

Response: Because the statute explicitly includes the emergency department as an applicable setting under the AUC program, we are unable to categorically exclude all advanced diagnostic imaging services furnished in the emergency department, including those furnished to patients whose insurance is unknown at the time of treatment.

Comment: One commenter asked whether, and if so, how to report low acuity scores from CDSM consultations and whether low acuity scores will be reimbursed. Another commenter requested CMS clarify if claims with modifier MF or MG will be denied during the penalty phase.

Response: We believe the commenter asking about low acuity scores is referring to consultations where the order for the imaging service would not adhere to the AUC consulted (modifier MF) and are responding under this assumption. The statute specifies that, in order for a claim to be paid, information about the appropriateness of the ordered service is to be included on the claim. This reflects the certification or documentation qualified CDSMs are required to generate at the time of order under § 414.94(g)(1)(vi) when an ordering professional consults AUC and includes whether the service would adhere to the AUC consulted, whether the service would not adhere to the AUC consulted and whether the AUC consulted was not applicable to the service. As such, both modifier MF or MG may be appended to the claim to meet this requirement and the inclusion of these modifiers would not cause the claim for the service to be denied during the payment penalty phase.

Comment: We received many comments on our proposals for modifier MH. Two commenters supported the proposals to repurpose modifier MH for

use in situations in which the ordering professional is not required to consult AUC and the claim is not required to report AUC consultation information when other modifiers do not apply and claims system edits cannot automatically exclude the claims. Two commenters recommended repurposing modifier QQ instead of MH and four commenters requested modifier MH be maintained and CMS instead create a separate modifier for these scenarios. Commenters cited a variety of reasons for their disagreement with this proposal. Other commenters requested CMS maintain modifier MH unchanged because it will continue to be needed to identify situations when the ordering professional does not consult or provide AUC information to the furnishing professional. Some commenters noted that modifier MH is needed to identify outliers for the prior authorization component and two commenters stated that modifier MH was specifically created to indicate which ordering professionals were outliers so the Secretary can impose requirements to ensure the AUC program is followed. Still, other commenters stated that maintaining modifier MH is important to avoid imposing burden, like regulatory enforcement or follow-up with ordering professionals to track down AUC information, on furnishing professionals and facilities. Some commenters supported maintaining modifier MH to avoid delays or impediments to care. One commenter requested modifier MH be maintained at the start of the payment penalty phase as a failsafe to avoid delays in care if the ordering professional has not provided AUC consultation information. One commenter stated that requiring furnishing providers not to provide imaging services for non-compliant clinicians could create a dangerous situation where patients are unable to obtain medically necessary care. One commenter disagreed with repurposing MH because their systems have already been programmed for the current use of MH and significant resources would be needed to reprogram and train if MH is repurposed. Other commenters recommended creating a new modifier instead of repurposing modifier MH to avoid confusion and continued reporting of MH for its current use.

Response: To avoid confusion, CMS agrees with commenters that modifier MH should not be repurposed for use on claims as proposed. However, we do not agree with commenters requesting that modifier MH be maintained for current usage once the payment penalty phase begins because such a provision was not specified in statute. The statute requires consultations to occur and for specific consultation information to be reported on the claim for the subsequently furnished imaging service in order for the claim to be paid. Unless an exception applies, Congress did not include a caveat excluding claims for services ordered by ordering professionals who either did not consult AUC or failed to provide consultation information to the furnishing professional from the statutory reporting requirements. As such, CMS does not have the authority to exclude these scenarios from the AUC program requirements. We also note that modifier MH was not created specifically to inform the outlier identification and prior authorization component of the program, as some commenters believe. Instead the other modifiers created to report the appropriateness of the consultation will be integral for identifying outlier ordering professionals as directed by the statute. Section 1834(q)(5)(B)(i) of the Act describes that the determination of an outlier ordering professional is to be based on low adherence to applicable AUC without mention of ordering professionals who fail to comply with the program requirements altogether. The statute does not provide a means for excusing or otherwise acknowledging these ordering professionals and we do not believe continued use of modifier MH during the payment penalty phase is within the parameters of the statute. Therefore, we intend to fully retire modifier MH when the payment penalty phase of the program begins.

Comment: One commenter asked if an ordering professional would be expected to do something on a pro forma basis to see if the order did adhere to applicable AUC guidelines and urged CMS to provide some grounding of good faith expectation for the furnishing provider to address missing AUC data to correct a claim when the AUC information was not originally provided. One commenter recommended that CMS create a document for furnishing professionals to use that would assist them in explaining to ordering professionals why they are required to consult AUC and provide that information with the order because there will be situations where the ordering professionals continue to fail to provide consultation information which causes the furnishing professionals to either provide the service for free or refuse to provide the service until the ordering professional provides necessary information.

Response: The AUC program requirements do not include provisions for further or additional AUC consultations by ordering professionals. We recognize and have discussed the challenging nature of this program where the furnishing professional is subject to immediate penalty based on the actions (or lack thereof) of the ordering professional, whose behavior the furnishing professional is unable to control. Regardless, CMS is obligated to implement these statutory provisions and does not have the authority to modify or mitigate the requirements. We will continue to work on education and outreach and explore opportunities to update and expand our written outreach materials which may help to inform or remind ordering professionals of their responsibilities under the AUC program. Below, we summarize and respond to comments on education and outreach, as well as the general nature, utility and appropriateness of the AUC program.

Comment: One commenter stated that, similar to issues with patient relationship codes, automatic crossover to non-Medicare secondary payers results in denials from secondary insurance when AUC modifiers are sent. The claims are denied for invalid modifiers and CMS should find a way to strip out the modifiers before submission to secondary non-Medicare payers to reduce denials. Two commenters suggested CMS consider requesting a new value code to be used for facility reporting on a UB–04 when the entity is exempt. One commenter stated that CMS has not specified what G-codes or modifiers would be required for reporting and this approach has been rejected by the National Uniform Claim Committee (NUCC) and National Uniform Billing Committee (NUBC) which stated that G-codes and modifiers would be administratively burdensome. One commenter requested that CMS ensure there is a simplified tracking and reporting system.

Response: The modifiers the AUC program are valid HCPCS modifiers. Health Insurance Portability and Accountability Act of 1996 (HIPAA) transaction and code set regulations require all payers to accept all valid HCPCS modifiers. We will continue to consider all claims processing options. However, through extensive research and engagement with stakeholders including the NUCC and NUBC, we have not identified a more streamlined and less burdensome approach to capturing all statutorily required information on the Medicare claim in real time.

After consideration of public comments, we are finalizing our proposals and ending the use of modifier QQ when the payment penalty

phase begins. We will establish a new modifier to identify claims for services where the ordering professional is not required to consult AUC and the already established modifiers do not apply. This new modifier will apply when claims system edits cannot automatically exclude the claims to include the scenarios discussed in this final rule. Therefore, we are not finalizing our proposal to repurpose modifier MH for this use and instead, we intend to end the use of modifier MH when the payment penalty phase begins.

ix. Additional Claims Processing Information

Section 1834(q)(1)(D) of the Act specifies the applicable settings for the AUC program as a physician's office, a HOPD (including an emergency department), and ASC and any other provider-led outpatient setting determined appropriate by the Secretary. As discussed in the CY 2019 PFS final rule (83 FR 59690 and 59691), we added IDTFs to the definition of applicable setting at § 414.94(b) to the three applicable settings specified in statute because it is a provider-led outpatient setting in which advanced diagnostic imaging services are furnished by licensed, certified nonphysician personnel under appropriate physician supervision. To identify these settings through the Medicare claims system we evaluated type of bill and place of service codes to identify those aligned with applicable settings under the AUC program. For institutional claims, we proposed to limit AUC program claims processing edits to apply only to type of bill 13x (hospital outpatient). This claim type code encompasses the HOPD and the emergency department which represent all applicable settings under the program that will bill Medicare using institutional claims. For practitioner claims, we proposed to limit the edits to claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC). These place of service codes should encompass all applicable settings under the AUC program as defined at § 414.94(b). Because these type of bill and place of service codes reflect the applicable settings within which advanced diagnostic imaging services must be furnished to be subject to the AUC program requirements, we believe setting these parameters will allow us to more accurately pay claims while avoiding the need for other types of professionals and facilities to append modifiers to their claims.

We received public comments on limiting AUC program claims processing edits to apply only to institutional claims with type of bill 13x (hospital outpatient) and limiting the edits to professional claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC). The following is a summary of the comments we received and our responses.

Comment: One commenter noted that the proposals do not include claim types or place of service codes for IDTFs and requested that CMS clarify how claims processing edits would apply to IDTFs. Two commenters agreed with the place of service code proposals.

Response: We believe the institutional type of bill and professional claim place of service codes proposed above include all the applicable settings, including IDTFs, within which advanced diagnostic imaging services must be furnished to be subject to the AUC program requirements. We appreciate the comments.

After consideration of public comments, we are finalizing as proposed.

x. Claims Processing Summary

We have presented above some of the scenarios that CMS and stakeholders have identified as being potentially challenging or impracticable for application of the AUC program claims processing edits for purposes of the payment penalty phase. We requested feedback on whether additional scenarios require consideration and whether the proposed claims processing solutions will adequately address the issues raised. We also requested feedback on areas that stakeholders believe need more education to inform our ongoing outreach and education efforts. While much of the discussion is about identifying claims that are not subject to the AUC program, we note that physicians and other practitioners, or providers submitting claims for advanced imaging services that are not subject to the AUC program can voluntarily report AUC consultation information. We intend to allow those claims to process through the system. We requested commenters to provide additional information to assist us in developing edits that ensure only appropriate claims are subject to AUC claims processing edits.

c. Timing of Payment Penalties

We had previously announced in August 2020, via the CMS AUC website, that the education and operations testing period of the AUC program would be extended through 2021 and the payment penalty phase will begin in January 2022. However, given the many complexities around the scope and application of AUC program claims processing edits, we believe that notice and comment rulemaking is the most appropriate means for us to discuss the implementation and claims processing issues, the start date of the payment penalty phase, and to obtain stakeholder feedback before subsequently finalizing a course of action in the final rule. This process will help ensure that we will appropriately identify claims for denial when the payment penalty phase of the program begins. In addition, we acknowledge the circumstances of physicians and other practitioners, and providers, due to the PHE for COVID–19 and that additional time may be needed to prepare for the payment penalty phase given the challenges and practice disruptions they have experienced while responding to the PHE.

The earliest that our claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. This is because it would not be possible for us to finalize implementation and claims processing plans in this final rule (typically published on or before November 1) and make those decisions effective any earlier than the 3rd calendar quarter of 2022. Implementing the types of claims processing edits necessary for this program generally requires a long lead time. However, we note that an effective date for the claims processing edits in October 2022 may be misaligned with typical annual updates to the systems used by the health care providers that are subject to the AUC program such as EHR, CDSM or claims submission systems. Therefore, we believe the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023.

While the above date takes into account technical system and programming concerns, it does not expressly take into the account the impact that the PHE for COVID–19 has had, and may yet have, on practitioners, providers and beneficiaries. Therefore, we proposed a flexible effective date for AUC program claims processing edits and payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19.

We acknowledge that the AUC program has been significantly delayed. We solicited public comment on this

proposal for the payment penalty phase to begin, and whether we have appropriately taken into account the PHE for COVID–19 and other factors. We recognize that some practitioners and institutions have already invested in qualified CDSMs, while others have had to redirect their resources during the PHE. We solicited information from the public on the state of readiness of practitioners, facilities, and EHR and CDSM vendors.

We received public comments on these proposals for the start of the payment penalty phase of the AUC program. The following is a summary of the comments we received and our responses.

Comment: One commenter requested no further delay to starting the program, and 94 commenters supported the proposal to begin the payment penalty of the program on the later of January 1, 2023 or the January 1 of the year after the year in which the PHE for COVID–19 ends. One commenter supported delaying the start of the payment penalty phase in 2022, but encouraged full implementation in 2023, another commenter requested CMS ensure full implementation in 2023. One commenter requested the payment penalty phase be delayed until 2024, while other commenters requested the payment penalty phase not begin until January 1, 2024 or January 1 of the year after the year in which the PHE ends, whichever is later. One of these commenters recommended this timeframe to ensure a testing year with all coding and billing requirements in place to allow time for HIT developers to make software changes to accommodate claims processing requirements. One commenter stated that physicians must be given at least 12 months to prepare for the penalty phase of the program once CMS makes public that all claims processing edits have been made and tested successfully. One commenter stressed the importance of ensuring physicians have the opportunity to adjust to the AUC program in a thoughtful and deliberate manner that would allow interoperability and the opportunity to develop solutions for data exchange between the ordering and furnishing professionals to leverage IT to reduce burden and suggested gradual implementation where claims are paid regardless of whether information is included on the claim. One commenter recommended using 2023 as an educational year where claims with errors are returned for correction without any financial penalty or denial due to AUC and implement the payment penalty phase no earlier than 2024. Another commenter suggested that CMS continue voluntary participation where AUC consultation using a CDSM is not required and reimbursement is not contingent on documentation of consultation on the furnishing professional's claim.

Two commenters stated that they do not support the AUC program, one commenter requested that the AUC program should be abandoned and another commenter requested that the policy be revoked because it impacts timely access to care. Two commenters, citing implementation challenges and costs, stated that it is inconsistent with the best interests of Medicare and practices to divert resources from patient care to fully implement the AUC program. Another commenter asserted that imposing AUC requirements on ordering professionals for radiologists to be paid will be an ''administrative nightmare.'' One commenter noted that hospitals are working on the implementation of AUC within their systems and the process has not been easy. Several commenters addressed the burden of the AUC program requesting that CMS ensure a least burdensome approach for implementation and work to alleviate burden and improve relevance of the program to physicians and Medicare. One commenter noted that, as designed, the AUC program does not foster the type of education about AUC that is necessary for AUC to have its intended effect.

Other commenters offered suggestions on further delays. Some commenters suggested the program not progress to the payment penalty phase until the vast majority of claims would meet the requirements to be paid. One commenter encouraged CMS to continue to analyze claims to ensure significantly higher percentage of claims report compliant AUC information and consider additional delays in the future. Another commenter also requested that CMS continue to monitor claims and consider deferring the payment penalty phase until at least 75 percent of claims for advanced diagnostic imaging services for the particular clinical specialty include adequate information for payment. Two commenters recommended CMS delay the program and solicit feedback on whether it requires updating before full implementation. Two commenters suggested additional delays and one commenter suggested indefinite delay. One commenter supported further delay in the absence of full program repeal with consideration for the overlap and duplicative burden with Medicare quality programs.

Commenters offered additional opinions on the AUC program in light of Medicare quality programs. Seven commenters asserted that the AUC program is unnecessary for APM participants because they are accountable for quality and cost of care, including incentives to reduce unnecessary imaging. These commenters noted that the AUC program does not consider quality, patient outcomes or other important factors more appropriately addressed in APMs. Two commenters requested CMS consider if a stand-alone AUC program is necessary or if requirements are redundant for QPP participants and one commenter requested CMS consider combining the AUC program with existing quality programs. One commenter suggested CMS consider aligning the goals and requirements of the AUC program with APMs and quality reporting programs to minimize burden and duplication. Other commenters requested CMS reduce burden of the AUC program since it has been superseded by the QPP. One commenter expressed disappointment at the absence of dialogue about how existing quality programs can be leveraged to encourage AUC consultation.

Some commenters suggested alternate options for enforcing compliance with AUC consultation requirements. Two commenters recommended allowing the use of qualified clinical data registries and another commenter recommended collecting requisite data directly from CDSMs. One commenter requested an annual attestation and CDSM audit approach and another suggested replacing claim-by-claim adjudication with provider attestation. Two commenters recommended CMS consider limiting AUC reporting to priority areas. Two commenters suggested revising the program so that payment penalties are paid by the referring physician and not the rendering provider. One commenter recommended CMS re-evaluate the foundational design of the program and the value it brings relative to potential burden and disruptions to clinical workflow. One commenter suggested a better solution than the AUC program would be to have rheumatology societies, orthopedic societies and primary care societies write best practice white papers, incorporate those guidelines into training and into a quality measure for those specialties.

Some commenters recommended that CMS engage with Congress to address the future of the AUC program. Two commenters requested the program be further delayed so CMS can work with

Congress to re-evaluate the feasibility and utility of the program and how appropriate use of imaging can be addressed through the QPP or other value-based initiatives and one commenter recommended CMS work with Congress to evaluate the validity of the AUC program given the significant time lapse between program inception and implementation. Some commenters also referenced the provision accompanying H.R. 4502 directing CMS to prepare a report to Congress on program implementation. Specifically, H. Rept. 117–96 ''requests a report within 180 days of enactment of this Act on implementation of this program, including challenges and successes. In this report, CMS shall consider existing quality improvement programs and relevant models authorized under section 1115A of the Act and their influence on encouraging appropriate use of advanced diagnostic imaging. The Committee directs CMS to consult with stakeholders, including medical professional societies and developers of AUC and clinical guidelines, when formulating its report.'' [91] One commenter requested that CMS work expeditiously and in consultation with medical societies to fulfill the Congressional request once the appropriations bill is finalized and that the report include a comprehensive examination of existing and emerging quality improvement programs and relevant models being pursued by CMS Innovation Center and how they can influence appropriate use of advanced diagnostic imaging.

Many commenters requested that CMS use the additional time resulting from the proposed delay of the payment penalty phase to increase education and outreach efforts. One commenter shared that radiology practices are finding that ordering professionals are non-compliant and hospitals are non-responsive, thinking that they are not required to comply with the AUC program requirements so more education and webinars are needed. Commenters encouraged stakeholder engagement and identification of additional guidance and new flexibilities, significant education and technical assistance efforts, ongoing dialogue with providers and CDSM vendors to resolve remaining implementation issues and feedback on best practices. One commenter requested CMS provide regular program updates quarterly beginning at the end of the first quarter of 2022 on the status of implementation and the anticipated payment penalty start date. One commenter stated that CMS initiate an education and outreach campaign akin to efforts for operationalizing the new Medicare Beneficiary Identifier. Several commenters requested CMS release claims information more frequently. One commenter requested quarterly claims data updates about AUC reporting uptake and common errors. One commenter requested that CMS release more detailed information on claims that were compliant with AUC, particularly what percentage included modifier MH. This commenter stated that a high percentage of claims with modifier MH would indicate that citing a 9–10 percent compliance rate in the proposed rule is disingenuous since modifier MH likely indicates that the ordering professional and furnishing professional have not established a communication process and those claims would have been denied in the payment penalty phase.

Response: We appreciate the extensive and thoughtful comments and recommendations on the AUC program and the proposal to begin the payment penalty phase of the program on the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19. We also appreciate that stakeholders would like CMS to do more to address the extensive concerns stakeholders have about the appropriateness of the AUC program. However, we note that this program is required by statute, and must implement the program within the bounds of our statutory authority. We will continue to explore opportunities for reducing burden of the AUC program by leveraging other quality programs within the provisions set forth in statute. We further appreciate the requests and suggestions for expanded education and outreach efforts. We will continue to make information available on the AUC website and explore more opportunities for increasing these efforts and the scope of information available, including reporting compliance during the remainder of the educational and operations testing period, to assist all stakeholders in better understanding and complying with the AUC program requirements.

After consideration of public comments, we are finalizing our proposal to begin the payment penalty phase of the AUC program on the later of January 1, 2023 or the January 1 that follows the declared end of the PHE for COVID–19.

5. Summary

In summary, we provided clarifications and proposals around the scope of the AUC program specifically pertaining to updates or modifications to orders for advanced diagnostic imaging services and the extreme and uncontrollable circumstances significant hardship exception. We also proposed several claims processing solutions to ensure accurate identification of claims that are and are not subject to the AUC program requirements. These proposals addressed special circumstances related to: services furnished by a CAH, services paid under the Maryland Total Cost of Care Model, inpatients converted to outpatients, situations when Medicare is the secondary payer, and imaging services ordered prior to the payment penalty phase but furnished on or after the start of the payment penalty phase. We also discussed identifying the ordering professional on practitioner claims for the imaging service and request feedback on whether it is more appropriate to deny or return claims that fail AUC claims processing edits. We also proposed to begin the AUC claims processing systems edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the PHE for COVID–19 ends. We invited the public to submit comments on these clarifications and proposals.

We are finalizing all proposals except our proposal to repurpose modifier MH. Specifically, we are finalizing the following:

Provisions specific to orders for advanced diagnostic imaging services that are modified in accordance with chapter 15, sections 80.6.1–4 of the Medicare BPM. When the ordering professional cannot be reached to submit a new order, the AUC consultation information that accompanied the original order is to be included on the claim for the imaging service(s) ultimately furnished.

Claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting are not subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. A new HCPCS modifier will be established to identify claims for services where the ordering professional is not required to consult AUC and when previously established modifiers described above (MA–MG) do not apply. These are claims for which system edits cannot automatically exclude the claim. This new modifier will be used to identify practitioner claims for the PC of advanced diagnostic imaging services

[91] *https://www.govinfo.gov/content/pkg/CRPT-117hrpt96/pdf/CRPT-117hrpt96.pdf.*

that are not subject to the AUC program because the TC was not furnished in an applicable setting and when CMS has not identified an automated mechanism to identify the claim.

We will allow institutional claims with condition code 44 to bypass AUC claims processing edits.

We will allow claims that identify Medicare as the secondary payer (using block 1 or the electronic equivalent of the practitioner claims and using FL 50/51 or the electronic equivalent of institutional claims) to bypass the AUC program claims processing edits.

For imaging services ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, the furnishing professional is to apply the new HCPCS modifier that will be created as discussed above for use on claims for advanced diagnostic imaging services that are not subject to the AUC program that are not otherwise identified by modifiers MA—MG or edits within the claims processing system.

End the use of modifier QQ when the payment penalty phase begins and use a specific modifier to identify scenarios where the ordering professional is not required to consult AUC and the claim is not required to report AUC consultation information when other modifiers do not apply and claims system edits cannot automatically exclude the claims. We will not finalize as proposed, to repurpose modifier MH for this purpose. Instead, we will establish a new HCPCS modifier and intend to end the use of modifier MH when the payment penalty phase begins.

Limit AUC program claims processing edits to apply only to institutional claim type of bill 13x (hospital outpatient) and, for professional claims, limit the edits to claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC).

Begin the payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19.

We will continue to post information on our website for this program, accessible at *www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.*

G. Removal of Selected National Coverage Determinations

CMS periodically identifies and removes National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. Clinical science and technology evolve, and items and services that were once considered state-of-the-art or cutting edge and experimental may be established as reasonable and necessary for Medicare beneficiaries or replaced by more beneficial technologies or clinical paradigms.

In the CY 2021 PFS final rule (85 FR 84472), we established rulemaking as an appropriate vehicle for receiving public comment on removing outdated NCDs, replacing the prior subregulatory administrative process used on two occasions in 2013 and 2015. Using rulemaking under section 1871(a)(2) of the Act allows us to consider removal of several NCDs at once as compared to the public comment process established in section 1862(l) of the Act, to be used in making and reconsidering individual NCDs.

Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). On the other hand, removing an NCD that bars coverage for an item or service under title XVIII of the Act (that is, national noncoverage NCD), allows MACs to cover the item or service if the MAC determines that such action is appropriate under the statute. Removing a national non-coverage NCD may permit more immediate access to technologies that may now be beneficial for some uses. As the scientific community continues to conduct research, which produces new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions.

In the CY 2021 PFS final rule, we did not establish an exclusive list of criteria that we would use for identifying and evaluating NCDs for removal. Instead, based on recommendations in public comments, and to be more flexible and nimble, we added considerations to the six factors established in 2013 to guide our decision making process. In addition to the six factors listed below, we also consider the general age of an NCD, changes in medical practice/standard of care, the pace of medical technology development since the last determination, and availability and quality of clinical evidence and information to support removal of an NCD. We would consider proposing the removal of an NCD if any of the following factors are present:

- We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an ''NCD'' as defined in sections 1862(l) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the statute.

When we evaluate particular NCDs for removal, we take into account information gathered from stakeholders, the claims data for those items and services, and factors such as whether there may be documentation requirements within the NCD that are outdated and create a barrier to coverage. The rulemaking process provides an opportunity to consider public input before the NCD would be removed. We could decide to retain those NCDs after considering public comments.

In Table 33, we list the NCDs that we proposed to remove. In addition to conducting an internal review to identify appropriate NCDs for removal, we receive removal requests from a variety of external stakeholders, such as medical specialty societies, device manufacturers, beneficiaries, physicians and providers, and other interested individuals. Additionally, sometimes topics are brought to our attention by the MAC medical directors. Also, we received comments to the NCD Removal proposal in response to the CY 2021 PFS proposed rule suggesting another seven NCDs for CMS to consider removing. After reviewing those comments and considering other available evidence and information, we proposed to remove one of those seven NCDs in this rulemaking cycle. We have opened a national coverage analysis (NCA) using the NCD process for one and stated in the CY 2021 PFS proposed rule that we believed the other five NCDs should be retained.

We solicited comment on the two NCDs discussed in Table 33, as well as comments recommending other NCDs for CMS to consider for removal in a future rulemaking or through the NCD process.

TABLE 33: NCDs for Removal

NCD Manual Citation	Name of NCD
180.2	Enteral and Parenteral Nutritional Therapy (7/11/1984)
220.6	Positron Emission Tomography (PET) Scans (09/03/2013)

The following outlines each NCD and provides a summary of the rationale for removal. Each of the current NCDs below is available in the Medicare National Coverage Determinations Manual located at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.*

1. NCD 180.2 Enteral and Parenteral Nutritional Therapy (July 11, 1984)

- *Circumstances/Factor:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- *Rationale:* External stakeholders suggested that portions of this NCD are outdated. Enteral nutrition is the delivery of food to a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength. Enteral nutrition is provided through a nasogastric, jejunostomy, or gastrostomy tube. Parenteral nutrition is provided intravenously to the patient with pathology of the alimentary tract severe enough, that it does not allow for absorption of sufficient nutrients. This NCD does not provide as a matter of course, for pharmacy prepared parental solutions, which would increase patient safety. It also unnecessarily adds to patient and provider burden as it requires repeated reviews of medical necessity for those individuals who need enteral or parenteral nutrition services as a result of chronic diseases that affect the ability to eat or to digest/absorb nutrition. Local contractors have proposed LCDs that, if finalized, would provide parenteral and enteral nutrition coverage for certain Medicare beneficiaries. Therefore, we believe that removing this NCD would better serve the needs of the Medicare program and its beneficiaries.

2. NCD 220.6 Positron Emission Tomography (PET) Scans (September 3, 2013)

- *Circumstances/Factor:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- *Rationale:* External stakeholders suggested this NCD may be outdated. NCD 220.6 established broad national non-coverage for non-oncologic indications of PET and was established in 2000. Thus, we required that every non-oncologic indication for PET must have its own NCD in order to receive coverage. In 2013, we reconsidered the NCD to allow coverage for diagnostic PET imaging for oncologic uses not already determined by an NCD, to be made at the discretion of local MACs, due to ''various improvements in the technical, regulatory and professional aspects of PET imaging for diagnosis.'' Since the 2013 reconsideration, new non-oncologic PET agents have been approved by the FDA and multiple professional medical societies have published guidelines relevant to appropriate use of these agents. We believe that local contractor discretion provides an immediate avenue to potential coverage in appropriate candidates for non-oncologic indications. Therefore, we proposed to eliminate subsection 220.6 to remove the broad national bar to coverage of PET scans for non-oncologic indications, thus allowing local Medicare contractors to make a coverage determination under section 1862(a)(1)(A) of the Act for beneficiaries. We believe this framework better serves the needs of the Medicare program and its beneficiaries. For clarity, we did not propose to change any other subsections of 220.6. Thus, the NCDs listed at 220.6.1 through 220.6.20 will not be changed by removing this NCD.

In summary, we solicited comment on the proposal to remove the two NCDs, as well as comments recommending other NCDs for CMS to consider for future removal. We requested commenters include a rationale to support their comments. We use the public comments to help inform our decision to take one of three actions on the three NCDs proposed for removal:

- Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.
- Retain the current policy as an NCD.
- Reconsider the NCD by opening a National Coverage Analysis. Comments suggesting that the NCD should be revised, rather than eliminated, should include new evidence that was not previously available at the time of the original NCD or at the time the NCD was last reconsidered, in order to support a change in national coverage.

We received public comments on the Removal of Selected National Coverage Determinations (NCDs). The following is a summary of the comments we received and our responses.

Comment: Many commenters supported removing NCD 220.6 Positron Emission Tomography (PET) Scans. No commenters opposed removing this NCD. Several commenters additionally offered suggestions for replacement language to be placed in Pub. 100–3 the Medicare National Coverage Determinations (NCD) Manual to specify that non-oncologic uses of PET will be at MAC discretion.

Response: We thank commenters for their support and for suggested revisions to the NCD Manual. We will finalize removal as proposed. When we remove an NCD, as part of the implementation process we update the applicable section of the Manual. We generally replace the prior NCD Manual section with language indicating that the NCD has been removed and that in the absence of an NCD, coverage determinations will be made by the MACs under section 1862(a)(1)(A) of the Act.

Comment: One commenter, while supporting removal of NCD 220.6, expressed concern that we might also remove NCDs 220.6.1 PET for Perfusion of the Heart and 220.6.8 FDG PET for Myocardial Viability.

Response: We did not propose to remove NCDs 220.6.1 or 220.6.8. The NCDs listed at 220.6.1 through 220.6.20 are not repealed or changed.

Comment: Several commenters supported the removal of NCD 180.2 Enteral and Parenteral Nutritional Therapy. One commenter stated that local coverage will create opportunities for new guidance through new coverage articles and coding guidance and will increase the opportunity to for the commenter to provide the best care possible to Medicare beneficiaries. Several commenters agreed that the 1984 NCD is outdated and does not reflect current clinical practice. Several commenters agreed with CMS' goal of

improving patient access, as well as efficacy and safety and several agreed that removing this NCD would better serve the needs of the Medicare program and its beneficiaries.

Response: We thank commenters for their support.

Comment: Several commenters requested that instead of removing NCD 180.2 that CMS reconsider the NCD. A few of these commenters also cited general concerns about allowing MACs to make local coverage determinations (LCDs) including perceived discrepancies in the availability of coverage across regions of the country.

Response: We appreciate the commenters' suggestion, but because the current NCD is outdated we believe it should be removed, rather than revised through the NCD process. As we have noted, the NCD does not provide as a matter of course, for coverage of pharmacy prepared parenteral solutions. Removing the NCD is the fastest way to enable coverage for pharmacy developed formulas and to advance patient safety. The NCD also unnecessarily adds to patient and provider burden as it requires repeated reviews of medical necessity for those individuals who need enteral or parenteral nutrition services as a result of chronic diseases that affect the ability to eat or to digest/absorb nutrition. Therefore, we believe that removing this NCD would better serve the needs of the Medicare program and its beneficiaries, instead of reconsidering and revising the NCD.

Comment: Some commenters requested that CMS reconsider NCD 180.2 and create a new benefit category for enteral and parenteral nutrition to encompass more than the current statutory definition of prosthetic devices. We also received several comments requesting that CMS either reconsider NCD 180.2 or open a new NCA to add coverage for amino acid supplements and medical foods for Inborn Errors of Metabolism (IEM), such as Phenylketonuria, Maple Syrup Urine Disease, and Homocystinuria.

Response: The scope of benefits available to eligible Medicare beneficiaries under Parts A and B is prescribed by law in title XVIII of the Act. See sections 1812, 1833, and 1861(s) (definition of medical and other health services) of the Act. Congress has not empowered the Secretary to establish and add new benefit categories. We have covered parenteral and enteral nutrition based on the prosthetic devices benefit in section 1861(s)(8) of the Act for certain patients. Enteral nutrition is the delivery of food to a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength. Enteral nutrition is provided through a nasogastric, jejunostomy, or gastrostomy tube. Parenteral nutrition is provided intravenously to the patient with pathology of the alimentary tract severe enough, that it does not allow for absorption of sufficient nutrients. We do not have the authority to establish new Medicare benefit categories or to establish coverage through NCDs for items or services that fall outside the scope of the Medicare Part A or Part B benefits prescribed in the Act. We do not have authority under the current statute to cover oral nutritional material for patients whose medical condition would not require a prosthetic device.

Comment: Some commenters stated that nutritional supplements for IEM should be considered and covered as medications.

Response: Although Medicare does cover certain drugs and biologicals under Part B, the nutritional materials do not meet the statutory definition of drugs under the statutory definition in section1861(t)(1) of the Act because they do not have a monograph in USP–NF (the United States Pharmacopeia (USP) and the National Formulary (NF)).

Comment: Some commenters discussing coverage for IEM expressed fears that the proposal to remove NCD 180.2 will take away their current coverage for these nutritional formulas for their children or family members under other health insurance programs.

Response: A Medicare NCD establishes whether or not an item or service is covered nationally under Title XVIII of the Act. Although the NCD is a controlling authority for Medicare contractors and Administrative Law Judges as specified in § 405.1060, it does not have the force of law and is not controlling for other programs.

Comment: One commenter requested that CMS require the MACs to act quickly to update local coverage decisions and applicable coverage articles.

Response: We understand that the MACs have completed updates to two LCDs, one each for enteral nutrition and parenteral nutrition, and associated coverage articles which became effective for services performed on or after September 5, 2021, and apply to each of the DME MACs.

Comment: Several commenters were also concerned that the new LCDs that recently became effective in September 2021, as well as other CMS manuals and local coverage articles still follow and reference NCD 180.2.

Response: Once our NCD is removed from the National Coverage Determinations Manual, we will coordinate any necessary technical changes to remove cross-references to the removed NCD 180.2 from any, LCDs, CMS manuals, guidance documents, or articles.

Comment: A few commenters requested that CMS address in NCD 180.2 the role of registered dietician nutritionists (RDNs) as part of the health care team in supporting both the ordering physician and the Medicare beneficiary in developing, implementing, and monitoring the enteral or parental nutrition plan of care. The commenters also requested CMS provide coverage for medical nutrition therapy (MNT) provided by RDNs for enteral and parenteral nutrition therapy.

Response: The Enteral and Parenteral Nutritional Therapy NCD (NCD 180.2) does not include a discussion of coverage for related practitioner services or Medical Nutrition Therapy that is addressed in a separate regulation. We are not accepting the commenters' suggestion to retain and revise the NCD to address those issues. We are, however, addressing other issues related to Medical Nutrition Therapy separately in this final rule.

Comment: Some commenters recommended additional NCDs for future removal including: NCD 20.7 Percutaneous Transluminal Angioplasty (PTA); NCD 140.1 Abortion; NCD 160.22 Ambulatory EEG Monitoring; NCD 220.6.19 Positron Emission Tomography (NaF–18) to Identify Bone Metastasis of Cancer; NCD 220.6.20 Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease; NCD 220.13 Percutaneous Image-Guided Breast Biopsy; NCD 230.2 Uroflowmetric Evaluations; NCD 230.11 Diagnostic Pap Smears; and NCD 230.16 Bladder Stimulators (Pacemakers).

Response: We thank commenters for their recommendations and will take the suggestions under advisement for future review.

Comment: One commenter, while agreeing with using the rulemaking process to remove NCDs, stated that 10 years may be too long to keep pace with current science and clinical developments. The commenter suggested that a ''hybrid of annual review as an opportunity to remove obviously outdated NCDs with 10 years as a marker for an additional level of scrutiny may be effective to maintain NCD relevance''. The commenter stated that this would require an additional

level of effort and commitment that may prove challenging for CMS and stakeholders to manage.

Response: We appreciate the commenter's recommendation and agree that this would prove challenging for CMS to manage. We will consider whether the hybrid approach could be included as part of our internal process. We acknowledge the rapid pace of medical technology development and changes in standard of care and/or clinical evidence may occur more rapidly than every 10 years, and we will consider those factors, as well as we evaluate whether existing NCDs should be removed.

After consideration of public comments, we are finalizing as proposed removal of both NCD 180.2 Enteral and Parenteral Nutrition Therapy and NCD 220.6 Positron Emission Tomography (PET) Scans because removing these two NCDs better serves the needs of the Medicare program and its beneficiaries.

H. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation

Conditions of coverage for pulmonary rehabilitation (PR), cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) are codified at 42 CFR 410.47 and 410.49. We proposed revisions to the PR and CR/ICR regulations to emphasize that though one program treats a respiratory disease and one treats cardiac conditions, both types of programs aim to improve quality of life for their participants using similar methods. Because many components are shared between PR and CR/ICR, we strive to ensure consistency in the regulatory language used for these therapeutic programs. Additionally, we proposed to more closely conform the PR and CR regulations by removing a PR requirement, and to add COVID–19 as a covered condition for PR for certain beneficiaries. As discussed by Fleg and colleagues (2020),[92] CR and PR continue to be severely underutilized despite clear benefits on clinical and patient-centered outcomes. In fact, Million Hearts® 2022, a national initiative co-led by the Centers for Disease Control and Prevention (CDC) and CMS to prevent 1 million heart attacks and strokes within 5 years, has incorporated a goal for increasing CR utilization. Million Hearts® worked with CR professionals to set a goal of 70 percent CR participation for eligible patients.[93] With these proposals to improve accuracy and consistency of the regulatory language specifying Medicare conditions of coverage for PR and CR/ICR, we hope to assist programs to better understand the PR and CR/ICR conditions of coverage.

We received 29 public comments on these proposals. Commenters overwhelmingly supported adding COVID–19 as a covered condition for PR for certain beneficiaries. Commenters also largely agreed with the proposed revisions to the PR and CR/ICR regulatory text to improve consistency and accuracy across PR and CR/ICR conditions of coverage.

In the following sections, we provide detailed summaries and responses to the comments submitted on these proposals.

1. Statutory Authority

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, July 15, 2008) (MIPPA) amended Title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare part B, as well as new section 1861(fff) of the Act to provide coverage of PR under Medicare part B. The statute specified certain conditions for coverage of these services and an effective date of January 1, 2010. Conditions of coverage for PR, CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in §§ 410.47 and 410.49 respectively through the CY 2010 PFS final rule with comment period (74 FR 61872 through 61886 and 62002 through 62003 (PR) 62004 through 62005 (CR/ICR)).

2. Background

Under § 410.47(b), Medicare part B covers PR for beneficiaries with moderate to very severe chronic obstructive pulmonary disease (COPD) (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease and allows additional medical indications to be established through a national coverage determination (NCD). We have not expanded coverage of PR further using the NCD process.

The conditions of coverage for CR and ICR set forth in MIPPA were codified in § 410.49 through the CY 2010 PFS final rule with comment period. In 2014, we expanded coverage of CR through the NCD process (NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03) to beneficiaries with stable, chronic heart failure. Section 51004 of the Bipartisan Budget Act (Pub. L. 115–123, February 9, 2018) (BBA of 2018), amended section 1861(eee)(4)(B) of the Act to expand coverage of ICR to include patients with stable, chronic heart failure. Section 410.49 was updated to codify this expansion through the CY 2020 PFS final rule (84 FR 62897 through 62899 and 63188).

Under § 410.49(b), Medicare part B covers CR and ICR for beneficiaries who have experienced one or more of the following: (1) An acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; (6) a heart or heart-lung transplant; (7) stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or (8) other cardiac conditions as specified through an NCD. The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

As set forth in statute, PR, CR and ICR are programs furnishing physician-supervised items and services that may be furnished in a physician's office or hospital outpatient setting or in other settings determined appropriate by the Secretary.[94] When items and services are furnished under these programs, a physician must be immediately available and accessible for medical consultation and medical emergencies. PR, CR and ICR programs must include: Physician-prescribed exercise, psychosocial assessment, outcomes assessment, cardiac risk factor modification (for CR/ICR) and education or training (for PR), and individualized treatment plans (ITPs) established, reviewed and signed by a physician every 30 days. The statute also includes physician requirements for PR and CR/ICR programs. Namely, section

[92] Fleg JL, Keteyian SJ, Peterson PN, Benzo R, Finkelstein J, Forman DE, Gaalema DE, Cooper LS, Punturieri A, Joseph L, Shero S, Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[93] *https://millionhearts.hhs.gov/tools-protocols/action-guides/cardiac-change-package/index.html.*

[94] Section 51008 of the BBA of 2018 makes changes to the statute that will permit other specific practitioners to supervise the items and services effective on January 1, 2024.

1861(eee)(5) of the Act requires that the Secretary establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology is responsible for the CR/ICR program and that such physician, in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program. Section 1861(fff)(3) of the Act similarly requires the Secretary establish standards that ensure that a physician with expertise in the management of individuals with respiratory pathophysiology is responsible for the PR program and, in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program. We established physician standards for PR at § 410.47 and for CR/ICR at § 410.49.

Under the statute, PR and CR/ICR programs include individualized treatment that is furnished under a written plan established, reviewed, and signed by a physician every 30 days. We codified this requirement in §§ 410.47 and 410.49 by defining and describing the ITP which must be established, reviewed, and signed by a physician every 30 days. Because the statute requires a plan to be established, reviewed, and signed by a physician every 30 days, we cannot alter this requirement.

Stakeholders have indicated to us that it is very challenging for a program to fulfill these tasks on each patient's first day of PR or CR/ICR. Stakeholders have also expressed concerns that there is not separate and additional payment for medical directors or other physicians to develop and sign the ITPs. In response to these concerns, we note that the medical director and any staff physician(s) working in the PR or CR/ICR program who is involved in the patient's care and has knowledge related to the patient's condition, or the patient's treating and/or referring physician, may establish, review and sign ITPs. When appropriate and when all billing requirements are met, a separately billable E/M service may be furnished by the medical director or other PR or CR/ICR staff physician(s) working in the program in connection with establishing and signing the ITP on or before the first day of PR or CR/ICR. Additionally, physicians treating patients for their cardiovascular or respiratory conditions, but who are not staff of the PR or CR/ICR programs, are not precluded from developing and signing ITPs for their patients before they begin PR or CR/ICR programs. While the CY 2010 PFS final rule for PR (74 FR at 61883) stated that the PR physician must review and sign the ITP prior to initiation of PR even if the plan was developed by a different physician, we recognize that this imposes greater burden and may potentially delay treatment. ITPs developed and signed on or before the first day of PR by a physician who is treating the patient's respiratory condition outside of the PR program will not require an additional signature from the PR medical director (or any other physician working in the program) on or before the first day of PR. Similarly, ITPs developed and signed on or before the first day of CR/ICR by a physician outside of the CR/ICR program treating the patient's cardiovascular condition, do not require an additional signature from the CR/ICR medical director (or other physician working in the program) on or before the first day of CR/ICR. The PR and CR/ICR medical director and other appropriate staff would review these ITPs on or before the first day services are furnished. The medical director or other physician working in the program, in consultation with staff, may revise the ITP as needed to ensure the plan is appropriately individualized, regardless of which physician establishes and signs the plan.

3. Revisions

As described above, PR and CR/ICR programs are subject to many of the same statutory requirements. Despite the consistency in requirements set forth in statute, we recognize that some of the conditions of coverage codified in regulation are not identical across both programs. We proposed conforming changes to the regulatory text for both PR and CR/ICR to establish consistency in terminology, definitions and requirements where appropriate which will result in clearer and more streamlined regulatory text. We also proposed to adjust the regulatory structure of § 410.47 to align with § 410.49. The revisions will also enable stakeholders with interest in both PR and CR/ICR programs to more easily compare requirements and implement programs.

a. Definitions

We proposed revisions to six PR definitions at § 410.47(a), including individualized treatment plan, medical director, outcomes assessment, physician-prescribed exercise, psychosocial assessment and supervising physician; and revisions to three CR/ICR definitions at § 410.49(a), including medical director, outcomes assessment, and physician-prescribed exercise. Specifically, the proposed revisions to the PR definitions of ITP, psychosocial assessment and supervising physician align with the definitions of the same terms for CR/ICR. The proposed revisions to the PR definition of physician-prescribed exercise align with the definition of physician-prescribed exercise for CR/ICR and also include revisions to provide examples of physical activities appropriate to the patient population (which were relocated from the PR components section (previously § 410.47(c)). Similar revisions were proposed for the CR/ICR definition of physician-prescribed exercise. We proposed to modify language in the PR definition of medical director to align with the CR/ICR definition of medical director to more specifically describe the role of the PR medical director. We proposed conforming changes to the CR/ICR definition of medical director. Proposed revisions to the PR and CR/ICR definitions of outcomes assessment removed and revised redundant and unnecessary language. Also, we proposed to clearly state that outcome assessments may be performed by either the physician or the PR or CR/ICR program staff and that all results of these evaluations performed by program staff must be considered by the physician in the development and/or review of ITPs. These proposals are consistent with descriptions provided in the CY 2010 PFS proposed rule (74 FR at 33608, 33613) which state that PR and CR/ICR staff must provide outcomes assessments to the physician and serve to clearly communicate the important supportive role program staff may play to the physicians of these rehabilitation programs. The conforming changes are designed to more accurately define the existing terms and ensure consistency in definitions used for the same terms across PR and CR/ICR programs. We chose to largely maintain the CR/ICR regulatory text and align the PR regulatory text with CR/ICR based on stakeholder feedback and questions regarding the PR requirements. Aligning PR with CR/ICR, as opposed to aligning CR/ICR with PR requirements, better addresses stakeholder feedback and improves consistency in terminology, definitions and descriptions of conditions of coverage. With the proposed revisions and increased consistency, we also aimed to improve program efficiency in implementing the conditions of coverage.

We received 11 public comments generally addressing the conforming changes throughout our proposals. We received two public comments specific to the proposed definition changes. The

following is a summary of the comments we received and our responses.

Comment: We received one comment requesting the use of waiver authority (sections 1115A, 1899 and 1135 of the Act) to allow NPs to order, establish plans of care and supervise PR and CR/ICR.

Response: The scope of the proposed rule did not include proposals to use waiver authority to waive any requirements specified under the conditions of coverage at §§ 410.47 and 410.49, and, as such we will not address waivers in this final rule. As referenced above in section III.H.2. of this final rule (background), section 51008 of the BBA of 2018 makes changes to the statute that will permit other specific practitioners, including NPs, to supervise the items and services effective on January 1, 2024.

Comment: One commenter requested clarification on the role of resident level training and fellow level training and their billing status.

Response: The conditions of coverage for PR and CR/ICR do not modify or impact existing rules for residents and fellows. Provisions specific to residents, interns and fellows are included in the Medicare Benefit Policy Manual (Pub. 100–02), Chapter 15, section 30.3, and the Medicare Claims Processing Manual (Pub. 100–04), Chapter 12, section 100. Information is also included in the Medicare Learning Network (MLN) Booklet entitled *Guidelines for Teaching Physicians, Interns, and Residents.*[95] The existing requirements under Medicare for residents and fellows would apply as appropriate. We note that there are not separate provisions for residents, fellows and interns specific to PR and CR/ICR services.

Comment: Some commenters generally supported the proposed revisions for consistency and accuracy throughout the PR and CR/ICR regulatory text. One commenter specifically expressed agreement with the proposed definition changes. Another commenter supported the proposed changes to the outcomes assessment definition incorporating language recognizing the important role program staff serve with respect to developing and/or reviewing ITPs.

Response: We appreciate the commenters that submitted these supportive comments.

After consideration of public comments, we are finalizing the definition revisions as proposed.

[95] *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/teaching-physicians-fact-sheet-icn006437.pdf.*

b. Covered Conditions

The definition for PR at § 410.47(a) specifies that PR is a physician-supervised program for COPD and certain other chronic respiratory diseases. The CDC uses the term post-COVID conditions to describe health issues that persist more than 4 weeks after first being infected with the causative virus [96] indicating that this timeframe provides a rough approximation of effects that occur beyond the acute period. Similarly, the National Institute for Health and Care Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN) and the Royal College of General Practitioners (RCGP) have jointly used 4 weeks to differentiate the acute symptoms of COVID from 'long COVID,' the signs and symptoms that continue or develop after acute COVID–19.[97] Based on the information from the CDC, NICE, SIGN and RCGP, we consider COVID–19 to be chronic when symptoms persist for more than 4 weeks. Symptoms include dyspnea, depression and anxiety which can impair physical function and cause incapacitation.[98] [99] We proposed to cover PR for Medicare beneficiaries who have been diagnosed with severe manifestations of COVID–19, defined as requiring hospitalization in the ICU or otherwise, and who experience continuing symptomatology, including respiratory dysfunction, for at least 4 weeks post discharge.

Management of COVID–19 post-acute syndrome is an evolving issue in the health of our beneficiaries. We recognize that there is limited evidence available assessing the benefits that PR may provide for patients who were diagnosed with COVID–19. However, early research and consensus statements emphasize the restorative role that PR will likely play in the patient recovering from COVID–19.[100] [101] We solicited comments regarding the appropriateness of the coverage criteria for PR for beneficiaries diagnosed with COVID–19, including both the characteristics of the patients for whom PR is covered and the timing of their symptoms as presented above.

We received public comments on this proposal to cover PR for Medicare beneficiaries who have been diagnosed with severe manifestations of COVID–19, defined as requiring hospitalization in the ICU or otherwise, and who experience continuing symptomatology, including respiratory dysfunction, for at least 4 weeks post discharge, as well as the appropriateness of the proposed coverage criteria. The following is a summary of the comments we received and our responses.

Comment: All commenters supported expanding coverage of PR to include beneficiaries who had COVID–19; however, commenters had varying opinions regarding the specific coverage parameters appropriate for this patient population. Some commenters expressed agreement with the coverage parameters as proposed. Other commenters recommended expanding coverage to include all beneficiaries who have been diagnosed with severe COVID–19 and are experiencing post-COVID syndrome and further noted that the PR conditions of coverage should evolve and change as the definition and understanding of post-COVID syndrome improve. Some commenters requested that the requirements for patients to be hospitalized and also wait 4 weeks after hospitalization to participate in PR be removed. Other commenters recommended removing the hospitalization requirement. One commenter requested that CMS confirm that the proposal would mean any hospitalized patient would be eligible for PR if they have symptoms beyond 4 weeks. This commenter requested that CMS clarify the phrasing of the policy. Commenters requesting further expansion of the proposed coverage criteria to include patients who were not hospitalized cited data and publications that continue to be released as more information becomes available to inform treatment options for COVID–19 patients. These commenters noted that early experience indicates that, in addition to hospitalized patients, patients who are not hospitalized may still experience severe and persistent symptoms from COVID–19 and PR has helped to improve such patients'

[96] Centers for Disease Control and Prevention. Post-COVID Conditions: Information for Healthcare Providers. Updated July 9, 2021. Accessed 9/16/2021 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-conditions.html.*

[97] NICE guideline [NG188]. COVID–19 rapid guideline: Managing the long-term effects of COVID–19. December 18, 2020. Accessed 4/30/2021 at *https://www.nice.org.uk/guidance/ng188.*

[98] Post-COVID Conditions updated 7/12/2021 accessed 9/16/2021 at *https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects.html.*

[99] NIH launches new initiative to study ''Long COVID'' updated 2/23/21 accessed at *https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-launches-new-initiative-study-long-covid.*

[100] Liu K, Zhang W, Yang Y, Zhang J, Li Y, Chen Y. Respiratory rehabilitation in elderly patients with COVID–19: A randomized controlled study. Complement Ther Clin Pract. 2020 May;39:101166. doi: 10.1016/j.ctcp.2020.101166. Epub 2020 Apr 1. PMID: 32379637.

[101] Barker-Davies RM, O'Sullivan O, Senaratne KPP, et al. The Stanford Hall consensus statement for post-COVID–19 rehabilitation. Br J Sports Med. 2020;54(16):949–959. doi:10.1136/bjsports-2020–102596. PMID: 33743391.

conditions. One commenter requested that coverage not be limited to only patients with ''severe manifestations'' of COVID–19 because mild cases can also result in ongoing pulmonary complications. Another commenter supported the proposed language covering PR for patients with ''severe manifestations of COVID–19'' and stated it is not diagnosis driven and these patients should be treated similarly to patients with emphysema and COPD.

Response: We agree that coverage of PR for beneficiaries who experienced COVID–19 is important in treating ongoing symptoms and complications of the disease. We recognize that patients recovering from COVID–19 who were able to be treated at home, also exhibit long-term symptoms of this disease, though usually of a lesser severity than those who were hospitalized for their treatment (Boutou, et al., 2021).[102] In a series of 150 outpatients treated for COVID–19 studied by Lougue, et al., 2021,[103] persistent symptoms were reported by one-third of outpatients at a median 169 days (SD 37.1) after illness onset. Though the most frequent symptoms were those of fatigue and loss of smell, persistent breathing difficulties were reported by approximately 5–10 percent of these individuals.

Therefore, after consideration of public comments and the rapidly evolving evidence base, we believe it prudent to further expand coverage of PR for COVID–19 beyond our proposal. As such, we are finalizing that PR is covered for beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks. To be clear, this includes beneficiaries regardless of whether they were hospitalized as this expanded coverage is agnostic to the setting in which they were treated for COVID–19. A positive COVID–19 test is not required, however eligible beneficiaries must have had confirmed or suspected COVID–19, and they must experience persistent symptoms of COVID–19 that include respiratory dysfunction for at least 4 weeks. The 4-week time frame may begin with symptom onset. We believe this expansion of coverage will equip healthcare providers with another tool to assist patients in overcoming long-lasting, residual symptoms of COVID–19 that, for many, significantly impact activities of daily living. Furthermore, we are aware that data suggests individuals belonging to racial and ethnic minority groups are at an increased risk of acquiring COVID–19 compared to other individuals and also that they may experience worse clinical outcomes from the disease.[104] [105] Expanding coverage of PR will afford physicians the ability to refer more individuals who require restorative therapies to rehabilitation services that may allow for as full a recovery as possible. This expansion of PR coverage to beneficiaries that had COVID–19, whether hospitalized or not, offers an important treatment option, especially for those in racial and ethnic minority groups that have been disproportionately affected by COVID–19.

We will continue to monitor the evidence base for PR and COVID–19 and revisit this policy when and if appropriate based on clinical evidence.

Comment: Two commenters requested further expansion of covered conditions for PR and CR/ICR. One commenter requested coverage of PR for conditions like adult respiratory distress syndrome. One commenter requested that under the CR/ICR regulation, chronic heart failure patients should not have to wait 6 weeks after hospital discharge to participate in CR if they are able to tolerate rehabilitation sooner, as determined by their physician.

Response: In our proposed rule, we only sought to expand coverage of PR for beneficiaries who experienced COVID–19. We believe it is important to make changes to coverage provisions, including covered conditions, with the public's input using processes like notice and comment rulemaking or the NCD process. Because we did not propose to cover other conditions (nor receive public comments on proposals to cover other conditions), we will not expand coverage to other conditions in this final rule. As discussed in section III.H.2. (background) of this final rule, we may use the NCD process to cover additional conditions for PR, CR and ICR. Information on how to request an NCD is available at *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD.*

After consideration of public comments and the evolving evidence base, we are finalizing that PR is covered for beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks.

c. Components

We proposed revisions to the description of each of the five PR components under § 410.47(b)(2) (previously § 410.47(c)). Revisions to the descriptions of physician prescribed exercise, psychosocial assessment and outcomes assessment include removing language already used in the definition of each term or references to the definitions in § 410.47(a). The inclusion of already established definition language is redundant, and therefore, unnecessary. Revisions to the education or training component more concisely explain, but do not change, the existing requirements for meeting this component. Revisions to the description of the ITP align with the description used for the CR/ICR ITP. As noted in the section above, we largely aligned the PR regulatory text with CR/ICR to better address stakeholder feedback and improve consistency in terminology, definitions and descriptions of conditions of coverage to assist in improving program efficiency in implementing the conditions of coverage.

We received 11 public comments generally addressing the conforming changes throughout our proposals. We also received several comments related to requirements we did not propose to change. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed general support of the revisions for consistency and accuracy throughout the PR and CR/ICR regulatory text.

Response: We appreciate these comments.

Comment: One commenter requested clarification that NPPs may provide prescribed exercises for beneficiaries in a PR program.

Response: We are not adopting the commenter's suggestion because our regulations do not specify staff requirements or responsibilities. The medical director is responsible for the program, and thus, the staff roles and responsibilities.

Comment: Several commenters offered feedback on the requirement for the ITP to be signed by a physician by the first day PR or CR/ICR services are

[102] Boutou AK, Asimakos A, Kortianou E, Vogiatzis I, Tzouvelekis A. Long COVID–19 Pulmonary Sequelae and Management Considerations. *Journal of Personalized Medicine.* 2021; 11(9):838. *https://doi.org/10.3390/jpm11090838.*

[103] Logue JK, Franko NM, McCulloch DJ, et al. Sequelae in Adults at 6 Months After COVID–19 Infection. *JAMA Netw Open.* 2021;4(2):e210830. doi:10.1001/jamanetworkopen.2021.0830.

[104] Centers for Disease Control and Prevention. Health Equity Considerations and Racial and Ethnic Minority Groups. Updated 4/19/2021. Accessed 10/4/20 21 at *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[105] Mishra V, Seyedzenouzi G, Almohtadi A, et al. Health Inequalities During COVID–19 and Their Effects on Morbidity and Mortality. J Healthc Leadersh. 2021;13:19–26. Published 2021 Jan 19. doi:10.2147/JHL.S270175.

furnished. Specifically, one commenter requested that the regulations allow more time to acquire the appropriate signatures on the treatment plan because sometimes providers are unavailable to immediately sign off on the first day, with another commenter echoing this concern by explaining that it is challenging to obtain a physician signature on the ITP no later than the same date of the first PR or CR/ICR session.

Response: As we discussed above in section III.H.2. of this final rule (background) that, under the statute, PR and CR/ICR programs include individualized treatment that is furnished under a written plan established, reviewed, and signed by a physician every 30 days. Because this timeframe is specified in statute, we do not have the authority to allow for the ITP to be signed by a physician after the first day services are furnished. In section III.H.2. of this final rule, we also address potential opportunities for the ITPs to be established and signed by a physician during separate E/M visits prior to a beneficiary's first session of PR or CR/ICR.

Comment: One commenter indicated that the clarification was helpful in section III.H.2. of this final rule (background) that a separately billable E/M visit may be furnished by the program medical director or other program staff physicians in connection with establishing and signing the ITP on or before the first PR or CR/ICR session. This commenter stated that this will not be billable by outside physicians, but did not further expand on this statement.

Response: Our regulations do not preclude outside physicians (who are independent from the PR or CR/ICR program) from developing and signing ITPs during E/M visits for the treatment of the respiratory or cardiac condition.

After consideration of public comments, we are finalizing the revisions to the component descriptions as proposed.

d. Settings

We proposed minor edits to align the PR setting text in § 410.47(b)(3)(i) (previously § 410.47(d)(1)) with the CR/ICR setting text and reorganize this section to move and update, consistent with the corresponding CR/ICR section, the requirement that all settings must have a physician immediately available and accessible for medical consultations and emergencies.

We received 11 public comments generally addressing the conforming changes throughout our proposals. We also received several comments requesting coverage of PR in additional settings and comments requesting revisions to the requirement that a physician be immediately available and accessible. The following is a summary of the comments we received and our responses.

Comment: One commenter requested physical therapy and occupational therapy private practices and rehabilitation agency settings be added to covered settings. One commenter requested coverage for in home virtual CR (without reference to the separate telehealth provisions discussed in other sections of the proposed rule).

Response: The scope of the proposed revisions to the setting requirements for PR were limited to reorganizing and updating the language for consistency and accuracy with corresponding CR/ICR regulatory text. We did not consider or propose to add settings. We believe it is important to make changes to coverage provisions, including covered settings, with the public's input using notice and comment rulemaking. Because we did not propose and receive public comments on covering other settings, we will not expand coverage to other settings in this final rule. If supported by clinical evidence and within the parameters set forth in statute, we may consider other settings in future notice and comment rulemaking. In response to the PHE for COVID–19, we established numerous temporary waivers and flexibilities. For example, effective through the end of the year in which the PHE for COVID–19 ends, direct supervision of PR and CR/ICR can include a virtual presence of the physician through two-way, audio-video communications technology. Additionally, the HCPCS codes for PR, CR and ICR, were added to the Medicare telehealth services list on a temporary basis for the duration of the PHE which means providers can furnish these services in accordance with the telehealth flexibilities available during the PHE using audio and video equipment permitting two-way, real-time interactive communication. Furthermore, through the Hospitals without Walls initiative, PR, CR and ICR services can be furnished in a patient's home that is serving as part of the hospital during the PHE for COVID–19, provided the patient is registered as a hospital outpatient when the services are furnished and other conditions are met. Additional information about PHE related waivers and flexibilities is available on the CMS website at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page.* Additional information about telehealth rules and requirements are available both in this final rule and on the CMS website at *https://www.cms.gov/medicare/medicare-general-information/telehealth.*

Comment: One commenter requested that the PR and CR/ICR regulations be updated to allow PR and CR/ICR patients to be treated in the same setting at the same time. This commenter stated that currently the services cannot be provided in the same location at the same time.

Response: We believe this commenter is referencing situations where a distinct patient or group of patients are participating in PR while a separate distinct patient or group of patients are participating in CR/ICR in the same location. We do not interpret this comment as referencing a single patient receiving PR and CR/ICR at the same time during the same session. The conditions of coverage for PR and CR/ICR do not prohibit PR services from being furnished to PR patients in the same setting and at the same time that CR/ICR services are furnished to CR/ICR patients. However, all coverage requirements for each distinct program must be met to comply with the conditions of coverage specified in the regulations. Both PR and CR/ICR services may not be furnished to a single patient at the same time. In other words, programs may not furnish and bill for PR and CR/ICR services furnished to the same patient during a single session. If a patient is participating in both PR and CR/ICR, the patient would need to separately complete sessions for each program and cannot receive PR program services during the same session in which they are receiving CR/ICR program services.

Comment: Several commenters stated that requiring a physician to be immediately available and accessible is an insurmountable obstacle in rural areas. These commenters requested the CR NCD be revised to allow CR programs to operate under general supervision of a physician when an automated external defibrillator (AED) is immediately available and the patient is attended by nursing staff currently trained in Basic Life Support and AED use.

Response: The requirement for a physician to be immediately available and accessible is specified in statute at section 1861(eee)(2)(B) of the Act and we are not waiving this requirement for rural areas.

Comment: Several commenters suggested that CMS permit the CR supervising physician to be immediately available and accessible through a

virtual presence, particularly in rural areas.

Response: In response to the PHE for COVID–19, we established numerous temporary waivers and flexibilities. For example, effective through the end of the year in which the PHE for COVID–19 ends, direct supervision of PR and CR/ICR can include a virtual presence of the physician through two-way, audio-video communications technology. Additionally, the HCPCS codes for PR, CR and ICR, were added to the Medicare telehealth services list on a temporary basis for the duration of the PHE which means providers can furnish these services in accordance with the telehealth flexibilities available during the PHE using audio and video equipment permitting two-way, real-time interactive communication.

Comment: Some commenters expressed general support of the revisions for consistency and accuracy throughout the PR and CR/ICR regulatory text.

Response: We appreciate the support.

After consideration of public comments, we are finalizing the setting revisions as proposed.

e. Physician Standards

We proposed revisions to align regulatory text regarding the standards for the PR medical director and the supervising physician found at § 410.47(c) and (d) (previously § 410.47(e)) with the corresponding CR/ICR medical director and supervising physician text and minor conforming changes to CR/ICR language § 410.49(d) and (e). These revisions will not only align similar requirements for PR and CR/ICR programs, but also more accurately describe the roles and responsibilities of physicians in PR programs, and thereby address stakeholder feedback requesting more specificity around the roles and standards for the physicians involved in PR programs. Specifically, we proposed to replace the existing PR ''physician standards'' section with two separate sections. The first, entitled ''medical director standards'' delineates requirements for the PR medical director, and the second, ''supervising physician standards'' delineates requirements for physicians fulfilling the supervising physician role when PR items and services are furnished. These revisions also include removing language that is redundant to the definition for medical director already set forth in § 410.47(a) and the requirement that a physician have ''direct patient contact related to the periodic review of his or her treatment plan.'' We proposed to remove the direct patient contact language because this requirement is overly burdensome and unnecessary since a physician is already required to, in consultation with staff, review patient ITPs every 30 days. Direct physician-patient contact can be written into an ITP for patients who require such attention; however, it is not necessary for every patient and the need for it should instead be specified by the clinician. Furthermore, while we believe direct physician-patient contact within the PR program every 30 days is not necessary for every PR patient, we note that patients are seen by PR staff and their progress is tracked at each session where staff are able to identify the need for direct physician-patient contact as appropriate. Additionally, patients participating in PR generally continue to have ongoing interactions with their treating physicians outside of PR. Because the need for direct physician-patient contact is individualized and patients continue to engage with their treating physicians outside of PR, we proposed to remove the requirement for direct physician-patient contact within the PR program every 30 days. We requested public comment on whether removing the regulatory requirement for direct physician-patient contact every 30 days would be potentially detrimental to PR patients by eliminating a critical physician interaction, or if necessary interactions are already occurring outside of the PR program at appropriate intervals as determined by a physician treating the patient for his or her respiratory condition.

These revisions and clearer delineations of the roles and standards for the PR medical director and, separately, the supervising physician, are important to address stakeholder feedback and reduce burden on PR programs, physicians and patients while ensuring treatment is truly individualized as directed by statute. As these revisions, more accurately describe and delineate the roles and standards for the medical director and the supervising physician, please note that the PR or CR/ICR medical director may serve as a supervising physician if he or she also meets the requirements for a supervising physician. Two different physicians are not necessarily required, as long as the definitions and descriptions in §§ 410.47 and 410.49 are met.

The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed general support of the revisions for consistency and accuracy throughout the PR and CR/ICR regulatory text. One commenter specifically supported the proposed alignment of standards between CR/ICR and PR for the medical director and supervising physician standards.

Response: We appreciate the support.

Comment: One commenter requested that the requirement for the medical director to possess a license from the State in which the program is offered be removed and instead allow a license from any State.

Response: Under sections 1861(eee)(5) and (fff)(3) of the Act, the physician responsible for both PR and CR/ICR programs (the medical director as defined in regulation) is required to be licensed to practice medicine in the State in which the PR or CR/ICR program is offered. Because this requirement is specified in statute, we do not have the authority to modify it.

Comment: Some commenters supported removing the PR requirement that a physician have ''direct patient contact related to the periodic review of his or her treatment plan.'' All commenters agreed with this proposal and no commenters indicated that removing the requirement would be potentially detrimental to PR patients.

Response: We appreciate the support.

After consideration of public comments, we are finalizing the physician standards revisions as proposed, including removal of the direct physician-patient contact requirement. We reiterate that for patients that may require greater interaction with a physician, such direct physician-patient contact may be included in the patient's ITP. However, as discussed above, we believe this requirement is overly burdensome and unnecessary for all patients and, as such, we are finalizing our proposal to remove the requirement.

f. Limitations

We proposed conforming changes to §§ 410.47(e) (previously § 410.47(f)) and 410.49(f) to improve clarity of these sections and more closely align the descriptions for session duration, number of sessions covered and time-period over which sessions must be provided.

Comment: Some commenters expressed general support the revisions for consistency and accuracy throughout the PR and CR/ICR regulatory text.

Response: We appreciate the support.

After consideration of public comments, we are finalizing the revisions in this section as proposed.

4. Summary

To improve consistency and accuracy across PR and CR/ICR conditions of

coverage, we proposed largely conforming changes throughout §§ 410.47 and 410.49. We also proposed to add coverage of PR for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for least 4 weeks after hospital discharge and to remove a PR program requirement that is overly burdensome and unnecessary for all PR patients which was also not expressly required in statute. After considering public comments and additional clinical evidence, we are finalizing the revisions to improve consistency and accuracy across PR and CR/ICR conditions of coverage as proposed. We are also finalizing the removal of the PR requirement for direct physician-patient contact. We are expanding upon our proposal to cover PR for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge. We are removing the proposed hospitalization requirement and finalizing coverage of PR for beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks.

We believe these revisions will result in clearer and more streamlined regulatory text and better assist stakeholders in understanding and implementing PR, CR and ICR programs. Furthermore, we believe coverage of PR for beneficiaries who experienced COVID–19 is an important treatment option for patients as they recover.

I. Medical Nutrition Therapy

Medical nutrition therapy became a distinct Medicare benefit under section 1861(s)(2) of the Act under section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (BIPA). Medicare beneficiaries with diabetes or renal disease can receive individualized medical nutrition therapy (MNT) provided by a registered dietitian or nutrition professional, pursuant to a referral by a physician (as defined in section 1861(r)(1) of the Act), with no cost to the beneficiary. Currently, 42 CFR 410.132(c), further requires that the referral must be made by the treating physician. The treating physician was defined as the primary care physician or specialist, coordinating care for the beneficiary with diabetes or renal disease. The regulation also specifically defines renal disease as including chronic renal insufficiency based on glomerular filtration rate (GFR) eligibility criteria.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Kidney Foundation and Academy of Nutrition and Dietetics support MNT for adults with chronic kidney disease (CKD). The National Kidney Foundation and the Academy of Nutrition and Dietetics' Clinical Practice Guideline on Nutrition in Chronic Kidney Disease [106] acknowledges that the goals of MNT are to optimize nutritional status, and to minimize risks imposed by comorbid conditions and alterations in metabolism on the progression of kidney disease and on adverse clinical outcomes. The authors recognize that patients with CKD have changing needs according to their disease stage and they recommended MNT for each stage of CKD.

In addition, evidence supports the use of MNT as a component of quality diabetes care, including its integration into the medical management of diabetes. Nutrition therapy that includes the development of an eating plan designed to improve blood glucose, blood pressure, and lipid profiles is important in the management of diabetes and can lower the risk of cardiovascular disease, coronary heart disease, and stroke. Despite these findings and endorsement by leading clinical societies, including the American Diabetes Association, American College of Cardiology and the National Kidney Foundation, less than 2 percent of the estimated 14 million eligible Medicare beneficiaries have accessed MNT.

Over the years, we have heard from several stakeholder groups requesting that we update the MNT regulations to improve beneficiary access. In the proposed rule, we provided background on the MNT services, discussed the MNT regulation revisions, and included proposals to implement these modifications. We proposed to make changes to the treating physician requirements and update the chronic renal insufficiency GFR criteria in order to improve access and utilization of the MNT benefit. The statute expressly requires the order of a physician; therefore, we are unable to extend referral privileges to NPPs.

1. Background: MNT

MNT is defined in sections 1861(s)(2)(V) and 1861(vv)(1) of the Act and codified in §§ 410.130 (definitions), 410.132 (MNT), and 410.134 (provider qualifications).

[106] *https://www.kidney.org/sites/default/files/Nutrition_GL%2BSubmission_101719_Public_Review_Copy.pdf.*

a. Definitions (§ 410.130)

In 42 CFR subpart G, we define the following definitions that apply to MNT at § 410.130:

- Chronic renal insufficiency.
- Diabetes.
- Episode of care.
- Medical nutrition therapy services.
- Physician.
- Renal disease.
- Treating physician.

b. Medical Nutrition Therapy (§ 410.132).

In § 410.132(a), we outline the conditions for coverage of MNT services. That is, Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the treating physician. Services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally-accepted dietary or nutritional protocols. The regulation contains an exception that permits MNT services to be provided as telehealth services under § 410.78.

In § 410.132(b), we outline the limitations on coverage of MNT services. First, the MNT services based on a diagnosis of renal disease as described in 42 CFR subpart G are not covered for beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Act. Also, a beneficiary may only receive the maximum number of hours covered under the DSMT benefit for both DSMT and MNT during the initial DSMT training period unless additional hours are determined to be medically necessary under the national coverage determination (NCD) process. In years when the beneficiary is eligible for MNT and follow-up DSMT, Medicare will cover the maximum number of hours covered under MNT unless additional hours are determined to be medically necessary under the NCD process. Under the current MNT NCD (NCD 180.1), Medicare covers 3 hours of MNT the initial year of referral and up to 2 hours of MNT for subsequent years. In addition, if a beneficiary has both diabetes and renal disease, Medicare will cover the maximum number of hours covered under the renal MNT benefit in one episode of care unless he or she is receiving initial DSMT services, in which case the beneficiary would receive whichever is greater. Finally, an exception to the maximum number of hours described here may be made when the treating physician determines that there is a change of

diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

At § 410.132(c), we discuss that a referral may only be made by the treating physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in 42 CFR subpart G with documentation maintained by the referring physician in the beneficiary's medical record. We also note that referrals must be made for each episode of care and any additional assessments or interventions required by a change of diagnosis, medical condition, or treatment regimen during an episode of care.

c. Provider Qualifications (§ 410.134)

For Medicare Part B coverage of MNT, only a registered dietitian or nutrition professional may provide the services. At § 410.134, we define registered dietitian or nutrition professional as an individual who, on or after December 22, 2000: (1) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose; (2) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and (3) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a registered dietitian by the Commission on Dietetic Registration or its successor organization. However, a dietitian or nutritionist licensed or certified in a State as of December 21, 2000 is not required to hold a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose; (2) and need not complete at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional. In addition, a registered dietitian in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met these requirements.

2. Proposal for MNT Revisions

a. Removal of the Treating Physician Restriction

For CY 2022, we proposed to revise the regulations at §§ 410.130 and 410.132. Sections 1861(s)(2)(V) and 1861(vv)(1) of the Act define MNT services as nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional pursuant to a referral by a physician (either an M.D. or D.O.) (as defined in section 1861(r)(1) of the Act). The current regulation further provides that Medicare pays for MNT services when the beneficiary is referred for the service by the treating physician, which is defined as the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease. As discussed above in section III.I.2. of this final rule and codified at § 410.132(c), we required referrals only by the treating physician when the beneficiary has been diagnosed with diabetes or a renal disease, with documentation maintained by the referring physician in the beneficiary's medical record. In the CY 2002 PFS final rule (66 FR 55246, November 1, 2001), we believed the treating physician requirement was necessary to ensure coordination of care by the primary care physician or specialist for beneficiaries with chronic diseases in order to assure quality (66 FR 55277). This relatively narrow definition, however, is now believed to have contributed to the low uptake of referrals to MNT services, although we note that few studies have examined MNT use.

We proposed to eliminate the requirement that the referral be made by the treating physician and, consistent with the language of the statute, require MNT services to be pursuant to a referral by a physician (as defined in section 1861(r)(1) of the Act) at §§ 410.130 and 410.132. It would be reasonable for any physician to refer a beneficiary to MNT. The treating physician restriction is no longer necessary to expect care to be coordinated. Care coordination between the hospital or post-acute care provider and the primary care provider is the goal and a standard of care in today's medical environment. We have worked to improve, through various efforts, the exchange of patient information between healthcare settings, and that a patient's healthcare information follows them after discharge from a hospital or post-acute care provider. Such improved transitions of care and exchange of information helps to assure that Medicare beneficiaries will continue to receive quality services. We proposed to delete the term treating and the definition of treating physician, as there is a separate definition for physician within this provision. Therefore, we did not propose any change to Medicare's definition of treating physician and the deletion of treating physician only applies to this provision.

b. Update the GFR Eligibility Criteria for Patients With CKD

We proposed to revise the regulations at § 410.130. Section 1861(s)(2)(V) of the Act states that MNT services are available to beneficiaries with diabetes or a renal disease. In 2001, we established the definition of chronic renal insufficiency for the purpose of the MNT benefit using definitions from the Institute of Medicine report, ''The Role of Nutrition in Maintaining Health in the Nation's Elderly.'' [107] The definitions and staging of CKD have evolved since the release of the report and stakeholders have noted that our definition does not reflect current medical practice. Therefore, we proposed to update the GFR eligibility criteria so that it aligns with up to date accepted standards for CKD stage 3 through stage 4, specifically GFR 15—59 mL/min/1.73m2. The accepted CKD staging system separates stage 3 into two parts: Stage 3–a; and Stage 3–b. Stage 3–a is GFR 45—59 mL/min/1.73m2. The existing regulatory upper limit of 50 mL/min/1.73m2 is mid stage 3–a and does not meet the widely accepted standard of when a person is diagnosed with moderate kidney disease. The NIDDK and National Kidney Foundation's staging of CKD align with the proposed change in GFR criteria.[108] [109]

We note that health care providers use estimated glomerular filtration rate, or eGFR, calculations to classify the severity of a person's disease, from mild loss of kidney function to end-stage

[107] IOM (2000). The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare. Retrieved from *http://www.nap.edu/catalog/9741.html.*

[108] NIH (National Institute of Diabetes and Digestive and Kidney Diseases) (2021). Kidney Disease Statistics for the United States. Retrieved from *https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.*

[109] National Kidney Foundation (2021). eGFR. Retrieved from *https://www.kidney.org/atoz/content/gfr.*

kidney disease.[110] The eGFR helps determine prognosis and treatment, such as when hemodialysis or a transplant may be needed. Since 1999, race has been a variable used in estimating GFR. Current eGFR calculations also use a person's age, sex, and serum creatinine levels. Serum creatinine, which the kidneys filter out, is a waste product from the normal metabolism of muscle cells in one's body. Studies have shown that Black Americans, on average, can have higher levels of serum creatinine in their blood, independent of kidney function. To account for this difference, eGFR calculations include a person's self-reported race to give more valid results. The use of self-reported race has been controversial. Misdiagnosis could lead to a person receiving incorrect drug dosing or delays in receiving dialysis or a kidney transplant. Current eGFR calculations could be exacerbating racial inequities in a disease that disproportionately affects Black people. Health care providers should be aware of ongoing research and evolving recommendations on GFR estimation in order to reduce and eliminate racial and ethnic disparities.

3. Summary of Regulatory Text Changes

We proposed to make changes to the treating physician requirements and GFR eligibility criteria outlined in §§ 410.130 and 410.132, consistent with statutory limitations. We proposed to revise §§ 410.130 (definitions) and 410.132 (MNT) by: (1) Revising the chronic renal insufficiency definition; (2) striking the treating physician definition; and (3) revising conditions for coverage of MNT services, limitations on coverage of MNT services, and referrals.

(1) Definition of Chronic Renal Insufficiency

We proposed to revise § 410.130 by revising the chronic renal insufficiency definition by removing the GFR eligibility criteria of 13—50 ml/min/1.73m2 and replacing with 15—59 ml/min/1.73m2.

(2) Definition of Treating Physician

We proposed to revise § 410.130 by removing the definition of treating physician.

[110] National Institutes of Health (2021). NIH-supported study suggests alternative to race-based kidney function calculations. Retrieved from *https://www.nih.gov/news-events/news-releases/nih-supported-study-suggests-alternative-race-based-kidney-function-calculations.*

(3) Proposed Changes to Conditions for Coverage of MNT Services, Limitations on Coverage of MNT Services, and Referrals

At § 410.132, we proposed to revise conditions for coverage of MNT services, limitations on coverage of MNT services, and referrals by removing the terms ''the'' and ''treating,'' and replacing them with ''a,'' at paragraphs (a), (b)(5), and (c). In paragraph (c), we also proposed to strike the term, ''maintained,'' and replace it with the term, ''noted.''

4. Summary of Public Comments and Responses

We received public comments on the proposed revisions to the MNT benefit. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported the proposals to remove the treating physician requirement and update the chronic renal insufficiency GFR criteria at §§ 410.130 and 410.132. The commenters stated that they believe that by removing the requirement that the MNT referral be made by the treating physician, CMS will expand the reach of this important benefit. Commenters also supported aligning the chronic renal insufficiency criteria to reflect current medical practice regarding the standards for CKD stages 3 through 4, which is GFR 15—59 mL/min/1.73m2.

Response: We appreciate the commenters for their support of CMS' efforts to improve access and utilization of the MNT benefit.

Comment: Numerous commenters requested that CMS expand coverage of MNT services to individuals with other diseases and conditions, including malnutrition, prediabetes, obesity, eating disorders, cancer, HIV/AIDS, hypertension, dyslipidemia, gastrointestinal diseases, cardiovascular disease, and other conditions causing unintended weight loss.

Response: We do not have the authority to extend coverage beyond beneficiaries with diabetes or a renal disease as the benefit is defined in statute in section 1861(s)(2)(V) of the Act.

Comment: Several commenters requested that the definition of diabetes in § 410.130 include Hemoglobin A1C greater than 6.5 percent, as they noted is recommended in national standards of medical care for diabetes. They believe that the MNT regulation definition of diabetes is outdated. They noted that both the USPSTF and the American Diabetes Association Standards of Care recommend use of any of the following three testing methods to screen for abnormal blood glucose: Fasting plasma glucose; Hemoglobin A1C; and 2-hour plasma glucose.

Response: We appreciate the submission of this additional information from the commenters. We believe it is important to make changes to coverage provisions, including definitions, with the public's input using processes like notice and comment rulemaking. Because we did not propose and receive public comments on the definition of diabetes, we will not amend the definition in this final rule. We will consider revisions to the § 410.130 definition of diabetes with future rulemaking, with the opportunity for further public feedback.

Comment: Commenters advocated further expansion of the definition of renal disease in § 410.130 to include CKD stage 1 and stage 2. They noted that section 1861(s)(2)(V)(ii) of the Act allows for MNT for a beneficiary with diabetes or a renal disease who is not receiving maintenance dialysis.

Response: We appreciate the comment but we are not adopting the suggested changes in the definition of renal disease to refer to stages 1 and 2. We believe chronic renal insufficiency or CKD stages 3–4 (cross-referenced in the definition of renal disease, both defined in § 410.130) is the stage that interventions are often initiated in attempts to prevent progression of kidney disease to kidney failure and does not align with CKD stage 1 or stage 2. Furthermore, our definition of renal disease provides coverage of MNT for beneficiaries with chronic renal insufficiency (CKD stages 3–4) or end-stage renal disease (CKD stage 5 or kidney failure) when dialysis is not received, or post-transplantation kidney patients for 36 months; however, this does not include MNT services for beneficiaries with CKD stage 1 or stage 2.

Comment: Several commenters requested that CMS allow NPPs to make referrals to MNT, including NPs, PAs, and CNSs. One commenter described a few ways that they believe CMS could authorize NPs to refer for MNT, including: Utilizing the waiver authorities under sections 1115A (CMS Innovation Center Model) and 1899 (Medicare Shared Savings Program) of the Act; and clarifying that NPs are authorized to refer for MNT services as a component of the initial preventive physical examination (IPPE) and the annual wellness visit (AWV). They stated that the IPPE and AWV are Medicare covered services when

furnished by NPs, which include MNT referrals.

Response: As noted previously in this section of the final rule, section 1861(vv)(1) of the Act expressly requires the order of a physician for MNT to be covered under Part B; therefore, we are unable to extend MNT referral privileges to NPPs even if the NPP attempted to provide a referral for the service as a participant in the Medicare Shared Savings Program (section 1899 of the Act) or as part of the IPPE or AWV. The comments addressing CMS 1115A waiver authorities are appreciated and we will take these comments into consideration; although, the process for the Center for Medicare and Medicaid Innovation to develop and select a test model is out of scope of this proposed rule, and therefore, we are not addressing in this final rule.

Comment: A few commenters expressed concern that the quality of care may be compromised if the treating physician requirement is removed. One commenter requested a reporting requirement to the treating physician by the registered dietician or nutrition professional at the onset of the MNT services, and periodic updates to the treating physician during the course of treatment. The commenter stated that the primary care physician or specialist is primarily responsible for coordinating all the patient's care and must be kept up to date on all critical services and resulting outcomes.

Response: We believe a reporting requirement would place undue burden on the registered dietitian or nutrition professional providing the MNT service. As noted previously in this section of the final rule, we believe the treating physician restriction is no longer necessary to expect care coordination between the referring provider and the primary care provider, and therefore, does not require a regulatory mandate for reporting. We have worked to advance the appropriate access and sharing of a beneficiary's medical information between health care settings. Such efforts help to improve the quality, safety, and efficiency of health care delivery.

After consideration of public comments, we are finalizing the changes as proposed to the treating physician requirement and to update the GFR criteria in the regulations at §§ 410.130 and 410.132. Therefore, we are also finalizing the regulatory language as proposed.

5. Summary

The MNT services may help reduce illnesses and improve quality of life for people with diabetes or renal disease. We believe the changes to the treating physician requirements and GFR eligibility criteria are in the best interest of the Medicare program and its beneficiaries. The physician requirement change will increase the capacity and availability of physicians who can refer beneficiaries to MNT, which would alleviate some of the demand on primary care physicians as the usual source to perform this particular function. We note that stakeholders have contacted us and suggested such flexibility in the past. We recognize that MNT is not a highly utilized service and we believe these revisions will allow for Medicare patients to gain greater access to MNT services.

J. Medicare Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.) Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255, December 13, 2016). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018), further amended section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-

Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Refer to the CY 2020 PFS proposed rule for a summary of policies finalized in prior PFS rules (84 FR 40705). In the CY 2020 PFS final rule (84 FR 62903 through 62914), we finalized refinements to the Shared Savings Program quality measure set and a technical change to the SNF 3-day rule waiver provision of the Shared Savings Program regulations. In the CY 2021 PFS final rule, we finalized new Shared Savings Program quality reporting requirements that align with the Alternative Payment Model (APM) Performance Pathway (APP) under the Quality Payment Program and revised the quality performance standard for performance years beginning on or after January 1, 2021, to reduce reporting burden and focus on patient outcomes. We also finalized a policy that waived the requirement that ACOs administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey for performance year 2020. In addition, we finalized updates to the definition of primary care services used for beneficiary assignment, and policies to reduce burden associated with repayment mechanisms. In the CY 2021 PFS final rule, we also finalized the Shared Savings Program provisions included in the March 31, 2020 COVID–19 IFC and the May 8, 2020 COVID–19 IFC, with several modifications in response to public comments received.

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program.

In sections III.J.1 through III.J.5. of this final rule, we summarize and respond to comments we received on the proposed modifications to the Shared Savings Program's policies discussed in section III.J of the CY 2022 PFS proposed rule (86 FR 39261 through 39291). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the policies addressed in section III.J. of the CY 2022 PFS proposed rule, and will not be addressed in this section of this final rule. As a general summary, in sections III.J.1 through III.J.5 of this final rule, we are finalizing the following changes to Shared Savings Program policies to:

- Amend the reporting requirements under the APM Performance Pathway (APP) for performance year 2022 and subsequent performance years.

++ Update the APM Performance Pathway (APP) measure set to remove the Risk-Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions (MCC) for ACOs and replace it with the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS.

- Amend the quality performance standard for performance year 2023 by freezing the quality performance standard at the 30th percentile MIPS Quality performance category score and publicly displaying prior year performance scores that equate to the

30th or 40th percentile MIPS Quality performance category scores.

- Revise the extreme and uncontrollable circumstances policy to align with the decision to freeze the quality performance standard at the 30th percentile MIPS Quality performance category score for performance year 2023.
- Update the definition of primary care services used in beneficiary assignment at § 425.400(c).
- Revise the repayment mechanism arrangement policy in the following manner:

++ To reduce the percentages used in the existing methodology for determining the repayment mechanism amount and to specify the number of assigned beneficiaries used as a multiplier in the calculations, such that the ACO's repayment mechanism amount would be calculated as the lesser of the following: (1) One-half percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures and the number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

++ To specify how we identify the number of assigned beneficiaries used in the repayment mechanism amount calculation and the annual repayment mechanism amount recalculation.

++ To allow a one-time opportunity for certain ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to decrease the amount of their existing repayment mechanisms.

++ To revise the threshold for determining whether an increase in the repayment mechanism amount is required.

- Streamline the application process by revising requirements concerning the disclosure of prior participation in the Shared Savings Program by the ACO, ACO participants, and ACO providers/suppliers, in light of other requirements that consider an ACO's prior participation.
- Reduce the frequency and circumstances under which ACOs submit sample ACO participant agreements and executed ACO participant agreements to CMS.
- Amend the beneficiary notification requirement as it applies to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation.

We also describe several comment solicitations that were included in section III.J of the CY 2022 PFS proposed rule in the following sections of this final rule: III.J.1.c.(1) (Addressing Health Disparities and Promoting Health Equity), III.J.1.c.(2) (Feasibility of TIN Level Reporting and Sampling for eCQMs/MIPS CQMs), III.J.1.c.(3) (Reporting Options for Specialist Providers within an ACO), and section III.J.6 (Considerations Related to the Use of Regional FFS Expenditures and the Risk Adjustment Methodology in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark).

1. Quality and Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. In the November 2011 final rule, we adopted a quality measure set spanning four domains: Patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We subsequently updated the measures comprising the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, and 83 FR 59707 through 59715 respectively).

Between performance years 2017 (the first performance year under MIPS) and 2020, eligible clinicians who were participating in an ACO and who were subject to MIPS (MIPS eligible clinicians) were scored under the APM scoring standard under MIPS (81 FR 77260). These clinicians include any MIPS eligible clinicians who were participating in an ACO in a track, or payment model within a track (Track 1 and Levels A through D of the BASIC track) of the Shared Savings Program that is not an Advanced APM, as well as those MIPS eligible clinicians participating in an ACO in a track, or payment model within a track (Track 2, Level E of the BASIC track, and the ENHANCED track, or the Medicare ACO Track 1+ Model (Track 1+ Model)) that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS.

In the CY 2021 PFS final rule, CMS finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for performance year 2021 and subsequent performance years (85 FR 84720 through 84736). For performance year 2021 and subsequent years, ACOs are required to report quality data via the APP. In addition, CMS finalized a phase-in approach to the new Shared Savings Program quality performance standard that ACOs must achieve in order to be eligible to share in savings or avoid maximum losses. This phase-in allows for a gradual increase of the quality performance standard from a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores in performance years 2021 and 2022 to a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores in performance year 2023 and subsequent years.

b. Clarification of the Application of CAHPS for MIPS Sampling Policies to Shared Savings Program ACOs

In the CY 2021 PFS final rule (85 FR 84722), we finalized that beginning in performance year 2021, Shared Savings Program Accountable Care Organizations (ACOs) are required to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). As part of the APP, ACOs are required to administer the CAHPS for MIPS survey (85 FR 84730 through 84732).

In the CY 2021 PFS final rule, we noted, in response to public comments, that the CAHPS for MIPS survey uses the same survey instrument to assess the same patient experience domains (or Summary Survey Measures (SSMs)) as the CAHPS for ACO survey. We noted that both the CAHPS for MIPS and the CAHPS for ACOs survey use the same shortened, streamlined version of the

survey that we implemented for both CAHPS for ACOs and CAHPS for MIPS in 2018, reflecting efforts by CMS to reduce the number of questions. Moreover, in 2019, the two programs used identical survey instruments.

As discussed in the CY 2021 PFS final rule, we conducted analyses to assess the impact of aligning CAHPS scoring and benchmarking using 2019 CAHPS for ACOs and CAHPS for MIPS data. The results of these analyses indicate that scoring ACOs using the MIPS methodology resulted in ACOs having a similar distribution of quality points as MIPS groups. This distribution was wider than the distribution of quality points using the ACO scoring methodology largely due to differences across the two programs in the approach to benchmarking (85 FR 84731).

In addition, we clarified that beneficiaries assigned to an ACO or MIPS group, who are eligible for the CAHPS for MIPS or CAHPS for ACOs survey, are randomly selected for inclusion in the sample. Samples are drawn at the ACO level for CAHPS for ACOs and at the TIN level for MIPS groups. Therefore, each ACO or MIPS group sample is representative of the ACO or group population.

We stated that due to the alignment of CAHPS for ACOs with CAHPS for MIPS, we will use the benchmarking and scoring methodology for CAHPS for MIPS to assess ACOs' performance on the CAHPS survey measures. We explained that a single set of benchmarks will be calculated using data from all applicable CAHPS for MIPS reporters. We score the CAHPS for MIPS survey as one quality measure, which is a different scoring approach from the Shared Savings Program quality scoring methodology, which scored the 10 CAHPS for ACOs SSMs in one patient/caregiver experience quality domain. As described in the CY 2017 Quality Payment Program final rule (81 FR 77284), each scored SSM has an individual benchmark and is scored individually and compared against the benchmark to establish the number of points earned. The CAHPS score is the average number of points across scored SSMs.

As stated in the CY 2021 PFS final rule (85 FR 84731), eligible beneficiaries assigned to an ACO or MIPS group are randomly selected to be included in the sample for the CAHPS for ACOs or CAHPS for MIPS survey. In the CY 2021 PFS final rule, we explained that the target sample size for CAHPS samples for all participating ACOs, groups, and virtual groups is 860; for ACOs, groups, and virtual groups with 860 or more survey-eligible patients, a random sample of 860 patients is drawn. We also noted that groups and virtual groups with fewer than 860 survey-eligible patients are eligible to participate in the CAHPS for MIPS if they meet the minimum sampling thresholds for CAHPS for MIPS:

- Large groups or virtual groups with 100 or more eligible clinicians: 416 eligible patients.
- Medium groups or virtual groups with 25–99 eligible clinicians: 255 eligible patients.
- Small groups or virtual groups with 2–24 eligible clinicians: 125 eligible patients.

These minimum sampling thresholds are necessary to ensure that groups have an adequate sample size to ensure that the survey responses will be representative of the care furnished by the clinicians in the group. Groups that do not have an adequate sample size would be at risk for not receiving enough survey responses to be representative of the care provided.

In the CY 2021 PFS final rule, we stated that we will continue to draw the CAHPS survey samples for Shared Savings Program ACOs administering the CAHPS for MIPS survey at the Shared Savings Program ACO level, with a target sample size of 860 going forward. Although we did not specifically state in the CY 2021 PFS final rule that the MIPS minimum sampling thresholds would also apply to ACOs participating in the Shared Savings Program, in the CY 2022 PFS proposed rule (86 FR 39264), we clarified that the sampling thresholds apply for performance year 2021 and subsequent years. As we explained in the CY 2022 PFS proposed rule, by adopting the APP as the reporting mechanism for Shared Savings Program ACOs, we replaced the CAHPS for ACOs that was previously used in the Shared Savings Program with the CAHPS for MIPS. In the CY 2022 PFS proposed rule, we stated that our intent in including the CAHPS for MIPS in the APP was to align reporting requirements under the Shared Savings Program with MIPS. Thus, as we noted in the CY 2022 PFS proposed rule, we believe that the discussion in the CY 2021 PFS final rule regarding the CAHPS for MIPS minimum sampling thresholds for groups and virtual groups can be reasonably understood to indicate that the CAHPS for MIPS minimum sampling thresholds would also apply to Shared Savings Program ACOs. We also noted that we had received stakeholder feedback after the publication of the CY 2021 PFS final rule asking whether the CAHPS for MIPS minimum sampling thresholds would also apply to Shared Savings Program ACOs. As stated in the CY 2022 PFS proposed rule, based on the feedback we had received, we determined that it was necessary to clarify that the minimum sampling threshold will apply.

As discussed in the CY 2022 PFS proposed rule, minimum sampling thresholds are necessary to ensure that ACOs have an adequate sample size to ensure that the survey responses will be representative of the care furnished by the ACO clinicians. As we stated in the proposed rule, we do not want ACOs to be required to contract with a vendor to administer the survey if there is a high risk that the ACO will not have a sufficient sample size to generate a response rate for the survey that will be sufficient to reliably calculate a score for the CAHPS for MIPS survey. We noted that aligning the minimum sampling thresholds for ACOs with the CAHPS for MIPS minimum sampling thresholds allows for consistency across all entities reporting the CAHPS for MIPS. Furthermore, we noted our belief that applying the CAHPS for MIPS minimum sampling thresholds does not negatively impact Shared Savings Program ACOs because only a few ACOs would potentially be impacted by these minimum sampling thresholds.

In the proposed rule, we noted that based on the analysis of proxy data from 2020, nearly all ACOs will fall into the large size classification; that is, they will have 100 or more eligible clinicians that have assigned their billing to TINs participating in the ACO. To quantify the actual number of eligible clinicians associated with each ACO, we used the latest available reassignment and claims data from an internal file that is regularly created twice each performance year to identify the number of individual providers (NPIs) associated with each ACO's participant TINs. We conducted an analysis with proxy ACO sampling frames from 2020 and 44 ACOs fell into the medium size category of 25–99 eligible clinicians, and no ACOs were determined to have fewer than 24 eligible clinicians. Based on this analysis, we estimated that few ACOs would not be able to administer the CAHPS for MIPS due to sample size. All ACOs classified as medium-sized had more than 860 beneficiaries eligible for sampling. However, based on our analysis, we noted that one large-sized ACO would not have been able to administer the CAHPS survey for performance year 2020, if we had required ACOs to administer a CAHPS for MIPS survey in performance year 2020 and these sampling rules had applied at that time because the sample

size requirements would not have been met. Two additional large-sized ACOs were close to the minimum sampling threshold and would have been at risk for not being able to administer the CAHPS for MIPS survey for performance year 2020. We noted that in both cases, these ACOs would have been eligible for CAHPS sampling based on their counts of assigned, quality-eligible [111] beneficiaries with two visits during the performance year; however, a large proportion (over 50 percent) of the beneficiaries assigned to these ACOs were residing in nursing homes and institutionalized beneficiaries are excluded from CAHPS for MIPS sampling.

Given that the minimum sampling sizes are set to ensure that groups or ACOs receive enough responses to be representative of the care their clinicians provide, we stated in the proposed rule that we believe it is important that we should not burden ACOs that fall below the thresholds with the cost of hiring a vendor and fielding a CAHPS for MIPS survey that may not produce enough responses to calculate the CAHPS for MIPS score. Accordingly, we stated that we will inform any ACO that is at risk of falling below the minimum sampling threshold that it may not have enough beneficiaries to field a CAHPS for MIPS survey prior to the deadline for contracting with a CAHPS for MIPS survey vendor. An ACO that does not meet the minimum sampling threshold to administer the survey will not receive a score for the CAHPS for MIPS survey under the APP. When an ACO fails to meet the sampling threshold and is unable to administer the survey, the ACO's measure set will be scored accordingly, and the number of measures included in the calculation of the ACO's quality performance score will be reduced from 10 to 9 measures or from 6 to 5 measures in the APP for performance year 2021. This means that the denominator used to calculate the quality score will be lower, such that an ACO that falls below the minimum threshold will not be penalized for its inability to administer a CAHPS for MIPS survey.

We solicited comment on this clarification. The following is a summary of the comments we received and our responses.

Comment: One commenter supported CMS' decision not to penalize ACOs that are unable to administer the CAHPS for MIPS survey because they fall below the minimum sampling threshold.

Response: We thank the commenter for their support.

Comment: One commenter expressed concern that the 860-beneficiary sample size is the same for all ACOs regardless of their size and may not adequately represent an ACO's full population.

Response: Although the overall number of assigned beneficiaries may differ between small, medium, and large ACOs, we believe that a sample size of 860 beneficiaries is reasonable and will produce scores on the CAHPS for MIPS measure meeting the adequate reliability threshold regardless of the size of an ACO's assigned beneficiary population. As we explained in the CY 2021 PFS final rule (85 FR 84731), eligible beneficiaries who are assigned to an ACO or MIPS group are randomly selected to be included in the sample for the CAHPS for MIPS survey. The use of a randomly selected survey sample ensures that the sample will be representative of the overall population served by the ACO or MIPS group. The target sample size of 860 beneficiaries was established using the results of analyses that sought to establish measures that allowed for meaningful comparisons to be made across ACOs and MIPS groups.

Accordingly, consistent with the clarification discussed in the CY 2022 PFS proposed rule, the CAHPS for MIPS minimum sampling thresholds will apply to Shared Savings Program ACOs for performance year 2021 and subsequent performance years.

In the CY 2022 PFS proposed rule (86 FR 39265), we also noted that the term ''performance period'' is used to describe the time-period over which quality performance is assessed under MIPS, which is a full calendar year (January 1 through December 31) (except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures). In contrast, the Shared Savings Program uses the term ''performance year'' to describe each period for which ACOs' quality performance is assessed. For performance year 2021 and subsequent performance years, the relevant period is also the full calendar year. Therefore, in the proposed rule, we further clarified that while the terminology used in the Shared Savings Program and MIPS differs, the period of time for which quality performance is assessed under the APP is the same for both programs.

c. Amending the Reporting Requirements Under the APM Performance Pathway for Performance Years 2022 and 2023

In the CY 2021 PFS final rule, we finalized a change to the quality reporting requirements for purposes of the Shared Savings Program (85 FR 84720 through 84734). Effective for performance year 2021 and subsequent performance years, Shared Savings Program ACOs are required to report quality data via the APP. The quality reporting requirements under the Shared Savings Program align with the requirements that apply under the APP under the Quality Payment Program. Under this new approach, ACOs only need to report one set of quality metrics via the APP to satisfy the quality reporting requirements under both the Shared Savings Program and the MIPS. The quality measures reported via the APP for purposes of the MIPS Quality performance category will also be used to determine the quality performance of the ACO for purposes of determining eligibility for shared savings and calculating shared losses, where applicable. We refer readers to the CY 2022 PFS proposed rule (86 FR 39265 and 39266) for an overview of the requirements for ACOs reporting under the APP that were adopted in the CY 2021 PFS final rule.

In the CY 2022 PFS proposed rule (86 FR 39266), we explained that, since the CY 2021 PFS final rule was issued, stakeholders have continued to express concerns about requiring ACOs to report eCQMs/MIPS CQMs via the APP due to the cost of purchasing and implementing a system wide infrastructure to aggregate data from multiple ACO participant TINs and varying EHR systems. We noted that for performance years beginning on or after January 1, 2019, ACOs are required to certify that they meet the CEHRT use requirements as specified at § 425.506(f). Specifically, an ACO in a track that:

- Does not meet the financial risk standard to be an Advanced APM must certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds 50 percent; or
- Meets the financial risk standard to be an Advanced APM must certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds

[111] Quality-eligible refers to assigned beneficiaries that were alive, enrolled in Medicare Part A and Part B for the whole performance period, were not in hospice, and did not reside outside of the United States.

the threshold established under § 414.1415(a)(1)(i).

We noted that we define CEHRT for purposes of the Shared Savings Program at § 425.20 and the term has the same meaning as provided under § 414.1305 for purposes of the Quality Payment Program. For 2019 and subsequent years, CEHRT is defined to mean EHR technology that meets the 2015 Edition Base EHR definition and that has been certified to the 2015 Edition health IT certification criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category and includes clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures that can be electronically accepted by CMS. Health IT certified to clinical quality measure certification criteria can help to support ACOs' efforts to meet quality measure reporting requirements.

We stated that, according to a National Association of Accountable Care Organizations (NAACOS) survey [112] regarding the readiness of ACOs to report eCQM/MIPS CQM data, 77 percent of respondents had indicated they do not have the infrastructure in place to aggregate data on behalf of their ACO participant TINs on quality performance across all payers starting in 2022. On average, an ACO has 36 ACO participant TINs and the largest Shared Savings Program ACO has 436 ACO participant TINs. The NAACOS survey also noted that almost 40 percent of ACOs have more than 15 EHR systems. Additionally, we noted that stakeholders had raised privacy and other concerns about reporting eCQMs/MIPS CQMs on all-payer populations, rather than a sample of assigned Medicare beneficiaries, as required for the CMS web interface measures. These concerns focused on perceived HIPAA Privacy Rule limitations on sharing protected health information (PHI) for non-Medicare beneficiaries with an ACO.

We also stated in the proposed rule (85 FR 39266) that we had heard concerns from ACOs that are acting, for the purpose of HIPAA compliance, as business associates of their health care provider ACO participants regarding their ability to update their business associate agreements (BAAs) to include the PHI of patients who are not covered by Medicare. Stakeholders indicated that their current agreements may only address sharing the PHI of Medicare beneficiaries. Therefore, they raised concerns that reporting all payer eCQMs would violate their BAAs, as well as the HIPAA Privacy Rule business associate requirements at 45 CFR 164.502(a) and 164.504(e).

As we noted in the proposed rule, to report eCQMs successfully, health care providers must adhere to the requirements identified by the CMS quality program in which they intend to participate (86 FR 39266). For purposes of reporting eCQMs/MIPS CQMs under MIPS, clinicians are expressly required under § 414.1340(a) to submit data on the applicable percentage of patients that meet the measure's denominator criteria, regardless of payer. Under § 414.1380(b)(1)(i)(B)(1)(*iii*), failure to meet this requirement may result in the clinician receiving zero points for the measure, which may adversely impact their MIPS final score and payment adjustment. As such, in the proposed rule, we stated our belief that the disclosure of all-payer data to CMS as required by § 414.1340(a) would be permitted by the HIPAA Privacy Rule under the provision that permits disclosures of PHI as ''required by law.'' [113] Under this provision, a HIPAA covered entity, or its business associate when authorized by its BAA, may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. We also noted that the HIPAA Privacy Rule minimum necessary standard does not apply to uses or disclosures that are required by law.[114]

Furthermore, we stated that the HIPAA Privacy Rule generally permits a covered entity to disclose PHI to a business associate and to allow a business associate to create, receive, maintain, or transmit PHI on its behalf, provided that the parties have a BAA that meets the requirements of 45 CFR 164.504(e) and permits the business associate to use or disclose PHI only as permitted or required by its BAA or as required by law. The BAA must, among other things, establish the permitted and required uses and disclosures of PHI by the business associate. Accordingly, we explained that ACO providers and suppliers that are MIPS eligible clinicians will need to review and update any relevant BAAs as necessary to include the disclosure of all-payer data, in addition to data for Medicare beneficiaries to the ACO. We stated that we believe ACO providers/suppliers should be able to update those agreements, in consultation with their legal counsel as necessary, to reflect the need to share data for patients covered by all payers with the ACO, in order to permit the ACO to completely and accurately report data on eCQMs/MIPS CQMs consistent with the MIPS reporting requirements.

In addition, we corrected a statement from the CY 2021 PFS final rule (85 FR 84730). In that final rule, we provided an example of how an ACO could aggregate eCQM measure data. In this example, we stated that an ACO could, on behalf of its ACO participants, combine the results from all the ACO participant TIN QRDA 3 files, by adding numerators, denominators, etc. and create an aggregate QRDA 3 file (or other compliant file format) and submit as an ACO to CMS. However, as explained in the CY 2022 PFS proposed rule (86 FR 39267), this example did not take into account the potential for duplicate patients for a given measure across the ACO participant TINs within an ACO. It also did not take into account that two of the three eCQMs require that the most recent blood pressure or HgbA1c be captured to assess performance for those measures. Accordingly, we clarified that an ACO that submits eCQM quality data to CMS must de-duplicate the patient level measures data across its ACO providers/suppliers to ensure that the aggregated QRDA 3 file that is submitted to CMS incorporates only quality data that meets the intent of the measure.

As discussed in section IV.A.3.d.(1)(d) of the CY 2022 PFS proposed rule, we proposed to extend the CMS Web Interface as a collection type for the Quality Payment Program for PY 2022 for MIPS Groups, Virtual groups, and Shared Savings Program ACOs reporting under the APP. For PY 2023, we proposed that the CMS Web Interface would be a collection type under the APP only for Shared Savings Program ACOs. Accordingly, we proposed to modify the quality measure set that must be reported by Shared Savings Program ACOs under the APP, as discussed in section III J.1.c. and section IV.A.3.c.(2)(a) of the CY 2022 PFS proposed rule.

To further address stakeholder feedback about ACOs' readiness to report all-payer measures, and in particular the concerns regarding aggregation of eCQM/MIPS CQM data across multiple ACO participant TINs using multiple different EHR technology, while also providing incentives for ACOs to take the steps necessary to report all-payer measures, we proposed that:

[112] *https://www.naacos.com/assets/docs/pdf/2021/NAACOS-QualityhandoutCCSQmeeting03222021.pdf.*

[113] See 45 CFR 164.512(a).

[114] See 45 CFR 164.502(b)(2)(v).

• For performance year 2022: An ACO would be required to report on either:

++ The ten CMS Web Interface measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims-based measures included under the APP, or

++ The three eCQM/MIPS CQMs and administer a CAHPS for MIPS survey and CMS would calculate the two claims-based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable, for that performance year. In the CY 2022 PFS proposed rule (86 FR 39267), we stated that we believed that allowing ACOs that report eCQMs/MIPS CQMs to meet the quality performance standard if they achieve a score that is equivalent to or higher than the 30th percentile benchmark on one measure in the APP measure set would provide an incentive to ACOs to report the eCQMs/MIPS CQMs, while allowing them time to gauge their performance on the eCQMs/MIPS CQMs before full reporting of these measures required beginning in performance year 2024. We proposed that if an ACO chooses this option, its performance on all three eCQMs/MIPS CQMs would be used for purposes of MIPS scoring under the APP. We also noted that if an ACO decides to report both the ten CMS Web Interface measures and the three eCQMs/MIPS CQMs, it will receive the higher of the two quality scores for purposes of the MIPS Quality performance category.

If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO would not meet the quality performance standard. We proposed that:

• For performance year 2023: The ACO would be required to report on either:

++ The ten CMS Web Interface measures, at least one eCQM/MIPS CQM, and administer a CAHPS for MIPS survey and CMS would calculate the two claims-based measures included under the APP; or

++ The three eCQMs/MIPS CQMs and administer a CAHPS for MIPS survey and CMS would calculate the two claims-based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable, for that performance year. If an ACO chooses this option, its performance on all three eCQMs/MIPS CQMs would be used for purposes of MIPS scoring under the APP. We also noted that if an ACO decides to report both the ten CMS Web Interface measures and the three eCQMs/MIPS CQMs, it will receive the higher of the two quality scores for purposes of the MIPS Quality performance category.

We also proposed that if an ACO does not report at least one eCQM/MIPS CQM in the APP measure set, the ACO would not meet the quality performance standard.

• For performance year 2024 and subsequent performance years: The ACO would be required to report the three eCQMs/MIPS CQMs and administer a CAHPS for MIPS survey and CMS would calculate the two claims-based measures included under the APP. If an ACO does not report any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO would not meet the quality performance standard.

Finally, for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO meets MIPS data completeness and case minimum requirements, we proposed that the ACO would meet the quality performance standard, if:

• For performance year 2022. The ACO reports the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs and administers a CAHPS for MIPS survey under the APP.

• For performance year 2023. The ACO reports the ten CMS Web Interface measures and at least one eCQM/MIPS CQM measure or reports the three eCQMs/MIPS CQMs, and administers a CAHPS for MIPS survey under the APP.

• For performance year 2024 and subsequent performance years. The ACO reports on the three eCQMs/MIPS CQMs and administers a CAHPS for MIPS survey under the APP.

We proposed changes to the regulation at § 425.512(a) to reflect these changes to the quality reporting requirements for performance years 2022 and 2023.

We solicited comment on these proposed updates to the reporting requirements under the APP for performance year 2022 and subsequent years. In addition, we solicited comment on whether we should extend the CMS Web Interface collection type for more than the 2 years proposed. We explained our belief that the proposed 2-year extension would provide sufficient time to allow ACOs and their ACO participants to take the necessary steps to address the concerns raised by stakeholders, but noted that we were interested in hearing if stakeholders believe additional time would be needed to enable ACOs and their ACO participants to prepare for eCQM/MIPS CQM reporting.

We received several public comments on the proposed updates to the reporting requirements under the APP for Shared Savings Program ACOs for performance year 2022 and subsequent years. We also received several public comments in response to our comment solicitation on the extension of the CMS Web Interface as a collection type. The following is a summary of the comments we received and our responses.

Comment: We received several comments in support of the proposed updates to the reporting requirements under the APP for Shared Savings Program ACOs. Several commenters supported CMS' acknowledgement of the complexity of the transition to all-payer eCQMs/MIPS CQMs. Another commenter appreciated the ability to test the reporting of eCQMs without the risk of being penalized. One commenter supported CMS' plans to improve data collection and reduce burden through digital quality measurement and applauded CMS for being responsive to ACO and other stakeholder concerns regarding the timeline. Several commenters appreciated CMS' proposal to provide more time to implement new systems to allow for aggregating all-payer data across multiple EHR systems and multiple health care practices. One commenter supported the transition to the reporting and submission of all-payer data for the three eCQMs/MIPS CQMs and stated their organization's readiness to support ACOs to be able to report on these measures. Another commenter encouraged CMS to improve education and guidance to support the transition.

Response: We have provided many resources and will continue to provide such resources to support ACOs as they

transition to reporting the 3 eCQMs/MIPS CQMs. Commenters should refer to the ''PY2021 APM Performance Pathway Toolkit'' that is available on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library.* This toolkit contains multiple documents on how to report under the APP for performance year 2021 and how to aggregate data to the ACO level, a scoring guide, and a document describing the specific APP policies that apply to Shared Savings Program ACOs. These documents will be updated for each upcoming performance year.

Comment: Several commenters expressed concerns about the proposed updates to the quality reporting requirements and the timeline for ACOs to transition to reporting eCQMs/MIPS CQMs given that it could be difficult for an ACO to test eCQM reporting. Further, these commenters expressed concerns regarding industry's readiness to implement, test, and prepare all systems to report eCQMs/MIPS CQMs in 2 years. Several commenters appreciated the gradual transition to reporting eCQMs/MIPS CQMs, but stated that the proposal to require reporting on just one eCQM/MIPS CQM would require the same technological and administrative lift as reporting on all three eCQMs/MIPS CQMs and recommended that CMS remove its proposal to require reporting on at least one eCQM/MIPS CQM in 2023.

Several commenters recommended that CMS delay the eCQM/MIPS CQM reporting requirements. Some commenters suggested a delay of 2–5 years, and a few commenters suggested delaying until there have been sufficient EHR and IT improvements to make reporting eCQMs ''feasible,'' including more standard data fields and interoperability to resolve issues with aggregating eCQM data at the ACO level. Some commenters stated that the need for IT improvements disproportionately impacts independent physician practices, and those serving rural and underserved populations.

Response: We interpret the commenters' note about the infeasibility of reporting eCQMs as a reference to the inability of ACOs to update their infrastructure and establish the workflows needed to aggregate data and report on the 3 eCQMs/MIPS CQMs. As such, we believe allowing an additional year beyond the 2-year extension of the CMS Web Interface collection type proposed in the CY 2022 PFS proposed rule will provide ACOs with the time necessary to prepare to implement and report on the eCQM/MIPS CQMs. This further extension will allow ACOs additional time to ensure that they have the necessary infrastructure in place to successfully meet the new quality reporting requirements. We further believe that this additional time will help to ensure appropriate development and testing of the systems necessary to collect and aggregate data across ACO participants. The additional time will also ensure that ACOs can begin to create the workflows in their systems and make the necessary updates to report on the eCQM/MIPS CQMs. We believe this extended transition will also address commenters' concerns about the impact of the new reporting requirements on independent physician practices serving rural and underserved populations.

We understand the concern that the components of implementing an interoperable system are the same regardless of the number of eCQM/MIPS CQMs required to be reported. As a result, we also understand commenters' concern that our proposed requirement that ACOs report on at least one eCQM/MIPS CQM for performance year 2023 would likely impose the same burden as reporting all three eCQM/MIPS CQMs, given the necessary updates to their EHR systems, data aggregation, and workflow mappings that would be required to report one eCQM/MIPS CQM. In light of these concerns, we are not finalizing our proposal to require ACOs to report on at least one eCQM/MIPS CQM for performance year 2023 as discussed in section III.J.1.c of this final rule.

Comment: Many commenters generally supported the use of eCQMs, but had concerns about whether accurate, complete, and comparable eCQM reporting can be accomplished in the proposed 2-year extension period and supported further extending the timeframe until these challenges have been addressed. One commenter had concerns about including data from patients who receive care from non-ACO physicians or specialists in the same practice locations as physicians who are ACO providers/suppliers. Another commenter had concerns with the inclusion of emergency physicians, who may be participating in a Shared Savings Program ACO, but may not have an active role in the ACO. Another commenter recommended that CMS allow ACOs to exclude ACO participant TINs that use EMRs with insufficient quality data reporting capabilities. Another commenter questioned how data completeness standards could be met, given the issues of de-duplication and patients adding or moving insurance coverage. Many commenters called for CMS to provide more education and guidance to support ACOs in successfully transitioning to eCQM reporting given the complexities. A few commenters pointed out the added difficulty of making the changes necessary to transition to eCQM reporting during a global pandemic. One commenter expressed concern that eCQMs include data from an ACO's entire patient population, stating that this could penalize ACOs that include safety net clinics whose patients face social determinants of health (SDOH) barriers that drive down quality results. One commenter shared their concern regarding the shift from comparing the quality of care provided between ACOs to broadening this comparison to include all MIPS eligible clinicians. This commenter noted that the quality data reported by ACOs reflects coordination of care across the care continuum while MIPS reporting reflects care provided by individual clinicians and groups.

Response: We understand the concerns raised by the commenters regarding reporting on care from non-ACO practitioners. The determination of whether a service provided by a non-ACO practitioner would be attributed to the ACO TIN depends on the type of care being provided, the timing of the service, and confirmation by the ACO TIN that the patient received the service. If a physician or other practitioner does not bill under the TIN of an ACO participant, and thus, is not considered to be participating in the ACO, then a visit with this health care provider would not need to be included in the denominator for a measure's performance data. However, actions taken by a practitioner outside the ACO could be included in the measure's numerator of the ACO if the action of the practitioner occurs within the same reporting period and meets the criteria for the measure's numerator and the practitioner is coordinating with health care providers in the ACO.

We appreciate the commenters' concerns and recommendations regarding the shift from comparing quality performance between ACOs to comparing all MIPS eligible clinicians. We believe by assessing ACO quality performance in relation to all Medicare FFS reporters, MIPS eligible clinicians, APM entities and other ACOs eliminates differences in the way ACOs are scored compared to their MIPS eligible clinicians.

In reference to the commenter's concern regarding how data completeness could be met given issues of de-duplication, we note that the ACO would utilize the QRDA I format, which specifies patient level collection of data

from each of the ACO's participant TINs. The ACO would then aggregate these data across the ACO and submit them to CMS in the QRDA III format. Collecting and aggregating these data in the QRDA I format allows for de-duplication given the granularity of the data. In reference to patients who change or add different insurance, we note that patients regularly change coverage but that does not remove the patients' data from the EHR. We believe requiring ACOs to transition to reporting eCQMs/MIPS CQMs should help further align quality measurement and improvement efforts, improving quality of care provided.

Comment: Several commenters expressed concerns regarding technical aspects of the data aggregation that is needed to report eCQMs/MIPS CQMs. One commenter cited that QRDA III files provide de-identified aggregate data, making it difficult to aggregate data or report eCQMs at the ACO level. Another commenter expressed concern that aggregated summary-level data submitted with QRDA III files for eCQMs, including data reported by specialists, would not be representative of the primary care received by the patient. A few commenters were concerned that aggregation of data would raise HIPAA concerns and require patient consent, to share non-Medicare patient information with the ACO and with CMS for a population that is not assigned to the ACO. They noted that obtaining this consent would be an additional burden.

Response: As noted previously, use of the QRDA I format does not have the same limitations with respect to de-identified aggregate data that make the QRDA III ill-suited for compiling the information needed to report eCQMs/MIPS CQMs at the ACO level.

We will continue to add documents to the ''PY2021 APM Performance Pathway Toolkit'' that is available on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library* to provide guidance on how the data should be reported to CMS.

We also recommend that ACOs refer to the measure specifications for each of the eCQMs. Specifications for all eCQMs can be found in the QPP resource library in the zip file titled ''2021 Electronic Clinical Quality Measures (eCQMs) Specifications''. These documents can be found in the QPP resource library at *https://qpp.cms.gov/resources/resource-library*.

With respect to the HIPAA concerns raised by commenters, for the reasons discussed in the CY 2022 PFS proposed rule (86 FR 39266 and 39267), we believe the disclosure of all-payer protected health information to CMS as required by § 414.1340(a) is permitted by the HIPAA Privacy rule under the provision that permits disclosures as ''required by law'' of an individual's PHI ''without the written authorization of the individual . . . or the opportunity for the individual to agree or to object.'' [115] As we noted in the proposed rule, the HIPAA Privacy Rule minimum necessary standard does not apply to uses or disclosures that are required by law.[116]

Regarding disclosures of PHI between an ACO participant TIN and the ACO, we encourage ACOs and their ACO participants to consult with their legal counsels as necessary to ensure that their Business Associate Agreements (BAAs) address the need to share data for patients covered by all payers with the ACO to permit the ACO to comply with its legal obligation to completely and accurately report data to CMS on eCQMs/MIPS CQMs. We noted in the proposed rule that the HIPAA Privacy rule generally permits a covered entity to disclose PHI to a business associate and to allow a business associate to create, receive, maintain, or transmit PHI on its behalf, provided that the parties have a BAA that meets the requirements of 45 CFR 164.504(e) and permits the business associate to use or disclose PHI only as permitted or required by its BAA or as required by law. We also note that we are considering whether it would be appropriate to revise the regulations at §§ 425.702(c)(5) and 425.704(b) to allow data sharing with an ACO that has structured its relationship with its ACO participants as an organized health care arrangement (OHCA), as that term is defined in the HIPAA regulations at 45 CFR 160.103. Any changes to the current requirements governing data sharing with ACOs would be addressed in notice-and-comment rulemaking for future performance years.

In light of the concerns raised by the commenters about the proposed timeline for implementing the eCQM/MIPS CQM reporting requirements under the APP for Shared Savings Program ACOs, we are finalizing our proposed changes to the quality reporting requirements with the following modifications. As discussed in section IV.A.3.d.(1)(d) of this final rule, we are extending the use of the CMS Web Interface as a collection type for the Quality Payment Program for performance years 2022, 2023, and 2024 for Shared Savings Program ACOs reporting under the APP. The CMS Web Interface will be unavailable starting with CY 2025. Accordingly, we are modifying the quality measure set for the APP for Shared Savings Program ACOs to retain the CMS Web Interface as an additional reporting option for performance year 2024, as discussed in sections IV.A.3.c.(2)(a) and IV.A.3.d.(1)(d) of this final rule. In addition, we are not finalizing the proposed requirement that an ACO must report at least one eCQM/MIPS CQM in performance year 2023 in order to meet the quality performance standard.

Accordingly, for performance year 2022 and subsequent performance years, ACOs must meet the requirements described below and summarized in Table 34 in order to meet the quality reporting requirements under the Shared Savings Program. Please see Table 35 of this final rule for the final APP measure set that must be reported by Shared Savings Program ACOs for performance year 2022 and subsequent performance years.

- For performance years 2022, 2023, and 2024: An ACO must report on either:

++ The 10 CMS Web Interface measures and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP, or

++ The three eCQM/MIPS CQMs and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP.

If an ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

To provide an incentive for ACOs to begin the transition to eCQM/MIPS CQM reporting before performance year 2025, we are finalizing in section III.J.A.1.d. of this final rule that, for performance years 2022 and 2023, if an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the

[115] 45 CFR 164.512(a).

[116] See 45 CFR 164.502(b)(2)(v).

quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable, for that performance year.

We believe that the quality performance standard policies we are finalizing for performance years 2022 and 2023 will provide an incentive to ACOs to report the eCQMs/MIPS CQMs, while allowing them time to gauge their performance on the eCQMs/MIPS CQMs before full reporting of these measures is required beginning in performance year 2025.

We note that if an ACO chooses to report the three eCQMs/MIPS CQMs, its performance on all three eCQMs/MIPS CQMs will be used for purposes of MIPS scoring under the APP. If an ACO decides to report both the 10 CMS Web Interface measures and the three eCQMs/MIPS CQMs, it will receive the higher of the two quality scores for purposes of the MIPS Quality performance category.

Please note that, as indicated in Tables 34 and 51 of this final rule, three of the CMS Web Interface measures (Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Cessation: Screening and Cessation Intervention (Quality ID# 226)) do not have benchmarks for performance year 2022, and therefore, will not be scored. However, these measures are required to be reported in order to complete the CMS Web Interface dataset. Based on the ACO's chosen reporting option, either 6 (three eCQMs/MIPS CQMs + two claims-based measures + CAHPS for MIPs Survey measure) or 10 measures (seven CMS Web Interface measures + two claims-based measures + CAHPS for MIPS Survey measure) will be included in the calculation of the ACO's quality performance score.

- For performance year 2025 and subsequent performance years: The ACO must report the three eCQMs/MIPS CQMs and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP. If an ACO does not report any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

We believe providing ACOs a total of 4 years (from performance year 2021 to performance year 2024) to transition to eCQM/MIPS CQM reporting is responsive to the commenters' concerns that it could take ACOs 3 to 5 years to transition to all-payer reporting. We believe this timeline will allow ACOs sufficient time to put IT infrastructure in place to capture, aggregate, and report all-payer quality measure data to CMS. Additionally, the removal of the proposed requirement that ACOs reporting the 10 CMS Web Interface measures in performance year 2023 must also report at least one of the three eCQMs/MIPS CQMs under the APP will prevent duplicate reporting of quality data given that the three eCQMs/MIPS CQMs are also CMS Web Interface measures. The removal of this proposed requirement also reduces burden for ACOs that elect to report through the CMS Web Interface in performance year 2023, by eliminating the requirement that these ACOs also take the steps necessary to report one eCQM/MIPS CQM.

We note that in addition to the comments discussed above regarding ACOs' readiness to report eCQMs/MIPS CQMs, in a recent ACO Learning System webinar entitled ''Harnessing Data to Improve Quality'', participants were asked, ''where is your ACO in your journey to implement eCQMs?''. In response, many ACOs indicated that they are reviewing measure specifications for the transition to reporting eCQMs/MIPS CQMs. Of the 46 respondents, half were reviewing measure specifications (50 percent), nearly half were engaging with ACO leadership on issues related to eCQM implementation (48 percent), and a number were beginning to educate providers on eCQMs (24 percent). Only 15 percent of respondents reported they had not yet started eCQM implementation. Since hearing concerns from stakeholders earlier this year regarding the burdens imposed by the requirement to report on eCQM/MIPS CQMs, we have been working with the CMS Office of Burden Reduction and Health Informatics (OBRHI) and ONC to identify barriers to implementation and plan to provide technical assistance to ACOs and IT vendors. OBRHI is developing case studies to assist ACOs in making the transition to eCQMs/MIPS CQMs, and we are in discussions with ONC regarding providing technical assistance to address the unique challenges facing ACOs with respect to reporting eCQMs/MIPS CQMs.

As noted previously in this section of the final rule, we also suggest that ACOs refer to the ''PY2021 APM Performance Pathway Toolkit'' that is available on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library.* This toolkit contains multiple documents related to how to report under the APP for performance year 2021, including a scoring guide and a document that specifically addresses the APP policies applicable to Shared Savings Program ACOs. These documents will be updated for each upcoming performance year. Furthermore, as stated in one of our previous responses, we have specifications for all eCQMs (including the three eCQMs/MIPS eCQMs that ACOs will report on under the APP) that can be found in the QPP resource library in the zip file titled ''2021 Electronic Clinical Quality Measures (eCQMs) Specifications''.

We did not receive any comments on the proposed quality performance standard for ACOs in the first performance year of their first agreement period under the Shared Savings Program. However, we are finalizing our proposal with modifications in order to align with the quality reporting requirements we are finalizing for performance year 2022 and subsequent years, as described below.

Accordingly, for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO meets MIPS data completeness and case minimum requirements, the ACO will meet the quality performance standard under the Shared Savings Program, if:

- For performance years 2022, 2023 and 2024. The ACO reports the ten CMS Web Interface measures or the three eCQMs/MIPS CQMs and administers a CAHPS for MIPS survey under the APP.

- For performance year 2025 and subsequent performance years. The ACO reports on the three eCQMs/MIPS CQMs and administers a CAHPS for MIPS survey under the APP.

We are also finalizing changes to the regulation at § 425.512(a) to reflect the final quality reporting requirements under the Shared Savings Program for performance years 2022 and subsequent performance years that we are adopting in this final rule. We note that it is now our preference to omit the word ''measures'' when describing the eCQMs/MIPS CQMs in order to avoid redundancy. Therefore, we are revising all references to ''eCQM/MIPS CQM measures'' in § 425.512(a) to read ''eCQMs/MIPS CQMs''.

TABLE 34: Comparison of APP Reporting Requirements for Performance Year 2021 and Subsequent Performance Years

	Performance Year 2021	Performance Years 2022 and 2023	Performance Year 2024	Performance year 2025 and Subsequent Performance Years
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface **or** the 3 eCQMs/MIPS CQMs and administer the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. Based on the ACO's chosen reporting option, either 6 or 10 measures will be included in calculating the ACO's quality performance score.	Same as performance year 2021	Same as performance year 2021	ACOs are required to report on the 3 eCQMs/MIPS CQMs and field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. All 6 measures will be included in calculating the ACO's quality performance score.
Shared Savings Program ACO Quality Performance Standard	A quality performance score that is equivalent to or higher than the **30th** percentile across all MIPS Quality performance category scores. Quality performance standard met: ACOs are eligible to share in savings at the maximum sharing rate; ACOs in two-sided models share in losses based on their quality score or at a fixed percentage based on Track. Quality performance standard not met: ACOs are ineligible to share savings and owe the maximum amount of shared losses, if applicable.	Same as performance year 2021. However, in order to encourage all-payer measure reporting if the ACO reports all 3 eCQMs/MIPS CQMs under the APP, the ACO will satisfy the quality performance standard if it achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a performance score that is equivalent to or higher than the 30th percentile on at least one of the remaining five measures in the APP measure set	A quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores.	Same as performance year 2024.

(1) Solicitation of Comments on Addressing Health Disparities and Promoting Health Equity

In the CY 2022 PFS proposed rule (86 FR 39269 and 39270), we solicited comments and recommendations on how ACOs can utilize their resources to ensure that patients, regardless of racial/ethnic group, geographic location and/or income status, have access to equal care and how ACOs can improve the quality of care provided to certain communities, while addressing the disparities that currently exist in healthcare. We also solicited comments and recommendations on how we can encourage health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives, including whether any adjustments should be made to quality

measure benchmarks to take into account ACOs serving vulnerable populations. We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

(2) Solicitation of Comments on Feasibility of TIN Level Reporting and Sampling for eCQMs/MIPS CQMs

We also solicited comment on allowing ACO providers/suppliers to submit eCQMs/MIPS CQMs to CMS at the ACO participant TIN level and potential approaches CMS could use to calculate/aggregate the TIN level quality data to create an ACO level score. We solicited comment on how stakeholders would envision CMS determining an appropriate beneficiary population. We also solicited comment on whether CMS should create a specific sampling methodology for ACOs, alternate sampling methodologies that could be used, as well as phase-in and tiered implementation strategies. We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

(3) Comment Solicitation for Reporting Options for Specialist Providers Within an ACO

In order to address measure applicability for specialist providers, we solicited comment on allowing ACO participant TINs to report either the eCQMs/MIPS CQMs in the APP measure set at the TIN level or the applicable MIPS Value Pathways, including how APP and MIPS Value Pathway data reported at the ACO participant TIN level could be aggregated in order to assess ACO quality performance. In addition, we solicited input on the role specialists play in ACOs and what specialty measures in the current eCQM or MIPS CQM set should be considered for inclusion in the Shared Savings Program quality measure set in future performance years. We appreciate the feedback we received in response to this comment solicitation. We may consider this information to inform future rulemaking.

(4) Updates to the APM Performance Pathway (APP) Measure Set

In the CY 2022 PFS proposed rule, we proposed to replace the Risk-Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs (MCC for ACOs measure) with the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS (MCC for MIPS measure) for performance year 2022 (86 FR 39270 and 39271). We also proposed to remove the MCC for ACOs measure from the APP measure set in order to reduce the potential for confusion around performance scores and feedback for MIPS eligible clinicians who might otherwise have been scored on both measures with differing results. We noted that this proposed change would continue the transition towards alignment of the quality measures reported by MIPS eligible clinicians who are not participants in APMs, such as the Shared Savings Program, and those who are, as discussed in the CY 2021 PFS final rule (85 FR 84720).

We explained that by removing the MCC for ACOs measure and aligning the quality measure set for the Shared Savings Program with MIPS, we would have the opportunity to align quality measurement between CMS programs. In addition, given that the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure included in the APP looks at an ACO's all Medicare population rather than just the ACO's assigned beneficiary population, we stated that we believed the proposal to move to the MCC for MIPS measure would be consistent with the approach under the APP of assessing, measuring and improving quality of care across a broader population of patients.

Table 25 of the CY 2022 PFS proposed rule (86 FR 39271) set forth the proposed measure set under the APP that we proposed would be reported by Shared Savings Program ACOs for performance year 2022 and subsequent performance years.

We received many public comments on our proposal to replace the MCC for ACOs measure with the MCC for MIPS measure and on the proposed APP measure set for performance year 2022 and subsequent performance years. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to replace the MCC for ACOs measure in the APP measure set with the MCC for MIPS measure for performance year 2022 and subsequent performance years. Some commenters stated that this change would reduce confusion for MIPS eligible clinicians who might otherwise have been scored on both measures with differing results and that it supports the agency's effort to align quality measures between MIPS and APMs. Other commenters explained that they support consolidation of measures across programs to reduce complexity. One commenter stated that adding the MCC for MIPS measure to the APP will create an opportunity for clinicians to become more familiar with the measure before transitioning to reporting under the APP.

Response: We agree that replacing the MCC for ACOs measure with the MCC for MIPS measure would permit the use of a single measure across both the Shared Savings Program and MIPS. We note that this policy is also consistent with our goal to align the measures and quality reporting requirements under the Shared Savings Program with MIPS as stated in the CY 2021 PFS final rule (85 FR 84720 through 84722). Further, this policy also improves the ability to compare performance across ACO participants and MIPS eligible clinicians.

Comment: A few commenters were opposed to the proposal and requested that CMS retain the current MCC for ACOs measure. Some commenters expressed concern that ACOs may not have the ability to meaningfully influence treatment of beneficiaries not assigned to the ACO. These commenters stated that the rationale for changing to the MCC for MIPS measure is likely flawed and that further testing is needed to assess the impact of the proposed change. The commenters explained that the broader denominator that will be produced when applying the MCC for MIPS measure to ACOs will be reflective of MIPS eligible clinicians' performance who may not participate in the Shared Savings Program, rather than the performance of ACOs, because many ACOs contract with a broad set of provider types that may or may not have an agreement with the ACO. The commenters recommended that CMS conduct analyses of the two MCC measures, such as comparisons of the measure denominators and resulting performance scores for ACOs and the associated eligible clinicians, to determine whether the assumption that scores will likely be similar is correct prior to finalizing this change. Another commenter cited the infeasibility of taking on responsibility for the full Medicare population in its ACO practices as a result of their patient population's preference to access care at the local Emergency Room (ER). Therefore, they are concerned that they do not have knowledge of these patients to assist with chronic disease management and care coordination needs.

Response: We acknowledge the concerns raised by the commenters regarding our proposal to include the MCC for MIPS measure in the APP measure set. In proposing to shift to the MCC for MIPS measure for ACOs

beginning in performance year 2022, we were guided by our goal of harmonizing measures across CMS programs. In addition, we cannot evaluate clinician group performance across CMS programs without eliminating the use of multiple benchmarks for the same measure. The shift to a single MCC measure allows us to compare the performance of ACOs to that of TINs in the traditional MIPS as part of a combined calculation that includes both MIPS providers and ACOs and generates a single distribution of scores for benchmarking.

The MCC for MIPS measure uses an office visit-based attribution algorithm to identify the clinician most responsible for the patient's care for purposes of determining the population to include in the measure denominator. The visit codes used for the attribution algorithm are the same as the visit codes used for the ACO beneficiary assignment. Based on the attribution algorithm, the patient is assigned to a primary care provider or to a relevant specialist based on the number and pattern of their visits. The patient then ''follows'' their clinician to the TIN designated by the clinician (that is, they are assigned to their clinician's TIN). ACO-level scores are determined after the TINs of ACO participants are mapped to their respective ACOs.

In our preliminary analysis comparing the MCC for MIPS measure with the MCC for ACOs measure, we note that there is a high correlation of 0.89 between ACO-level scores obtained using the old ACO MCC measure and the MIPS MCC measure. However, we acknowledge that ACOs' scores on the MCC measure may change as a result of including the MCC for MIPS measure in the APP measure set. We intend to conduct additional analyses to further model the impact of the shift to the MCC for MIPS measure on ACOs' scores for the MCC measure. The MCC for MIPS measure attribution considers only certain types of providers (primary care providers or specialists including cardiologists, pulmonologists, nephrologists, neurologists, and endocrinologists) who care for patients with MCCs, and excludes patients who would be attributed to hematologists/oncologists. In reference to commenters' concerns about taking on responsibilities of the full Medicare population, we continue to believe that moving to the MCC for MIPS measure will reduce the potential for confusion around performance scores and feedback for MIPS eligible clinicians who might otherwise have been scored on both measures with differing results. We also note that there is a strong overlap between the assigned beneficiary population for the MCC for ACOs measure and the attributed beneficiary population for the MCC for MIPS measure. Accordingly, we are finalizing our proposal to replace the MCC for ACOs measure with the MCC for MIPS measure in the APP measure set for performance year 2022 and subsequent performance years. Further details on the specifications for the MCC for MIPS measure can be found in Table A–5 in Appendix A of this final rule.

Comment: Several commenters generally supported the overall proposed APP measure set. One commenter applauded the inclusion of the evidence-based eCQMs combined with CAHPS and administrative measures of utilization. Another commenter appreciated the reduced number of measures because it will ease provider burden.

Response: We thank commenters for their positive feedback on the proposed APP quality measure set. The reduced measure set is intended to reduce reporting burden on ACOs and focus on quality measures that address patient outcomes.

Comment: Several commenters noted that the measure set selected for the APP is narrowly focused and could result in a greater emphasis being placed on patient satisfaction as there will only be three clinical measures. Some commenters stated that the measure set selected for the APP would result in an ACO's entire performance hinging on only two or three measures, with a commenter noting that a very small measure set may overemphasize certain metrics or underlying beneficiary conditions, or create clinical disruption. Several commenters stated it was inappropriate for an ACO's performance to be based on only a couple of measures in a program where ACOs are financially accountable for total cost of care losses for a large population.

One commenter expressed concern that the proposed measure set does not encourage or promote patient care. Another commenter stated that CMS had not yet struck the right balance between quality of care and minimizing burden. One commenter applauded CMS for moving toward more outcomes-based, primary care measures, but explained that this measure set did not yet achieve this goal. Several commenters mentioned that evaluating the totality of an ACO's quality performance on such a small measure set was inappropriate and unfair. Another commenter requested that CMS consult with the ACO community and patient representatives as it works to determine the measure set.

Response: As we stated in the CY 2021 PFS final rule (85 FR 84728), the transition to the APP measure set was intended to reduce reporting burden and eliminate differences in the way ACOs are scored under the Shared Savings Program compared to the way their MIPS eligible clinicians are scored under MIPS, while also moving toward a more outcome-based, primary care focused measure set. Additionally, we selected the measures to be included in the measure set because they are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program. These measures align with the Meaningful Measures framework while also being appropriate for assessing ACO quality performance as they focus on prevalent and high priority chronic health conditions. These measures are also relevant in assessing the quality of care furnished by the broad range of clinicians in a variety of specialties that participate in ACOs. For example, hypertension and diabetes are chronic conditions that are applicable to both primary care practitioners and specialists. Also, as noted in the CY 2021 PFS final rule (85 FR 84728), the APP measure set is intended to assess a sample of the areas where ACOs should be focused on improving the quality of care.

After consideration of the comments received, we are finalizing the APP measure set as proposed. Table 35 lists the measures included in the final APP measure set that will be reported by Shared Savings Program ACOs for performance year 2022 and subsequent performance years. As discussed in section III.J.1.c. of this final rule, we are finalizing the following quality reporting requirements for Shared Savings Program ACOs for performance year 2022 and subsequent performance years:

- For performance years 2022, 2023 and 2024: An ACO will be required to report either:

++ The 10 CMS Web Interface measures and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP, or

++ The three eCQM/MIPS CQMs and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP.

- For performance year 2025 and subsequent performance years: An ACO will be required to report the three eCQMs/MIPS CQMs and administer a CAHPS for MIPS survey and CMS will

calculate the two claims-based measures included under the APP.

TABLE 35: Measures included in the Final APM Performance Pathway Measure Set for Performance Year 2022 and Subsequent Performance Years[a]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

[a] We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) do not have benchmarks, and therefore, will not be scored for performance year 2022; they are, however, required to be reported in order to complete the Web Interface dataset.

* *ACOs will have the option to report via the Web Interface for the 2022, 2023, and 2024 performance years only.

d. Shared Savings Program Quality Performance Standard

(1) Freezing the Quality Performance Standard at the 30th percentile of All MIPS Quality Performance Category Scores for Performance Year 2023

The quality performance standard is the minimum performance level ACOs must achieve in order to be eligible to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions. As noted above, in the CY 2021 PFS final rule we finalized a gradual phase in of the revised quality performance standard.

Specifically, an ACO would meet the quality performance standard if:

- For performance years 2021 and 2022, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; and
- For performance year 2023 and subsequent performance years, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding

entities/providers eligible for facility-based scoring (85 FR 84735).

We finalized this phase-in approach to address the concerns raised by commenters about the limited time for ACOs to gain familiarity with the new quality reporting requirements under the APP and potential challenges in meeting the new quality performance standard, as well as concerns regarding the shift from a domain-based scoring approach to the original proposal to require an ACO to achieve an overall quality score equivalent to the 40th percentile across all MIPS quality performance category scores starting in performance year 2021. In conjunction with the decision to phase-in the quality performance standard, we also adopted a phase-in of the reporting requirements under the APP for Shared Savings Program ACOs, as described previously.

In the CY 2021 PFS final rule, we also discussed the potential impact of the final policies on ACO quality performance. We projected that, absent an improvement in quality performance by ACOs, roughly 1-in-5 ACOs, or approximately 20 percent of ACOs, could fall below the 40th percentile MIPS Quality performance category score by performance year 2023, and would not be eligible to share in savings or would owe maximum shared losses, if applicable (85 FR 85007 through 85008). For the CY 2021 rulemaking, we conducted an analysis in order to understand better how well ACOs might perform once the CMS Web Interface is no longer an available collection type. The analysis simulated ACO performance on eCQMs/MIPS CQMs using 2018 and 2019 quality data submitted via the CMS Web Interface. Based on the analysis of the 2018 and 2019 data, there were two differing estimates of the number of ACOs that would not meet the quality performance standard. The estimated percent of Shared Savings Program ACOs falling below the 40th percentile MIPS Quality performance category score was 6.5 percent based on a simulation using 2018 data and 22.9 percent based on a simulation using 2019 data.

In the CY 2022 PFS proposed rule (86 FR 39272), we acknowledged that even with the steps that ACOs are taking to develop their capacity for reporting of the eCQMs/MIPS CQMs and our proposals to phase-in reporting of these measures, transitioning to eCQM/MIPS CQM quality data reporting and aggregation may come with unforeseen data collection and/or system operational issues. Therefore, we explained that we had concluded that it would be appropriate to freeze the quality performance at the 30th percentile MIPS Quality performance category score for an additional year before raising the quality performance standard to the 40th percentile starting in performance year 2024. We explained that we believed this proposal, in conjunction with our proposal to extend the CMS Web Interface to allow for a gradual phase in of reporting the three eCQMs/MIPS CQMs, would be responsive to stakeholder concerns related to the transition to eCQMs/MIPS CQMs and the need for data aggregation and would provide time for both ACOs and EHR vendors to put in place processes and systems, such that ACOs will be well positioned to report eCQM/MIPS CQMs by performance year 2024.

As discussed earlier in this final rule, as part of the gradual phase-in to full reporting of eCQMs/MIPS CQMs, in the CY 2022 PFS proposed rule (86 FR 39272) we proposed to include incentives to encourage the early adoption of full eCQM/MIPS CQM reporting prior to performance year 2024. As part of the phase-in, and in order to transition ACOs to reporting all-payer eCQMs/MIPS CQMs, for performance year 2023 we proposed to require an ACO to report at least one eCQM/MIPS CQM (that meets data completeness and case minimum requirements) in addition to the CMS Web Interface measures in order to meet the quality performance standard. In addition, we also proposed for both performance year 2022 and performance year 2023 that ACOs that elect to report all three eCQMs/MIPS CQMs and meet the data completeness requirement and case minimum requirement for all three measures would meet the quality performance standard if they achieve a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

In the proposed rule, we noted that we believed our proposal to freeze the quality performance standard at the 30th percentile for an additional year was consistent with the requirement in the statute that CMS increase the quality performance standard over time. We explained that two ways to increase the quality performance standard are: (1) By increasing the threshold for the quality performance standard, and (2) by moving to a requirement that ACOs report for on all-payer measure populations for purposes of assessing Shared Savings Program quality performance. We proposed to do both by requiring that ACOs begin the transition to reporting all-payer measures before increasing the quality performance standard starting in performance year 2024.

Therefore, we proposed to freeze the quality performance standard at the 30th percentile across all MIPS Quality performance category scores for performance year 2023, and to establish incentives to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in performance year 2022 and performance year 2023. Under this proposal, CMS would designate the quality performance standard for Shared Savings Program ACOs as the ACO reporting via the APP established under § 414.1367 and for:

- Performance year 2022, if an ACO reports:

++ The 10 CMS Web Interface measures and achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ The three eCQMs/MIPS CQMs, meeting the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three measures, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

If the ACO does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

- Performance year 2023, if an ACO reports:

++ The 10 CMS Web Interface measures and at least one eCQM/MIPS CQM measure, and achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ The three eCQMs/MIPS CQMs, meeting the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three measures, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

If the ACO does not report at least one eCQM/MIPS CQM, the ACO would not meet the quality performance standard.

We also proposed that for performance year 2024 and all subsequent performance years, we would designate the quality performance standard for all Shared Savings Program ACOs, with the exception of ACOs in the first performance year of their first agreement period under the Shared

Savings Program, as the ACO reporting quality data via the APP established under § 414.1367 according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We also proposed to revise the regulation at § 425.512 to reflect the extended phase-in of the ACO quality performance standard.

In the proposed rule, we recognized the change from the CMS Web Interface collection type to the eCQM/MIPS CQM collection type would add complexity for ACOs as they may need to utilize new approaches to combining data across EHR systems to allow for a new data submission type, as well as aggregating ACO participant data for submission to CMS. However, we indicated that we believed the proposal to delay the increase in the quality performance standard, coupled with the proposal to extend the CMS Web Interface, with incentives for early adoption of eCQM/MIPS CQM reporting, would give ACOs ample time to prepare for the transition to full eCQM/MIPS CQM reporting in performance year 2024 and the incremental increase in the quality performance standard to the 40th percentile MIPS Quality performance category score. We also stated our belief that the proposed timeline for phasing in the new quality performance requirements under the Shared Savings Program would signal to ACOs, EHR vendors, and other stakeholders that eCQM/MIPS CQM reporting is the path forward for the Shared Savings Program and clearly establish the standard that ACOs would need to achieve in order to be eligible to share in maximum savings and avoid owing the maximum shared losses, if applicable.

Additionally, as noted in the proposed rule, we also considered the possibility of extending the freeze of the Shared Savings Program quality performance standard at the 30th percentile MIPS Quality performance category score for performance year 2024. We explained that this alternative would delay the incremental increase in the quality performance standard until all ACOs have at least one year of experience in reporting data for all three eCQM/MIPS CQM measures. This delay would allow ACOs additional time to gain experience reporting on the eCQMs/MIPS CQMs and also provide CMS with more information on ACO performance on all-payer measures and the ability of ACOs to aggregate data across multiple EHR systems and multiple practices, in order to inform the quality performance standard in outlying years.

We solicited comment on our proposal to freeze the Shared Savings Program quality performance standard at the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring for performance year 2023 and to increase the quality performance standard to the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring starting in performance year 2024. In addition, we solicited comment on the alternative of freezing the Shared Savings Program quality performance standard at the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring for PYs 2023 and 2024.

We received many public comments on our proposal and the alternative discussed in the proposed rule. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns with the proposed approach of setting the quality performance standard at the 30th percentile across all MIPS Quality performance category scores starting in performance year 2023. Commenters also had concerns about the quality scoring methodology, citing concerns with the comparison to the MIPS final quality scores. Specifically, the commenters found the current methodology to be unfair to ACOs, as ACOs must report on a set list of measures, while MIPS reporters may select from a broader measure set, making these groups incomparable. Commenters expressed concern that the current methodology would result in many ACOs not being able to meet the 40th percentile threshold for performance year 2024. One commenter indicated that the proposed increase could result in physician practices leaving the Shared Savings Program and suggested CMS allow more time for further questions about the transition to the APP to be clarified. Some commenters suggested reverting to the previous methodology for determining if an ACO met the quality performance standard, while other commenters suggested providing quality benchmarks ahead of the performance year and comparing ACOs only to other similarly situated ACOs. In addition, the commenters that supported establishing prospective quality benchmarks indicated that including 2020 data would be unfair on account of the challenges presented by the PHE for COVID–19. Another commenter indicated that freezing the quality performance standard would not resolve transparency issues surrounding the calculation of the quality performance score. Other commenters recommended CMS provide more information about how the threshold is calculated, indicating that without proper transparency, an increase to the 40th percentile would be too significant for many ACOs to achieve, especially those new to the program.

Response: We appreciate the commenters' concerns regarding the proposal to increase the quality performance standard to the 40th percentile across all MIPS Quality performance category scores starting in performance year 2023. The Shared Savings Program quality reporting requirements and quality performance standard that we are finalizing for performance year 2022 and subsequent performance years are described in sections III.J.1.c. and III.J.1.d. of this final rule, respectively. We stated in the CY 2021 PFS final rule (85 FR 84735) that each ACO's quality performance score will be calculated using the ACO's performance on the measures reported under the APP, any applicable MIPS bonus points, and quality improvement points. The methodology used to calculate MIPS Quality performance category scores is described in the ''2021 APM Performance Pathway Scoring Guide'' and the ''2021 APM Performance Pathway for Shared Savings Program Accountable Care Organizations (ACOs) User Guide'' found within the ''PY2021 APM Performance Pathway Toolkit'' that is available on the Quality Payment Program Resource Library website at *https://qpp.cms.gov/resources/resource-library.* These documents will be updated for each upcoming performance year. We believe that assessing an ACO's quality performance score against the quality performance scores for all individuals, groups, and APM entities is consistent with our goal to align the quality reporting requirements under the Shared Savings Program with the requirements that will apply under the APP for purposes of the Quality Payment Program.

It is important to note that ACOs can earn up to 10 additional percentage points based on their improvement in the quality performance category from the previous year which should help to increase the ACOs' scores and alleviate concerns about other MIPS eligible clinicians being able to pick the measures they report. We believe the

ability to earn points for quality improvement will assist ACOs in achieving quality performance scores equivalent to or higher than the 30th or 40th percentile across all MIPS Quality performance category scores. As noted in the CY 2022 PFS proposed rule (86 FR 39274) and in section III.J.1.d.(2). of this final rule, for performance year 2018, the MIPS Quality performance category score at the 30th percentile was equivalent to 83.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 93.3. For performance year 2019, the MIPS Quality performance category score at 30th percentile was equivalent to 87.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 95.7.

As discussed in section IV.A.3.e.(1)(c)(ii) of this final rule, we are not finalizing the proposal to use performance period benchmarks or data from the CY 2019 performance period/2021 MIPS payment year to calculate quality measure benchmarks for the CY 2022 performance period/2024 MIPS payment year. Analysis of the CY 2020 performance period/2022 MIPS payment year data supports its use for benchmarking purposes. Those quality measure benchmarks will be made available to clinicians before the start of the CY 2022 performance period.

Since the publication of the CY 2022 PFS proposed rule, we have identified standards in our regulations that prevent us from finalizing without modification our proposal to allow ACOs that elect to fully report all three eCQMs/MIPS CQMs to meet the quality performance standard if they achieve a quality performance score equivalent to or higher than the 30th percentile on at least one measure in the APP measure set. Adopting this policy would result in the ENHANCED track and the BASIC track level E of the Shared Savings Program no longer qualifying as Advanced APMs. This, in turn, would prevent eligible clinicians in the ACOs that participate in these tracks from becoming Qualifying APM Participants (QPs) based on their participation in the Shared Savings Program during performance years 2022 and 2023. They would instead be subject to the MIPS reporting requirements and payment adjustment. Therefore, we are finalizing a modified policy that avoids this result while still providing an incentive for ACOs to fully report all three eCQMs/MIPS CQMs.

Section 414.1410(a) provides that an APM is an Advanced APM for a payment year if CMS determines that it meets the criteria in § 414.1415 during the QP Performance Period. Section 414.1415(b)(1) requires that, to be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM. Section 414.1415(b)(2) requires, in relevant part, that at least one of the quality measures used in the payment arrangement be a MIPS-comparable measure. Section 414.1415(b)(3) provides that in addition to the quality measure described under paragraph (b)(2), the quality measures upon which an Advanced APM bases payment must include at least one additional measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period.

Our proposal to permit an ACO that reports the three eCQMs/MIPS CQMs and scores above the 30th percentile on at least one measure in the APP measure set is inconsistent with the requirements of § 414.1415(b)(1) through (3) for two reasons. First, under the proposed policy, the Shared Savings Program would base the quality performance scores for certain ACOs, and therefore, these ACOs' payments, on a single measure when § 414.1415(b)(1) and (3) require that payment be based on at least two measures. Second, our proposal did not require that one of the measures that is used to determine the quality performance score be an outcome measure, which is also required by § 414.1415(b)(1) and (3). As CMS must determine whether an APM is an Advanced APM based in part on the APM's compliance with the standards of § 414.1415(b), finalizing our proposal would require CMS to determine that the ENHANCED track and the BASIC track level E of the Shared Savings Program are not Advanced APMs.

While the policy options we can adopt in this final rule are limited by the aforementioned regulations and the scope of our proposal, based on the comments received raising concerns related to the current quality performance standard, we are already considering a broader set of policy options for performance year 2023 and future years that would provide an incentive for ACOs to transition to full eCQM/MIPS CQM reporting. Among other things, we are considering reinstating the sliding scale quality performance standard methodology for determining shared savings and shared losses in next year's rulemaking for ACOs that report on the three eCQMs/MIPS CQMs Under the sliding scale methodology, we would multiply the ACO's quality score, based on the ACO's performance on the three eCQMs/MIPS CQMs as reported by the ACO, the two claims-based measures calculated by CMS, and the CAHPS for MIPS survey, by the sharing rate for the track (or payment model within a track) to determine the ACO's shared savings. We believe this approach would avoid the all or nothing approach under the current regulations, under which ACOs that fail to achieve the required minimum quality performance score are ineligible to share in any of the savings they achieve. Given the high level of performance in the MIPS Quality performance category and the challenge of transitioning to full eCQM/MIPS CQM reporting, we believe it is appropriate to offer some reward to ACOs that elect to report the eCQM/MIPS CQMs, but may not be able to achieve a quality performance score equivalent to the 30th or 40th percentile across all MIPS Quality performance category scores. As a result, we believe a sliding scale methodology for calculating shared savings could provide an incentive for continuous improvement and also encourage ACOs, particularly ACOs that serve large vulnerable populations or have large numbers of specialists who may not perform as well on the eCQMs/MIPS CQMs, to take the steps necessary to transition to eCQM/MIPS CQM reporting.

We are finalizing, with modifications, our proposal to freeze the quality performance standard at the 30th percentile across all MIPS Quality performance category scores for performance year 2023, and to establish incentives to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in performance year 2022 and performance year 2023. Our final policies address the commenters' concerns by lowering the quality performance standard ACOs must meet in order to share in savings or avoid maximum shared losses, if applicable, during the transition to new reporting mechanisms. These final policies with respect to the quality performance standard are also aligned with the final quality reporting requirements discussed in section III.J.1.c. of this final rule. Accordingly, we are designating the quality performance standard for all Shared Savings Program ACOs, with the exception of ACOs in the first performance year of their first agreement period, as the ACO reporting quality data via the APP established under § 414.1367 according to the

method of submission established by CMS and for:

- Performance years 2022 and 2023:

++ Achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ If the ACO reports the three eCQMs/MIPS CQMs, meeting the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three measures, and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set. Consequently, the ACO would be required to meet the performance benchmark on either 2 outcome measures (one measure at the 10th percentile and the other at the 30th percentile), or 1 outcome measure at the 10th percentile and any other measure in the APP measure set at the 30th percentile. The outcome measures in the APP measure set are listed in Table 36.

If the ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

- Performance year 2024 and subsequent performance years: Achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

If the ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

We are also finalizing conforming revisions to the regulation at § 425.512(a) to reflect the extended phase-in of the ACO quality performance standard adopted in this final rule.

We will continue to monitor the ACOs' performance under the APP and determine whether they meet the quality performance standard and may revisit these policies in future rulemaking if necessary to promote an attainable quality performance standard and degree of improvement.

TABLE 36: APP Measure Set for eCQM/MIPS CQM Reporting for Performance Years 2022 and 2023

Measure #	Measure Title	Measure Type	SSP Quality Performance Standard	
			MIPS Comparable Measure	Outcome Measure
Quality ID#: 321	CAHPS for MIPS	Patient-Reported Outcome	Yes	No
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Outcome	Yes	Yes
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS	Outcome	Yes	Yes
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Intermediate Outcome	Yes	Yes
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Process	Yes	No
Quality ID#:236	Controlling High Blood Pressure	Intermediate Outcome	Yes	Yes

Comment: Several commenters supported the alternative of freezing the Shared Savings Program quality performance standard at the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring for performance years 2023 and 2024, with commenters citing their appreciation for the additional flexibility allowed by freezing the quality performance standard for an additional year. Commenters also noted that this alternative would give health care providers and ACOs sufficient time to adjust to the new reporting requirements and to recover from any financial and operational losses sustained as a result of the PHE for COVID–19. A commenter suggested that CMS freeze the standard through 2025, explaining that the additional time would provide ACOs with more time to adjust to the revised quality performance standard methodology.

Response: We appreciate the commenters' input on this alternative. However, we believe that the additional year of keeping the quality performance category score at the 30th percentile is sufficient, especially given the fact that we are extending the CMS Web Interface as a collection type until 2024 and ACOs typically perform well on the CMS Web Interface measures. We believe that the extension of the CMS Web Interface and the incentive to report eCQMs/MIPS CQMs will in fact help improve the ACOs' performance. However, we will continue to monitor the ACOs' performance under the APP and may consider this feedback in

developing policies for future rulemaking.

(2) Comment Solicitation on Publicly Displaying Prior Year Performance Scores That Equate to the 30th or 40th Percentile Across MIPS Quality Performance Category Scores

In the CY 2022 PFS proposed rule (86 FR 39274), we explained that stakeholders have expressed concerns regarding the lack of information on the level of quality performance that would equate to the 30th or 40th percentile MIPS Quality performance category score and that would enable an ACO to be eligible to share in savings or to avoid maximum shared losses, if applicable. We noted that stakeholders have expressed concern that these data are not publicly available prior to the start of a performance year and that they do not believe that ACOs have a way of determining what quality score they would need to achieve to meet the quality performance standard. For a given performance year, the 30th or 40th percentile MIPS Quality performance category score is calculated based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for scoring for facility-based scoring, only once MIPS final scoring is complete.

Therefore, we stated there is no information that can be provided prior to or during the performance year. However, we noted that for performance year 2018 the MIPS Quality performance category score at the 30th percentile was equivalent to 83.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 93.3. For performance year 2019 the MIPS Quality performance category score at 30th percentile was equivalent to 87.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 95.7.

We solicited comment on whether publicly displaying prior year performance scores that equate to the 30th or 40th MIPS Quality performance category scores would help to address ACOs' concerns regarding the lack of advance information regarding the quality performance score they must meet in order to satisfy the quality performance standard under the Shared Savings Program. We also solicited comment on other ways we could address these concerns.

The following is a summary of the public comments we received on this comment solicitation and our response.

Comment: Several commenters supported publicly displaying prior year performance scores that equate to the 30th or 40th percentile across all MIPS Quality category performance scores. Commenters explained that publicly displaying the information will promote transparency, enable ACOs to be better informed about the quality standards they must meet, and ensure ACOs' ability to appropriately track performance and increase the likelihood of achieving high-quality performance scores. One commenter expressed concern that publicly displaying prior year performance scores is not the optimal way to address stakeholder concerns and indicated that performance is volatile and the 30th (or 40th) percentile may change significantly from year to year depending upon changes in quality performance in MIPS. A few commenters suggested that CMS provide more information on the methodology used to calculate this standard.

Response: We thank commenters for their suggestions. As noted above and in the CY 2022 PFS proposed rule (86 FR 39274), the performance year 2018 MIPS Quality performance category score at the 30th percentile was equivalent to 83.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 93.3. For performance year 2019 the MIPS Quality performance category score at 30th percentile was equivalent to 87.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 95.7.

We will work toward providing additional historical information on performance scores as it becomes available. However, as noted in the CY 2022 PFS proposed rule (86 FR 39274), for a given performance year, the 30th or 40th percentile across all MIPS Quality performance category scores is calculated after MIPS final scoring is complete based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for scoring for facility-based scoring. Therefore, we are not able to provide this information prior to or during the performance year. Nevertheless, we believe that publicly displaying prior year performance scores that equate to the 30th and 40th percentile across all MIPS Quality performance category scores for the applicable performance year would still provide helpful information for ACOs to determine what level of quality performance they would need to meet in order to satisfy the quality performance standard under the Shared Savings Program. We will release this historical information on the Shared Savings Program website as soon as it becomes available.

Comment: One commenter requested that CMS provide additional information regarding how ''entities eligible for facility-based scoring'' will be removed from the calculations used to determine the 30th and 40th percentile across all MIPS Quality category performance scores, and whether, when reporting eCQMs/MIPS CQMs under the APP, ACOs will be accountable for reporting quality data for facilities such as FQHCs, and/or other entities eligible for facility-based scoring.

Response: Under the policies finalized in the CY 2021 PFS final rule (85 FR 84735), we exclude entities/providers eligible for facility-based scoring from the determination of the overall MIPS Quality performance category score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS), which includes quality and cost. Facility-based provider scores are not considered as part of ACO quality scores, and APM participants (including ACO participants) have not typically been eligible for facility-based scoring in previous years. As a result, ACO quality scores will not be impacted by this exemption.

e. Revisions to the Extreme and Uncontrollable Circumstances Policy

In the CY 2021 PFS final rule (85 FR 84744 through 84747), we updated the extreme and uncontrollable circumstances policy for performance year 2021 and subsequent performance years to align with the gradual phase in of the revised quality performance standard. Specifically, we finalized that for:

- Performance year 2021 and performance year 2022, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, will be set equal to the 30th percentile MIPS Quality performance category score. If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 30th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 30th percentile MIPS Quality performance category score.

• Performance year 2023, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, will be set equal to the 40th percentile MIPS Quality performance category score. If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 40th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 40th percentile MIPS Quality performance category score (85 FR 84746).

In the CY 2022 PFS proposed rule (86 FR 39274), we also proposed to update the extreme and uncontrollable circumstances policy under the Shared Savings Program consistent with our proposal to freeze the quality performance standard for Shared Savings Program ACOS at the 30th percentile for performance year 2023. Specifically, we proposed to set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during performance year 2023, including the applicable quality data reporting period for the performance year, to equal the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

If the ACO is able to report quality data via the APP, including at least one eCQM/MIPS CQM, and meets data completeness and case minimum requirements, we proposed to use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score. If the ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we proposed to apply the 30th percentile MIPS Quality performance category score.

Similarly, we proposed that for performance year 2024 and subsequent years, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, would be set equal to the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. We stated in the proposed rule that if the ACO is able to report quality data via the APP and meets the MIPS data completeness and case minimum requirements, we would use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance category score. If the ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we proposed to apply the 40th percentile MIPS Quality performance category score. We noted our belief that these proposed updates were appropriate to align with the proposed changes to the quality performance standard in the CY 2022 PFS proposed rule, and would also allow impacted ACOs to be eligible to share in savings at their maximum sharing rate or to avoid maximum shared losses, if applicable (86 FR 39274 and 3975). We also proposed to make conforming changes to the Shared Savings Program regulations at § 425.512(b) to reflect these proposed revisions to the extreme and uncontrollable circumstances policy.

We solicited comment on the proposed revisions to the extreme and uncontrollable circumstances policy and received few public comments. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed updates to the extreme and uncontrollable circumstances policy under the Shared Savings Program to align with the proposed changes to the quality performance standard.

Response: We appreciate the commenters' support.

As discussed in section III.J.1.d. of this final rule, we are finalizing the proposed updates to the quality performance standard with modifications. Therefore, we are finalizing the proposed changes to the extreme and uncontrollable circumstances policy under the Shared Savings Program with modifications to conform to the final policies we are adopting in this final rule regarding the quality performance standard.

For performance year 2023, if the ACO is able to report quality data via the APP and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's MIPS Quality performance category score or the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. If the ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 30th percentile across all MIPS Quality performance category score.

For performance year 2024 and subsequent performance years, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, will be set equal to the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. If the ACO is able to report quality data via the APP and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's MIPS Quality performance category score or the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. If the ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 40th percentile MIPS Quality performance category score.

We are also finalizing changes to the Shared Savings Program regulations at § 425.512(b)(2) and (b)(3) to reflect these revisions to the extreme and uncontrollable circumstances policy. We note that the changes to § 425.512(b)(3)(i) and (ii) we are adopting in this final rule differ slightly from the proposed rule because we are eliminating the references to the ACO reporting quality data via the APP and meeting the data completeness and case minimum requirements as duplicative of the existing introductory language in § 425.512(b)(3).

2. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

a. Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on

or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by RHCs and FQHCs. However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

In the June 2015 final rule (80 FR 32746 through 32748), we expanded the definition of primary care services to include two transitional care management (TCM) codes (CPT codes 99495 and 99496), and one chronic care management (CCM) code (CPT code 99490). As discussed in the final rule, the TCM codes were established to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or SNF stay. Including these codes in the definition of primary care services reflects our belief that the work of community physicians and practitioners in managing a patient's care following discharge from a hospital or nursing facility (NF) to ensure better continuity of care for these patients and help reduce avoidable readmissions is a key aspect of primary care.

In the CY 2016 PFS final rule (80 FR 71270 through 71273), we revised the definition of primary care services to exclude services billed under CPT codes 99304 through 99318, containing the place of service 31 modifier specifying that the service was furnished in a SNF. We also revised the definition of primary care services to include claims submitted by Electing Teaching Amendment (ETA) hospitals.

In the CY 2018 PFS final rule (82 FR 53212 and 53213), we revised the definition of primary care services to include three additional CCM service codes, 99487, 99489, and G0506, and four behavioral health integration (BHI) service codes, G0502, G0503, G0504 and G0507.

We further revised the definition of primary care services in the November 2018 final rule (also referred to as the CY 2019 PFS final rule) (83 FR 59964 through 59968), by adding new codes to the definition of primary care services (CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443), and by revising how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF.

In the May 8, 2020 COVID–19 IFC (85 FR 27582 through 27586), we revised the definition of primary care services for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the COVID–19 PHE defined in § 400.200, to include the following additions specified in § 425.400(c)(2): (1) HCPCS code G2010 (remote evaluation of patient video/images) and HCPCS code G2012 (virtual check-in); (2) CPT codes 99421, 99422 and 99423 (online digital evaluation and management service (e-visit)); and (3) CPT codes 99441, 99442, and 99443 (telephone evaluation and management services).

In the CY 2021 PFS final rule (85 FR 84786 through 84793), we finalized the additional primary care service codes adopted in the May 8, 2020 COVID–19 IFC with modifications to allow these codes to be used in determining beneficiary assignment when the assignment window (as defined at § 425.20) for a benchmark or performance year includes any months during the PHE for COVID–19 defined in § 400.200, and to apply these additional primary care service codes to all months of the assignment window, when the assignment window includes any month(s) during the PHE for COVID–19.

In the CY 2021 PFS final rule (85 FR 84748 through 84755), we expanded the definition of primary care services for purposes of determining beneficiary assignment to include: Online digital E/M CPT codes 99421, 99422, and 99423; assessment of and care planning for patients with cognitive impairment CPT code 99483; chronic care management code CPT code 99491; exclusion of advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting; remote evaluation of patient video/images HCPCS codes G2010; virtual check-in HCPCS code G2012; non-complex chronic care management HCPCS code G2058 and its replacement CPT code 99439; principal care management HCPCS codes G2064 and G2065; and psychiatric collaborative care model HCPCS code G2214. In this same final rule (85 FR 84755 through 84756), we finalized revisions to the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF.

For performance years beginning on January 1, 2021, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(v) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT Codes

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(3) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(4) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(5) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(6) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under § 425.400(c)(1)(v)).

(7) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(8) 99439 (code for non-complex chronic care management).

(9) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(10) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(11) 99487, 99489, 99490 and 99491 (codes for chronic care management).

(12) 99495 and 99496 (codes for transitional care management services).

(13) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

HCPCS Codes

(1) G0402 (code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0442 (code for alcohol misuse screening service).

(4) G0443 (code for alcohol misuse counseling service).

(5) G0444 (code for annual depression screening service).

(6) G0463 (code for services furnished in Electing Teaching Amendment hospitals).

(7) G0506 (code for chronic care management).

(8) G2010 (code for the remote evaluation of patient video/images).

(9) G2012 (code for virtual check-in).

(10) G2058 (code for non-complex chronic care management).

(11) G2064 and G2065 (codes for principal care management services).

(12) G2214 (code for psychiatric collaborative care model).

b. Revisions

(1) HCPCS and CPT Codes Used in Assignment

In the CY 2022 PFS proposed rule (86 FR 39276), we explained that based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believed it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and to make other technical changes to the definition of primary care services, for use in determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years.

We proposed to revise the definition of primary care services in the Shared Savings Program regulations to include the following additions: (1) Chronic Care Management (CCM) CPT code 99X21, if finalized through the CY 2022 PFS rulemaking; (2) Principal Care Management (PCM) CPT codes 99X22, 99X23, 99X24, and 99X25, if finalized through the CY 2022 PFS rulemaking; (3) Prolonged office or other outpatient evaluation and management (E/M) service HCPCS code G2212; and (4) Communication Technology-Based Service (CTBS) HCPCS code G2252, if payment for this code is made permanent through the CY 2022 PFS rulemaking. The following provides additional information about the CPT codes and HCPCS codes that we proposed to add to the definition of primary care services used in assignment:

• *Chronic Care Management (CCM) CPT code 99X21.* For CY 2022, the American Medical Association (AMA) CPT Editorial Panel created a new CPT code that describes CCM services furnished by clinical staff under the supervision of a physician or NPP who can bill E/M services, and CCM services personally furnished by a physician or NPP. In the proposed rule, we proposed valuation of CPT code 99X21 (*Chronic care management services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored; each additional 30 minutes by a physician or other qualified health care professional, per calendar month*). CPT code 99X21 is being finalized as CPT code 99437, as discussed elsewhere in this final rule.

In earlier rulemaking, we finalized the inclusion of CCM CPT codes 99487, 99489, 99490, and 99491 (codes for chronic care management) in the definition of primary care services for the Shared Savings Program. Refer to the June 2015 final rule (80 FR 32746 through 32748), CY 2018 PFS final rule (82 FR 53212 through 53213), and CY 2021 PFS final rule (85 FR 84749 through 84750 and 84754). ''Non-complex'' CCM services (CPT codes 99490 and 99491), and ''complex'' CCM services (CPT codes 99487 and 99489) share a common set of service elements, including the following: (1) Initiating visit, (2) structured recording of patient information using certified electronic health record technology (EHR), (3) 24/7 access to physicians or other qualified health care professionals or clinical staff and continuity of care, (4) comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs, (5) comprehensive care plan including a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed, and (6) management of care transitions. They differ in the amount of clinical staff service time provided, the involvement and work of the billing practitioner, and the extent of care planning performed.

In the proposed rule, we explained that the CCM services that will be furnished under the new CPT code 99X21 are similar to the CCM services that are billed under the existing CCM codes that are included in the Shared Savings Program's current definition of primary care services, which includes CCM CPT codes 99487, 99489, 99490, 99491 and HCPCS code G0506. Because the Shared Savings Program's definition of primary care services includes other CCM CPT codes and HCPCS codes, we proposed to include CPT code 99X21, if finalized, in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years.

• *Principal Care Management (PCM) services CPT Codes 99X22, 99X23, 99X24, and 99X25.* The AMA CPT Editorial Panel has created the following new CPT codes that describe PCM services furnished by clinical staff under the supervision of a physician or NPP who can bill E/M services, and PCM services personally furnished by a physician or NPP:

++ 99X22 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month).*

++ 99X23 *(Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant*

practitioners furnishing care; additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month).

++ 99X24 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*).

++ 99X25 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*). As discussed elsewhere in this final rule, CPT code 99X22 is being finalized as CPT code 99424, CPT code 99X23 is being finalized as CPT code 99425, CPT code 99X24 is being finalized as CPT code 99426, and CPT code 99X25 is being finalized as CPT code 99427.

In the CY 2022 PFS proposed rule (86 FR 39277), we explained our belief that because the Shared Savings Program's definition of primary care services already includes the temporary HCPCS codes G2064 and G2065 that will be replaced by the permanent CPT codes 99X22 and 99X24, and CPT codes 99X23 and 99X25 represent the same services furnished for a greater length of time, it would be appropriate to include CPT code 99X22, 99X23, 99X24, and 99X25, as finalized through the CY 2022 PFS rulemaking, in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years. Although the temporary HCPCS codes G2064 and G2065 will be replaced by the permanent CPT codes, we stated that the Shared Savings Program would retain the temporary HCPCS codes in the definition of primary care services used for assignment, to be used in conducting beneficiary assignment for benchmark years.

- *Prolonged office or other outpatient evaluation and management (E/M) service HCPCS code G2212:* In the CY 2021 PFS final rule (85 FR 84573 through 84574), CMS finalized a new HCPCS code G2212 (*Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services) (Do not report G2212 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416). (Do not report G2212 for any time unit less than 15 minutes)*) to be used when billing Medicare for prolonged office/outpatient E/M visits instead of CPT code 99417, starting in 2021. We stated our belief that the creation of HCPCS code G2212 will serve to resolve the potential differences between Medicare and other interpretations of CPT rules, and better address questions about the required times and what time may be counted toward the required time to report prolonged office/outpatient E/M visits (see the CY 2020 PFS final rule for a more detailed discussion of this issue, (84 FR 62849 through 62850)).

The current definition of primary care services used in the Shared Savings Program assignment methodology includes CPT codes 99201 and 99215 (codes for office or other outpatient visit for the E/M of a patient). Because HCPCS code G2212 is defined as an add-on code for those office/outpatient E/M services, representing the same underlying services being furnished for a longer period of time, we proposed to include HCPCS code G2212 in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years.

- *Communication Technology-Based Service (CTBS) HCPCS code G2252:* In the CY 2021 PFS final rule (85 FR 84536), CMS established additional coding and payment for services delivered via synchronous communication technology, which can include audio-only communication on an interim basis for CY 2021. We stated our belief that establishing payment for a longer service (11–20 minutes) on an interim basis would support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. Therefore, for CY 2021, on an interim basis, we established HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion).* As discussed elsewhere in this final rule, we are finalizing our proposal to permanently establish separate coding and payment for the longer virtual check-in service described by HCPCS code G2252.

HCPCS code G2252 is similar to G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion)*, but allows for an extended period of medical discussion. Because G2012 is already included the definition of primary care services at § 425.400(c), in the CY 2022 PFS proposed rule (86 FR 39277), we explained our belief that including G2252 in the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2022, would result in more accurate assignment of beneficiaries based on where they receive the plurality of their primary care services. Accordingly, we proposed to include HCPCS code G2252 in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years.

We proposed to specify a revised definition of primary care services in a

new provision of the Shared Savings Program regulations at § 425.400(c)(1)(vi) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(v) with the additional CPT codes 99X21, 99X22, 99X23, 99X24, and 99X25, and HCPCS codes G2212 and G2252, if finalized through the CY 2022 PFS rulemaking. As noted previously, elsewhere in this final rule, we are finalizing CPT code 99X21 as 99437, CPT code 99X22 as 99424, CPT code 99X23 as 99425, CPT code 99X24 as 99426, and CPT code 99X25 as 99427. We proposed that the new provision at § 425.400(c)(1)(vi) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years. Further, we proposed technical modifications to the introductory text in § 425.400(c)(1)(v) to specify the applicability of this provision for determining beneficiary assignment for the performance year starting on January 1, 2021.

(2) Extending the Applicability of the Expanded Definition of Primary Care Services in Response to the PHE for COVID–19

As previously described in this section III.J.2.a. of this final rule, in the May 8, 2020 COVID–19 IFC (85 FR 27582 through 27586), we adopted an expanded definition of primary care services for purposes of beneficiary assignment to reflect services furnished during the PHE for COVID–19. This expanded definition was finalized with modifications in the CY 2021 PFS final rule (85 FR 84785 through 84793). According to § 425.400(c)(2), when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the PHE for COVID–19 defined in § 400.200, in determining beneficiary assignment, we use the primary care service codes identified in § 425.400(c)(1), and additional primary care service codes as follows:

CPT codes:

(1) 99421, 99422, and 99423 (codes for online digital evaluation and management services).

(2) 99441, 99442, and 99443 (codes for telephone evaluation and management services).

HCPCS codes:

(1) G2010 (code for the remote evaluation of patient video/images).

(2) G2012 (code for virtual check-in).

These additional primary care services are applicable to all months of the assignment window, when the assignment window includes any month(s) during the COVID–19 PHE defined in § 400.200.

In the CY 2021 PFS final rule (85 FR 84748 through 84755), we updated the definition of primary care services under § 425.400(c) permanently for purposes of determining beneficiary assignment under § 425.402 for the performance year starting on January 1, 2021, and subsequent performance years, so that the following codes would not be linked to the duration of the PHE for COVID–19: (1) HCPCS code G2010 (remote evaluation of patient video/images) and HCPCS code G2012 (virtual check-in); (2) CPT codes 99421, 99422 and 99423 (online digital evaluation and management service (e-visit)).

In the CY 2021 PFS final rule, we noted that we did not consider including CPT codes 99441, 99442, and 99443 in the definition of primary care services at § 425.400(c) on a permanent basis (85 FR 84751). Telephone E/M services CPT codes 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*); 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*); and 99443 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion*) are non-covered services when not provided during the PHE for COVID–19, as defined in § 400.200, and so could not be included in the definition of primary care services for purposes of assignment outside the context of the PHE.

In the CY 2022 PFS proposed rule, we proposed to revise the timeframe for services added on a temporary basis to the Medicare telehealth services list to allow additional time for stakeholders to perform an adequate analysis of those services for consideration in determining whether to include them on the Medicare telehealth services list on a permanent basis. As discussed in section II.D of this final rule, we are finalizing this revised timeframe, as proposed, and will retain all services added to the Medicare telehealth services list on a temporary, Category 3 basis until the end of CY 2023.

In order to remain consistent with Medicare FFS payment policies, in the CY 2022 PFS proposed rule (86 FR 39278), we proposed to revise our existing definition of primary care services for purposes of beneficiary assignment in order to include CPT codes 99441, 99442, and 99443 until they are no longer payable under the Medicare FFS payment policies as specified under section 1834(m) of the Act and §§ 410.78 and 414.65. We proposed to specify this modification by revising § 425.400(c)(2)(i)(A)(2) to include an exception to the applicability of the expanded definition of primary care services, to extend the timeframe for use of CPT codes 99441, 99442, and 99443, and by making conforming revisions to paragraphs (c)(2)(i) and (c)(2)(ii).

(3) Incorporation of Replacement Codes Into the Definition of Primary Care Services to Reflect Current Coding

In the June 2015 final rule (80 FR 32746 through 32748), we established a policy under which we make any revisions to the definition of primary care services for purposes of beneficiary assignment through the annual PFS rulemaking process. We established this policy in order to promote flexibility for the Shared Savings Program and to allow the definition of primary care services used for assignment in the Shared Savings Program to respond quickly to HCPCS/CPT coding changes made in the annual PFS rulemaking process. Accordingly, as part of the PFS rulemaking process, we periodically update the definition of primary care services used for assignment to include additional codes that we designate as primary care services for purposes of the Shared Savings Program, including new HCPCS/CPT codes or revenue codes and any subsequently modified or replacement codes.

On a routine basis, the CPT Editorial Panel may delete existing CPT codes and replace them with new CPT codes. In addition, one use of HCPCS G-codes is to identify professional healthcare procedures and services that may not

have assigned CPT codes. Thus, the CPT Editorial Panel may also create new CPT codes to replace these temporary HCPCS codes.

Currently, there may be a period of time between the issuance of a replacement code and the effective date of the final rule that incorporates the replacement code into the definition of primary care services, when the replacement code is not captured in the Shared Savings Program assignment methodology. Therefore, in the CY 2022 PFS proposed rule (86 FR 39279), we proposed to incorporate into the definition of primary care services a permanent CPT code when it directly replaces another CPT code or a temporary HCPCS code (for example, a G-code) that is already included in the definition of primary care services for purposes of determining beneficiary assignment under the Shared Savings Program. In general, we would expect to determine that a code is a direct replacement for another code based either on it having a substantially similar code description or the relevant discussion in CMS rulemaking establishing payment for the replacement code. We explained that this approach would help to ensure the appropriate identification of primary care services used in the Shared Savings Program's assignment methodology by allowing for the immediate inclusion of replacement CPT codes in the determination of beneficiary assignment and lead to continuity in the assignment of beneficiaries receiving those services based on current coding. This continuity would improve predictability for ACOs, while also increasing the consistency of care coordination for their assigned beneficiaries.

We further proposed that such replacement codes would be incorporated into the definition of the primary care services for purposes of determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years, when the assignment window for a benchmark or performance year (as defined in § 425.20) includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare. For ACOs under preliminary prospective assignment with retrospective reconciliation, CMS assigns beneficiaries in a preliminary manner at the beginning of a performance year and quarterly based on the most recent 12 months of data available. For final assignment for a 12-month benchmark year or performance year, the assignment window is the 12-month calendar year that corresponds to the performance year or benchmark year. We stated that under this proposal, a replacement CPT code that becomes effective during a 12-month initial, quarterly, or final assignment window would be included in the definition of primary care services used to determine beneficiary assignment for the applicable performance year or benchmark year. For ACOs under prospective assignment, claims-based beneficiary assignment is determined prospectively at the beginning of each benchmark and performance year based on the beneficiary's use of primary care services in the most recent 12 months for which data are available, based on an offset assignment window before the start of the benchmark or performance year. We explained that under this proposal, a replacement CPT code that becomes effective during the offset assignment window would be included in the definition of primary care services used to determine beneficiary assignment for the applicable performance year or benchmark year.

In the CY 2022 PFS proposed rule, we noted that we anticipated that we would continue to undergo periodic notice and comment rulemaking, through the annual PFS rulemaking, to amend the list of CPT codes and HCPCS codes that make up the definition of primary care services used for assignment in the Shared Savings Program to codify the applicable replacement CPT codes.

We proposed to incorporate the revised definition of primary care services used for assignment in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(vi), applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years. As part of this revised definition, we proposed to incorporate a provision in paragraph (c)(1)(vi)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified in § 425.400(c)(1)(vi)(A) or a HCPCS code specified in § 425.400(c)(1)(vi)(B), when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

We solicited comment on these changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2022, and subsequent performance years. We also welcomed comments on any other existing HCPCS or CPT codes, and new HCPCS or CPT codes proposed elsewhere in the proposed rule, that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We received public comments on these proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2022, and subsequent performance years. Additionally, we received one comment suggesting further changes to the HCPCS and CPT codes that are considered for purposes of beneficiary assignment. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposals regarding the expansion of the definition of primary care services for purposes of assignment in the Shared Savings Program regulations. Many commenters agreed that the proposed updates to the definition of primary care services will help to improve the accuracy of beneficiary assignment to ACOs participating in the Shared Savings Program by keeping assignment closely aligned with primary care relationships. Several commenters agreed that the proposed additions are similar to services already included on the list of primary care services considered for purposes of assignment. One commenter indicated that including chronic care management and principal care management codes ensures that patients are correctly linked through the assignment process to the providers who provide their holistic spectrum of care. Another commenter appreciated the inclusion of care management services and stated that successful care coordination is a foundational element of ACOs' work and these codes are frequently used by ACO participants. An additional commenter supported the proposed changes and stated that the updates would increase opportunities for advanced practice registered nurses (APRNs) to participate in ACOs and would allow their patients to be assigned to ACOs participating in the Shared Savings Program through claims-based assignment. Another commenter, although supportive of the proposed changes, stated that CMS needs to continue to refine the existing assignment methodology by continuing the transition toward primary care as a base, but did not provide specific suggestions for additional modifications.

Response: We appreciate the commenters' support for our proposal to revise the definition of primary care

services used for assignment under the Shared Savings Program regulations to include the following additions: (1) Chronic Care Management (CCM) CPT code 99X21, which is being finalized as 99437 as discussed elsewhere in this final rule; (2) Principal Care Management (PCM) CPT codes 99X22, 99X23, 99X24, and 99X25, which are being finalized as CPT codes 99424, 99425, 99426, and 99427, respectively, as discussed elsewhere in this final rule; (3) Prolonged office or other outpatient evaluation and management (E/M) service HCPCS code G2212; and (4) Communication Technology-Based Service (CTBS) HCPCS code G2252. We agree that expanding the definition of primary care services used for beneficiary assignment as proposed will allow for more accurate assignment and that maintaining an updated list of codes that includes chronic care management (CCM), principal care management (PCM), and other E/M services is important in determining where patients receive most of their primary care while also ensuring that the definition of primary care services used for purposes of assignment remains in alignment with HCPCS/CPT coding changes made under the PFS.

After consideration of public comments, we are finalizing our proposal to incorporate the aforementioned codes into the definition of primary care services that will be used in determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years. We are also finalizing our proposal to specify the updated definition of primary care services used in assignment for these performance years in a new provision of the regulations at § 425.400(c)(1)(vi). We note that we have updated the organization of § 425.400(c)(1)(vi) for purposes of this final rule to ensure that the new CPT codes, as finalized elsewhere in this final rule, are listed in numerical order for simplicity and ease of identification.

Comment: Several commenters supported our proposal to revise the existing definition of primary care services for purposes of beneficiary assignment in order to include CPT codes 99441, 99442, and 99443 until they are no longer payable under the Medicare FFS payment policies as specified under section 1834(m) of the Act and §§ 410.78 and 414.65. Many commenters stated that they believe this proposal would align with payment policies under the PFS and help to ensure that beneficiaries are appropriately aligned with an ACO based on their receipt of primary care services, which will strengthen the Shared Savings Program assignment methodology. A few commenters noted that they supported our proposal to continue using CPT codes 99441, 99442, and 99443 in Shared Savings Program assignment until these codes are no longer payable under Medicare FFS policies, because telehealth has been an important lifeline during the pandemic for patients, who are able to receive necessary care while avoiding risks of in-person visits. These commenters described how they have relied on telehealth to maintain patient relationships during the PHE for COVID–19, including the audio-only telephone E/M services that were temporarily added to the list of services eligible to be delivered via telehealth during the PHE for COVID–19. One commenter stated that the extension of the use of telephone E&M CPT codes 99441 through 99443 would help to facilitate ACO participants' adaptation to changing clinical environments in response to the PHE. Another commenter appreciated CMS' proposal to extend these codes to allow time to conduct further analysis to determine if they should be permanently added to the Medicare telehealth service list. Another commenter fully supported the extension of these services' inclusion on the Medicare telehealth services list but requested that CMS closely monitor the impact telehealth has on populations assigned to ACOs. In particular, the commenter suggested that if ACOs are losing assigned beneficiaries as a result of telehealth visits with telehealth vendors that are not ACO participants, CMS should consider establishing a requirement that the telehealth vendor be an ACO participant or preferred provider in order for the services to be considered in beneficiary assignment.

Response: We agree that including CPT codes 99441, 99442, and 99443 in the definition of primary care services used for beneficiary assignment until they are no longer payable under the PFS FFS payment policies will allow for more accurate assignment and promote continuity of care. With regard to the impact of telehealth utilization on beneficiary assignment, we conduct ongoing monitoring of the impact of telehealth utilization on assignment and thus far the impact has been minimal and has not warranted policy changes.

After consideration of public comments, we are finalizing our proposal to revise the existing definition of primary care services for purposes of beneficiary assignment in order to include CPT codes 99441, 99442, and 99443 until they are no longer payable under Medicare FFS payment policies as specified under section 1834(m) of the Act and §§ 410.78 and 414.65.

Comment: Several commenters supported our proposal to incorporate into the definition of primary care services used for assignment a permanent CPT code when it directly replaces another CPT code or a temporary HCPCS code (for example, a G-code) that is already included in the definition of primary care services for purposes of determining beneficiary assignment under the Shared Savings Program. One commenter supported the finalization of this policy because it would streamline use of these services across the healthcare industry, presumably by accounting for the transition between the temporary and permanent codes and encouraging the adoption and use of new, permanent codes. Another commenter was supportive of the proposal because it would shorten the gap between when codes are updated and when they are available for use in assignment, which will align the claims-based assignment methodology with the PFS and help to ensure beneficiaries are appropriately aligned with the ACO that is responsible for their overall care.

Response: We agree that finalizing this proposal will ensure alignment between the Shared Savings Program assignment methodology and payment and coding guidelines under the PFS.

After consideration of the public comments, we are finalizing our proposal to incorporate into the definition of primary care services used for assignment a permanent CPT code when it directly replaces another CPT code or a temporary HCPCS code (for example, G-code) that is already included in the definition of primary care services for purposes of determining beneficiary assignment under the Shared Savings Program.

Comment: Regarding our solicitation for comment on any other existing HCPCS or CPT codes, and new HCPCS or CPT codes that we should consider adding to the definition of primary care services for purposes of assignment, one commenter stated that we should consider deleting HCPCS code G0506 *(Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services)* from the current definition of primary care services for the Medicare Shared Savings Program patient assignment methodology. The commenter stated that HCPCS code G0506 was identified as potentially misvalued in October 2020 and potentially duplicates the physician work valued under CPT code 99491,

and therefore, CMS should consider deleting G0506.

Response: We appreciate this feedback and will consider it for future rulemaking.

3. Repayment Mechanisms

a. Background

An ACO that will participate in a two-sided model must demonstrate that it has established an adequate repayment mechanism to provide CMS assurance of its ability to repay shared losses for which the ACO may be liable upon reconciliation for each performance year. The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in § 425.204(f), and we have provided additional program guidance on repayment mechanism arrangements.[117] We established the repayment mechanism requirements through earlier rulemaking,[118] and recently modified the repayment mechanism requirements in the December 2018 final rule (83 FR 67928 through 67938) and the CY 2021 PFS final rule (85 FR 84756 through 84763).

According to § 425.204(f)(4)(ii), for a BASIC track or ENHANCED track ACO, the repayment mechanism amount must be equal to the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. As discussed in the December 2018 final rule (83 FR 67866), this approach allows CMS to use the same sources of revenue and expenditure data during the program's annual application cycle to estimate the ACO's repayment mechanism amount and to determine the ACO's participation options according to whether the ACO is categorized as a low revenue ACO or high revenue ACO.

As specified under § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. We require an increase in the repayment mechanism amount if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value. Under § 425.204(f)(4)(iii), an ACO cannot decrease the amount of its repayment mechanism during its agreement period as a result of changes in its composition.

As discussed in prior rulemaking, program stakeholders have continued to identify the repayment mechanism requirement as a potential barrier for some ACOs to enter into performance-based risk tracks, particularly small, physician-only and rural ACOs that may lack access to the capital that is needed to establish a repayment mechanism with a large dollar amount (see for example, 83 FR 67929).

The design of the current repayment mechanism amount calculation, which is based on a percentage of expenditures for the ACO's assigned beneficiaries or a percentage of ACO participant revenue, seeks to approximate a percentage of the ACO's maximum possible shared losses, according to the loss recoupment limits (also referred to as the loss sharing limits) applicable to ACOs under two-sided models. As described in the CY 2022 PFS proposed rule (86 FR 39280), comparing the calculations for determining repayment mechanism amounts to the calculations for determining the loss sharing limits indicates that repayment mechanisms cover approximately 25 percent of estimated maximum possible losses for ACOs in the BASIC track (determined by dividing 1 percent, the percentage used in the repayment mechanism amount calculation under § 425.204(f)(4)(ii)(A), by 4 percent, the percentage of the benchmark-based loss sharing limit under Level E of the BASIC track under § 425.605(d)(1)(v)(D)(2)), and 7 percent of estimated maximum possible losses for ACOs in the ENHANCED track (determined by dividing 1 percent, the percentage used in the repayment mechanism amount calculation under § 425.204(f)(4)(ii)(A), by 15 percent, the percentage of the benchmark-based loss sharing limit under the ENHANCED track under § 425.610(g)). Based on operational experience, we have found that the repayment mechanism amounts for most ACOs are much larger than needed to cover actual losses, as repayment mechanism amount calculations have been based on a percentage of an amount that approximates the ACO's loss sharing limit (which is as high as 15 percent of updated benchmark expenditures in the ENHANCED track),[119] and actual historical shared losses have been much lower than the loss sharing limit, averaging 0.96 percent of the ACO's benchmark. Some ACOs have been required to establish repayment mechanisms with amounts that are 9 times greater than their actual shared losses. Additionally, of the 35 times ACOs have owed shared losses, as determined based on reconciliation for the Shared Savings Program's first performance year concluding on December 31, 2013, through performance years (or a performance period) in 2019, only one ACO has neglected to repay CMS timely, and most ACOs chose to repay shared losses without the use of their repayment mechanism arrangements. For the one ACO that did not repay CMS, we were able to recoup more than half of the shared losses owed using the ACO's repayment mechanism, and the remaining debt was referred to the Department of Treasury for collection.

As we explained in the CY 2022 PFS proposed rule (86 FR 39280), considering this experience, which suggests there may be low risk to the Shared Savings Program by allowing lower repayment mechanism amounts, and the potential reduction in burden on ACOs by lower repayment

[117] Medicare Shared Savings Program, Repayment Mechanism Arrangements, Guidance Document, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf* (hereinafter Repayment Mechanism Arrangements Guidance).

[118] Refer to the November 2011 final rule, 76 FR 67802, 67937 through 67940 (establishing the requirement for Track 2 ACOs). Refer to the June 2015 final rule, 80 FR 32692, 32781 through 32785 (adopting the same general requirements for Track 3 ACOs with respect to the repayment mechanism and discussing modifications to reduce burden of the repayment requirements on ACOs).

[119] The repayment mechanism amount calculations have varied over time, and the loss sharing limits are variable based on track/level. For reference: For BASIC track or ENHANCED track ACOs, refer to the repayment mechanism amount calculation methodology specified in § 425.204(f)(4)(ii), as described in this section of this final rule.

Repayment mechanism amounts for ACOs participating in Track 2 and Track 3 (subsequently renamed the ENHANCED track), in agreement periods beginning on or before January 1, 2019, are calculated as 1 percent of total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for a reference year (refer to 76 FR 67978 and 67979, 80 FR 32838, and § 425.204(f)(4)(i)).

Refer to the loss recoupment limits for Levels C, D and E of the BASIC track, Track 2 and the ENHANCED track as specified in subpart G of the Shared Savings Program regulations.

Refer to the Medicare ACO Track 1+ Model Participation Agreement (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf*), specifying a bifurcated approach used to determine the estimated amount of an ACO's repayment mechanism for consistency with the bifurcated approach to determining the loss sharing limit under the Track 1+ Model.

mechanism amounts, we believe it is appropriate to modify the approach to calculating repayment mechanism amounts. Further, we noted that we believe reducing the required amounts of repayment mechanisms may allow ACOs to use these funds to improve patient care and coordination and reduce a potential barrier to entry into performance-based risk models.

In the CY 2022 PFS proposed rule (86 FR 39279 through 39288), we discussed four proposed policy changes regarding required repayment mechanism amounts. Under the first policy, we would modify the methodology for calculating repayment mechanism amounts to reduce the required amounts. Second, we would specify how we identify the number of assigned beneficiaries used in the repayment mechanism amount calculation and the annual repayment mechanism amount recalculation. Third, we would permit eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to reduce the amount of their existing repayment mechanisms if their recalculated repayment mechanism amount for performance year 2022 is lower than their existing repayment mechanism amount. Fourth, we would modify the threshold for determining whether an ACO is required to increase its repayment mechanism amount during its ACO's agreement period.

Within this section of this final rule we respond to more general comments received on the proposed modifications to the Shared Savings Program's repayment mechanism requirements, and summarize comments that go beyond the scope of these proposals. In section III.J.3.b of this final rule, we summarize and respond to public comments we received on the proposed changes more specifically.

Comment: Several commenters explained that securing a repayment mechanism is a time consuming, costly regulatory burden for ACOs. Some commenters explained that the administrative burden and financial cost of securing a repayment mechanism pose barriers for ACOs to move to two-sided models, can act as a deterrent to ACO participation, or cause ACOs to divert resources away from care improvement initiatives. Some commenters stated more generally their appreciation for and support of CMS proposing ways to minimize the burdens associated with the repayment mechanisms. Several commenters pointed to CMS' determination, as described in the CY 2022 PFS proposed rule, that the repayment mechanism amounts for most ACOs are larger than needed to cover actual losses, and reduced repayment mechanism amounts would better reflect the amounts needed to cover potential shared losses under the Shared Savings Program.

Commenters addressing the proposed revisions to required repayment mechanism amounts expressed support for a combination of policies that would decrease the amount of repayment mechanisms, including all or several of the following: Modifying the methodology for calculating repayment mechanism amounts, permitting eligible ACOs in two-sided models a one-time opportunity to reduce their repayment mechanism amount, and modifying the threshold for when an ACO needs to increase its repayment mechanism amount during an ongoing agreement period. Some commenters explained that such changes would decrease the administrative burden and financial burden of participation in the Shared Savings Program. Several commenters indicated that these changes could free financial resources for investing in other aspects of ACO operations, including patient care and coordination, and initiatives to improve quality, access, and patient experience. A commenter described the proposed modifications to repayment mechanism obligations as ''ACO-friendly'' and welcomed the additional flexibility in the Shared Savings Program.

Response: We appreciate commenters' support for the modifications to the repayment mechanism calculation methodology that we proposed in the CY 2022 PFS proposed rule that would result in lower required repayment mechanism amounts for ACOs. We appreciate commenters' support for our assessment that lower repayment mechanism amounts under the proposed calculation methodology would better reflect the amounts needed to cover actual shared losses under the Shared Savings Program. These comments also reaffirm our belief that lower repayment mechanism amounts under the proposed approach would reduce administrative burden and financial costs on ACOs, potentially allowing ACOs to use these funds to improve patient care and coordination and reduce a potential barrier to entry into performance-based risk models. Further, we continue to believe that the lower repayment mechanism amounts under the proposals would provide CMS with reasonable assurance of an ACO's ability to repay shared losses and would help protect the Medicare trust funds in the event CMS uses an ACO's repayment mechanism funds to support recoupment of shared losses.

As described in greater detail in section III.J.3.b of this final rule, we are finalizing our proposed modifications to the Shared Savings Programs' repayment mechanism requirements. Although not addressed specifically in the CY 2022 PFS proposed rule, we believe this collection of repayment mechanism policy changes may have a number of beneficial health equity impacts on Shared Savings Program ACOs and the populations of Medicare FFS beneficiaries they serve. Lower repayment mechanism requirements would require ACOs to set aside relatively smaller dollar amounts, such as for ACOs establishing and maintaining an escrow account as their repayment mechanism, or could result in lower fees charged by financial institutions for letters of credit and by insurance companies for surety bonds. As a result, low revenue ACOs and smaller, rural and physician-only ACOs may be better able to afford repayment mechanisms, and therefore, may more readily transition to performance-based risk. We have indicated in earlier rulemaking that ACOs under performance-based risk models, and specifically those participating under higher levels of risk and potential reward, have greater potential to control their assigned beneficiaries' Medicare Parts A and B FFS expenditures by coordinating care across care settings, and thus may achieve significant change in spending. Additionally, we anticipate that relatively lower repayment mechanism amounts and less frequent repayment mechanism amount increases during the ACO's agreement period would give ACOs an opportunity to repurpose these funds for other uses, such as to improve patient care and coordination, or support quality improvement activities. That, in turn, may lead to care improvements for the ACO's Medicare FFS beneficiaries generally, including care for medically complex and high-risk populations. Further, repayment mechanism amount requirements based on either a percentage of expenditures for an ACO's assigned beneficiaries or percentage of its ACO participant revenue, reflect the higher cost of care that may be associated with serving medically complex Medicare FFS beneficiaries. We believe that reducing the percentages used in these repayment mechanism amount calculations will result in relatively lower burden on ACOs serving medically complex populations, and such ACOs may see a larger absolute dollar value reduction in

their repayment mechanism amounts compared to other ACOs.

Comment: Some commenters suggested changes to repayment mechanism policies that were outside the scope of this rulemaking, including the following:

- Suggestions that CMS share its lessons learned about the amount of repayment mechanisms for Shared Savings Program ACOs with the Innovation Center, and that CMS consider lowering the financial collateral requirements for the Global and Professional Direct Contracting (GPDC) model and Comprehensive Kidney Care Contracting (CKCC) under the Kidney Care Choices model.
- Requests for additional modifications to Shared Savings Program requirements, including that CMS eliminate the requirement for ACOs to maintain their repayment mechanism for the 12-month ''tail period'' beyond the expiration of their agreement period which was described as creating unnecessary, additional burden which is costly for ACOs.
- Suggestions that CMS provide greater flexibility for ACOs needing to adjust their repayment mechanisms over time, such as by permitting the release funds for a limited window, such as 60 days, for ACOs changing repayment mechanisms.
- Suggestions that CMS expand the permissible repayment mechanism types under the Shared Savings Program, to include reinsurance and withholding Medicare payments.

Response: Comments of this nature are beyond the scope of the policies and are not being addressed in this final rule.

b. Revisions

(1) Repayment Mechanism Amount Calculations

In the CY 2022 PFS proposed rule (86 FR 39280 through 39283), we considered two options for modifying the calculation of repayment mechanism amounts to result in lower amounts: (1) Reducing the percentages used in the existing repayment mechanism amount calculations specified in § 425.204(f)(4)(ii); or (2) revising the methodology to use a per beneficiary dollar amount estimation methodology. In evaluating these options, we considered the potential impact on low revenue ACOs and high revenue ACOs, as defined according to § 425.20. We also considered a balance of factors, including whether to retain an approach similar to the existing methodology or to use an alternative approach that could simplify the repayment mechanism amount calculation to make it more predictable. Additionally, we considered the magnitude of potential decreases in the repayment mechanism amounts under each option. We proposed the first option, to reduce the percentages used in the existing repayment mechanism amount calculations, but we solicited comment on the second, alternative option we considered. We proposed to lower the repayment mechanism amounts by reducing the percentages used in our current methodology, under which we calculate the repayment mechanism amount as the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. Specifically, we proposed to calculate the amount as the lesser of the following: (1) One-half (0.5) percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

As discussed in the CY 2022 PFS proposed rule, under this proposal, ACOs would receive a 50 percent decrease in their repayment mechanism amounts compared to the current methodology. These amounts would offer lower repayment mechanism amounts for ACOs, while still reserving what we believe to be a reasonable amount in the event CMS uses an ACO's repayment mechanism funds to support recoupment of shared losses. Our review of data for ACOs under a two-sided model revealed that if this repayment mechanism amount calculation method were in place for performance year 2021, the amount by which repayment mechanism amounts would be reduced (the ''repayment mechanism savings'') would average $297,665 for low revenue ACOs and $2.31 million for high revenue ACOs; the minimum repayment mechanism savings would be $27,030 for low revenue ACOs and $78,106 for high revenue ACOs; and the maximum repayment mechanism savings would be $1.97 million for low revenue ACOs and $11.70 million for high revenue ACOs.

A second, alternative option we considered would be to estimate the repayment mechanism amount using a per beneficiary dollar amount that would be based on a percentage of actual historical median per capita shared losses for Shared Savings Program ACOs, multiplied by an estimate of the size of the ACO's assigned population as identified during the annual application or annual change request cycle. In considering this option, we analyzed data from the 35 instances when Shared Savings Program ACOs in two-sided models have ever incurred shared losses, defined as performance year expenditures above the ACO's benchmark by an amount equal to or greater than the ACO's minimum loss rate. Using data from actual historical shared losses, we determined median per beneficiary shared losses were $100.90 and calculated per beneficiary dollar amounts projected to cover 5 to 25 percent of shared losses for ACOs, as illustrated in Table 37.

TABLE 37: Percentage and Dollar Amounts of Median Per Beneficiary Actual Historical Shared Losses

Percentage	Dollar Amount Corresponding to Percentage of $100.90 Per Beneficiary Losses
5 percent	$5.05
7.5 percent	$7.57
10.0 percent	$10.09
12.5 percent	$12.61
15.0 percent	$15.14
17.5 percent	$17.66
20.0 percent	$20.18
22.5 percent	$22.70
25.0 percent	$25.23

Under this second, alternative option, we considered using separate per beneficiary dollar amounts for low revenue ACOs and high revenue ACOs. We stated our belief that using two separate percentages is supported for a number of reasons. Compared to high revenue ACOs, low revenue ACOs are likely to have a lower loss sharing limit in the BASIC track (determined as a percentage of ACO participant revenue not to exceed a percentage of the ACO's updated benchmark), under which eligible low revenue ACOs may participate for up to two agreement periods. Historically, low revenue ACOs have owed shared losses less often and have had lower amounts of per beneficiary shared losses compared to high revenue ACOs. Additionally, we stated that high revenue ACOs, which tend to include institutional providers and are typically larger and better capitalized, are likely better financially prepared to secure a higher amount in their repayment mechanism than low revenue ACOs, which tend to be smaller and have less capital. For low revenue ACOs, to cover 10 percent of median actual historical shared losses, rounding to the nearest $1 increment, we considered requiring a repayment mechanism amount equal to $10 per beneficiary. For high revenue ACOs, to cover 20 percent of median actual historical shared losses we considered requiring $20 per beneficiary (refer to Table 37). These amounts would offer a lower repayment mechanism amount for 99 percent of low and high revenue ACOs with existing repayment mechanisms, while still reserving what we believe to be a reasonable amount in the event CMS uses an ACO's repayment mechanism funds to support recoupment of shared losses. Our review of data for ACOs in a two-sided model revealed that if this repayment mechanism amount calculation method were in place for performance year 2021, the repayment mechanism savings would average $410,682 for low revenue ACOs and $3.84 million for high revenue ACOs; the minimum repayment mechanism savings would be $6,513 for low revenue ACOs and $120,491 for high revenue ACOs; and the maximum repayment mechanism savings would be $3.45 million for low revenue ACOs and $19.73 million for high revenue ACOs.

In the CY 2022 PFS proposed rule, we explained that there are a number of advantages to the option under which we would calculate repayment mechanism amounts using per beneficiary dollar amounts for low revenue ACOs and high revenue ACOs. For one, low revenue ACOs would receive additional relief through lower repayment mechanism amounts, relative to high revenue ACOs, under this approach. We explained our belief that this is appropriate considering the lower potential loss liability for low revenue ACOs and the fact that low revenue ACOs tend to be less well capitalized and may face potential barriers to establishing repayment mechanisms. Second, this approach aligns with the existing repayment mechanism amount calculation methodology, which tends to require proportionally higher amounts for high revenue ACOs because those ACOs tend to have higher average total expenditures for ACO assigned beneficiaries and higher total ACO participant revenue, compared to low revenue ACOs. Third, an approach that uses a per beneficiary dollar amount would simplify the method to calculate the repayment mechanism amount, compared to the existing methodology, and may help ACOs better project repayment mechanism amounts prior to entering two-sided models, either at the point of application to a new agreement period or during the ACO's agreement period within the BASIC track's glide path as ACOs transition from a one-sided model to a two-sided model. Lastly, this approach would lower the mean repayment mechanism amount for ACOs more than the reduction that would occur under our proposal to lower the percentages used in the existing amount calculation methodology.

However, we noted significant concerns with an approach that uses a per beneficiary dollar amount that is applied based on whether an ACO is determined to be a low revenue ACO or a high revenue ACO, which if unresolved outweigh the potential benefits of the approach. For one, there would be a significant repayment mechanism amount difference for ACOs near the 35 percent threshold that differentiates low revenue ACOs and high revenue ACOs, and this difference in repayment mechanism amount may not correlate to covering a significant additional increase in risk.

Second, the determination of whether an ACO is a low revenue ACO or high revenue ACO can change during the application cycle and between performance years within an agreement period. Although changes in ACO composition have the potential to affect repayment mechanism amounts determined under the existing calculation methodology, ACO composition changes could result in a greater magnitude of change in the repayment mechanism amount under an approach that applies a $10 per beneficiary amount for low revenue ACOs and a $20 per beneficiary amount for high revenue ACOs.

For ACOs establishing a repayment mechanism under the per beneficiary dollar amount approach, a change in revenue determination in later stages of the application cycle or change request cycle would delay calculation of an ACO's final repayment mechanism amount. In turn, this could delay when

the ACO could submit finalized repayment mechanism documentation to demonstrate it meets the repayment mechanism requirement for entering a two-sided model. We are also concerned that ACOs whose revenue determinations change from low revenue to high revenue would face a substantial increase in the required repayment mechanism amount which they could find challenging to finance. However, based on our operational experience there have been relatively few cases where an ACO's revenue determination changes during the later stages of the application review period or change request cycle.

During an ACO's agreement period, a change in the ACO's revenue determination may cause significant fluctuation in an ACO's repayment mechanism amount under an approach that calculates the repayment mechanism amount using a per beneficiary dollar amount based on whether an ACO is determined to be a low revenue ACO or a high revenue ACO. Based on our operational experience, however, few ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, have experienced a change in revenue determination during their agreement period. Section 425.600(e) specifies an approach to addressing the circumstance where an ACO that entered an agreement period under Level E of the BASIC track because it was low revenue and experienced with performance-based risk Medicare ACO initiatives, becomes high revenue during its agreement period. This approach requires the ACO to take corrective action to meet the definition of low revenue ACO, or CMS takes compliance action as specified in §§ 425.216 and 425.218, which may include termination of the participation agreement. Further, in the absence of a policy to permit decreases in the repayment mechanism amount during the ACO's agreement period, ACOs that establish a repayment mechanism based on a high revenue ACO determination and are subsequently determined to be a low revenue ACO would need to maintain a relatively higher repayment mechanism amount for the duration of their 5-year agreement period.

To resolve these concerns, we considered using a single per beneficiary dollar amount for all ACOs, based on the values described in Table 37. However, we were unable to identify a single per beneficiary dollar amount that would account for historically higher per beneficiary shared losses owed by high revenue ACOs, while resulting in lower repayment mechanism amounts compared to the existing repayment mechanism calculation approach for most low revenue ACOs. Specifically, the dollar amount that would allow for relatively lower repayment mechanism amounts for all ACOs would be $8 per beneficiary, to cover 7.5 percent of median actual historical shared losses, rounding to the nearest $1 increment, which we believe is too low for high revenue ACOs. A higher per beneficiary dollar amount, such as $15, to cover 15 percent of median actual historical shared losses, rounding to the nearest $1 increment, would be relatively disadvantageous to approximately 20 percent of low revenue ACOs.

As we noted in the CY 2022 PFS proposed rule, both our proposal and the second, alternative option would lower repayment mechanism amounts, and therefore, would reduce the amount available to CMS to support repayment of shared losses. However, we explained our belief that the risk of not collecting shared losses is mitigated for a number of reasons. As noted in the CY 2022 PFS proposed rule, in our analysis of repayment mechanism amounts compared to actual historical shared losses, we believe the lower amounts would continue to provide CMS with reasonable assurance of an ACO's ability to repay shared losses. Further, as discussed in earlier rulemaking (85 FR 50249), the Shared Savings Program's existing policies require ACOs to pay shared losses, in full, within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), and 425.610(h)(3)). ACOs have an interest in fully paying the amount of shared losses owed within the 90-day payment window to remain in compliance with the Shared Savings Program's requirements and avoid compliance actions including involuntary termination from the program. CMS may terminate an ACO's participation agreement for reasons including, but not limited to, non-compliance with requirements in § 425.218(b)(1), such as failure to repay shared losses owed according to the program's regulations and may take pre-termination actions as described in § 425.216(a). Under § 425.221(b)(2)(ii)(B), an ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. ACOs must also timely repay shared losses owed to avoid accruing interest on any unpaid amounts and to avoid referral of an unpaid debt to the Department of Treasury for collection. Based on our operational experience, nearly all ACOs fully repay shared losses without use of their repayment mechanism arrangement. Under our proposal, ACOs would continue to have the option to secure a repayment mechanism at an amount greater than the CMS required amount, if they believe that is appropriate to prepare their ACO to repay all shared losses.

Furthermore, we explained our belief that reduced repayment mechanism amounts could reduce costs for ACOs in fees charged by financial institutions for letters of credit and by insurance companies for surety bonds, although we would not anticipate a significant reduction in fees charged by banks or credit unions for establishing and maintaining escrow accounts. For example, reducing the required repayment mechanism amount of a given ACO by $1 million, could reduce the cost of obtaining a letter of credit or surety bond by roughly 1 or 2 percent, in this example resulting in $10,000 or $20,000 in reduced fees for the ACO. We estimated that such relief, in total for all participating ACOs, could be worth $2 to $4 million annually under the proposed approach (assuming a reduction of approximately $196 million in repayment mechanism amounts, in aggregate) and $3 to $6 million annually under the second, alternative option (assuming a reduction of approximately $322 million in repayment mechanism amounts, in aggregate).

In light of these considerations, we proposed to revise the regulations at § 425.204(f)(4)(ii) to reduce by one-half the percentages used in the methodology for calculating repayment mechanism amounts for ACOs in a two-sided model of the BASIC track or the ENHANCED track. We proposed to revise the percentage specified in § 425.204(f)(4)(ii)(A), for calculating an amount based on expenditures for the ACO's assigned beneficiaries, from 1 percent to one-half percent. We proposed to revise the percentage specified in § 425.204(f)(4)(ii)(B), for calculating an amount based on ACO participant revenue, from 2 percent to 1 percent. Under this approach for calculating repayment mechanism amounts for ACOs in a two-sided model of the BASIC track or the ENHANCED track, the repayment mechanism amount would be equal to the lesser of the following: (1) One-half percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent

calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

We solicited comments on this proposal and the second, alternative option for calculating repayment mechanism amounts using a per beneficiary dollar amount, based on a percentage of actual historical median per capita shared losses for Shared Savings Program ACOs, multiplied by an estimate of the size of the ACO's assigned population as identified during the annual application or annual change request cycle. We also solicited comments on applying different per beneficiary dollar amounts for low revenue ACOs and high revenue ACOs under this alternative approach. We welcomed comments to address the dollar amounts projected to cover the percentage of median actual historical shared losses that would be an appropriate basis for low revenue ACOs (such as $10) and high revenue ACOs (such as $20) under this methodology. Additionally, we solicited comments on approaches for addressing our concerns about changes in revenue determinations significantly affecting an ACO's repayment mechanism amount, such as applying a single per beneficiary dollar amount to all ACOs. We also noted that if we were to adopt such an approach, we would need to address with greater specificity factors including: (1) How we would identify the population of assigned beneficiaries that would be used in the calculation as a multiplier for the per beneficiary dollar amount; and (2) the frequency with which we would consider modifications to the per beneficiary dollar amount. We welcomed comments on these considerations.

We proposed that these modifications would be effective and applicable on January 1, 2022. We noted that the Shared Savings Program's application cycle (for new, renewing and re-entering ACOs) and change request cycle (for ACOs within an agreement period) for the performance year beginning on January 1, 2022 occurs between spring and fall 2021. During this timeframe, ACOs preparing to enter two-sided models for performance year 2022 are awaiting the final repayment mechanism amount for establishing a repayment mechanism, and ACOs within two-sided models are awaiting the determination of whether their repayment mechanism amount must be increased in accordance with § 425.204(f)(4)(iii) (as discussed in section III.J.3.b.(4) of this final rule). We explained that if the proposed modifications to the repayment mechanism amount calculation methodology are finalized and become effective and applicable on January 1, 2022, we would communicate to ACOs their final repayment mechanism amounts after the issuance of the final rule. We committed to ensuring that ACOs do not overfund their repayment mechanism arrangements according to the existing methodology if we finalized the proposed revisions to reduce repayment mechanism amounts.

We received public comments on the proposed modifications to the Shared Savings Program repayment mechanism amount calculations, and the alternative approach on which we solicited comments. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to modify the methodology for calculating repayment mechanism amounts to reduce the required amounts by one-half such that the required repayment mechanism amount would be the lesser of the following: (1) One-half percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12-months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12-months of data are available.

More specifically, several commenters suggested that this reduction in the required repayment mechanism amounts would minimize administrative costs of, or reduce administrative barriers for, ACOs participating in the Shared Savings Program. A commenter supporting this proposal stated that the modification would allow ACOs to use these funds to improve patient care and coordination. Several commenters explained their support for this proposed change as it would encourage more providers to enter or stay in the Shared Savings Program, particularly small and rural providers that have not yet had to take on performance-based risk.

Some commenters stated that reducing the required repayment mechanism amounts better reflects an appropriate portion of potential shared losses under the program's financial models.

Response: We agree with commenters and appreciate their support for the proposal.

Comment: Commenters also supported our findings, described in the CY 2022 PFS proposed rule, and restated in section III.J.3.a of this final rule, that the repayment mechanism amounts for most ACOs are much larger than needed to cover actual losses, as determined based on the existing amount calculation methodology and in light of CMS' operational experience at the time of the CY 2022 PFS proposed rule.

Response: We agree with commenters and appreciate their support for the findings underlying our proposed modifications to the repayment mechanism calculation methodology, as described in the CY 2022 PFS proposed rule.

Comment: Several commenters explained that the relatively lower repayment mechanism amounts that would result from the proposed approach are sufficient to prompt third-party due diligence and establish credit worthiness for ACOs seeking to obtain a repayment mechanism arrangement.

Response: We believe that a financial institution issuing a repayment mechanism conducts some form of due diligence on the financial strength, solvency and credit worthiness of the ACO, and this external review serves as further validation of the ACO's financial readiness to participate in a two-sided model. We agree this is an important function of the repayment mechanism requirements.

Comment: Several commenters addressed the alternative approach CMS described for calculating the required repayment amount values using a per beneficiary dollar amount, based on a percentage of actual historical median per capita shared losses for ACOs and multiplied by an estimate of the size of the ACO's assigned population. Several commenters preferred the alternative approach to utilize a per beneficiary dollar amount to calculate required repayment mechanism values, explaining this approach would improve transparency and allow ACOs to better predict their repayment mechanism amount prior to moving to two-sided risk. However, these commenters were not supportive of setting different per beneficiary dollar amounts for high revenue ACOs and low revenue ACOs, explaining that the high-low revenue distinction in the Shared Savings Program is arbitrary and creates an uneven playing field for ACO participants. These commenters suggested that CMS should generally stop distinguishing ACOs based on ACO revenue status in the Shared Savings Program, explaining that it has the unintended consequence of

discouraging partnerships between certain types of providers, such as hospitals and specialists, and penalizes ACOs that work to include a variety of provider types in their ACO participant list. A commenter expressed support for the proposal to reduce the percentages used in the repayment mechanism amount calculation, explaining that setting a per Medicare beneficiary amount would not reflect the difference in the per capita costs of Medicare beneficiaries that can vary from $8,500 all the way up to $17,000 even in similarly composed low revenue ACOs.

Response: We appreciate the comments received on the alternative option we considered for calculating repayment mechanism amounts using a per beneficiary dollar amount. We also appreciate comments that inform our consideration of using separate per beneficiary dollar amounts for low revenue ACOs and high revenue ACOs. However, the comments suggesting that CMS should generally stop distinguishing ACOs based on ACO revenue status are beyond the scope of the alternative approach to calculating repayment mechanism amounts, and therefore, will not be addressed in this final rule.

Although several commenters supported the alternative approach that would use per beneficiary dollar amounts to calculate repayment mechanism amounts, we decline to adopt this alternative approach with this final rule. We believe there are a number of aspects of such an approach that would require additional time to develop and evaluate, and we believe that the proposed approach to lowering the percentages in the existing repayment mechanism amount calculations would be a more appropriate method for reducing repayment mechanism burden on ACOs in the near term. In particular, we appreciate the commenter pointing to the variability in per capita costs of Medicare beneficiaries among ACOs, and providing the example of the range in per capita costs for similarly composed low revenue ACOs. We believe this suggests that using a single per beneficiary dollar amount for determining repayment mechanism amounts for each revenue status, or a single per beneficiary dollar amount for all ACOs, could potentially oversimplify the repayment mechanism calculation by removing an ACO-specific measure of costs (such as ACO participant revenue or ACO assigned beneficiary expenditures). This points to the need for additional considerations for identifying an appropriate per beneficiary dollar amount value under the alternative approach. Further, as we described in the CY 2022 PFS proposed rule, and restated elsewhere in this section of this final rule, we would need to decide how to identify the population of assigned beneficiaries that would be used in the calculation as a multiplier for the per beneficiary dollar amount, and the frequency with which we would consider modifications to the per beneficiary dollar amount. We did not receive comments on these other factors. Although we are not adopting an approach that uses per beneficiary dollar amounts to calculate repayment mechanism amounts with this final rule, we continue to believe such an approach could help ACOs better project repayment mechanism amounts prior to entering two-sided models, and therefore, be more transparent. We may revisit considerations for calculating repayment mechanism amounts using an alternative approach, such as per beneficiary dollar amounts, in future notice and comment rulemaking for the Shared Savings Program.

After consideration of public comments, we are finalizing as proposed to revise the percentage specified in § 425.204(f)(4)(ii)(A), for calculating an amount based on expenditures for the ACO's assigned beneficiaries, from 1 percent to one-half percent, and to revise the percentage specified in § 425.204(f)(4)(ii)(B), for calculating an amount based on ACO participant revenue, from 2 percent to 1 percent. Under this approach for calculating repayment mechanism amounts for ACOs in a two-sided model of the BASIC track or the ENHANCED track, the repayment mechanism amount will be equal to the lesser of the following: (1) One-half percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

(2) Population of Assigned Beneficiaries Used in Calculating and Recalculating Repayment Mechanism Amounts

In the CY 2022 PFS proposed rule (86 FR 39283 through 39286), we proposed to amend the regulations at §§ 425.204(f)(4)(ii) and 425.204(f)(4)(iii) to specify how we identify the number of assigned beneficiaries used in calculating and recalculating the repayment mechanism amount (respectively). For context, our current approach for calculating repayment mechanism amounts is described at § 425.204(f)(4)(ii) (for ACOs establishing a repayment mechanism to support their participation under a two-sided model) and under § 425.204(f)(4)(iii) (the annual recalculation to determine if an ACO is required to increase the amount of its repayment mechanism).

In accordance with § 425.204(f)(4)(ii), for ACOs in a two-sided model of the BASIC track, or the ENHANCED track, the repayment mechanism amount must be equal to the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available (hereinafter referred to as an expenditure-based amount); or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available (hereinafter referred to as a revenue-based amount).

In the CY 2022 PFS proposed rule, we explained that we use the following steps to calculate the expenditure-based amount specified in § 425.204(f)(4)(ii)(A), which is a percentage of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available (referred to below as the ''relevant historical calendar year''):

- *Step 1:* Identify the beneficiaries that would have been assigned to the ACO for the relevant historical calendar year (determined based on the ACO participant list for the upcoming performance year submitted by the ACO for CMS' review during the application cycle or change request cycle, referred to below as the ''ACO participant list for the upcoming performance year'') and multiply the number of such beneficiaries by an assignment growth factor to account for expected growth in assignment.
- *Step 2:* Determine estimated per capita FFS expenditures by calculating the total per capita Medicare Parts A and B FFS expenditures incurred during the relevant historical calendar year by the beneficiaries identified in step 1, and dividing that amount by the total number of beneficiaries identified in step 1 before the assignment growth factor is applied; and multiplying the resulting per capita FFS expenditure amount by a dollar trend factor to account for expected growth in Medicare FFS expenditures.

- *Step 3:* Calculate the product of the number of assigned beneficiaries determined according to step 1, and the estimated per capita FFS expenditures determined according to step 2.
- *Step 4:* Calculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage (1 percent under the existing regulations).

We also explained in the proposed rule that we use the following steps in calculating the revenue-based amount specified in § 425.204(f)(4)(ii)(B), which is based on revenue for the most recent calendar year for which 12 months of data are available (referred to below as the ''relevant historical calendar year''):

- *Step 1:* Identify the beneficiaries that would have been assigned to the ACO for the relevant historical calendar year (determined based on the ACO participant list for the upcoming performance year) and multiply the number of such beneficiaries by an assignment growth factor.
- *Step 2:* Using the ACO participant list for the upcoming performance year, determine the estimated per capita FFS revenues of ACO participants by calculating ACO participants' total Medicare Parts A and B FFS revenue based on claims for services furnished to any beneficiary by ACO participants during the relevant historical calendar year, and dividing the dollar amount by the total number of assigned beneficiaries identified in step 1 before the assignment growth factor is applied; [120] and multiplying the resulting number by a dollar trend factor to account for expected growth in Medicare FFS revenue.
- *Step 3:* Calculate the product of the number of assigned beneficiaries determined according to step 1, and the estimated per capita FFS revenues of ACO participants determined according to step 2.
- *Step 4:* Calculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage (2 percent under the existing regulations).

Regardless of the ACO's selected assignment methodology, within step 1 of the expenditure-based and revenue-based repayment mechanism amount calculations, CMS uses an assigned beneficiary population identified based on preliminary prospective assignment with retrospective reconciliation as described in § 425.400(a)(2). This ensures that the assignment window used to determine assigned beneficiaries aligns with the relevant historical calendar year used to calculate expenditures and revenue used in step 2 of the expenditure-based amount and revenue-based amount calculation.

In the proposed rule, we explained that there are several important reasons why we use historical data for determining the assigned beneficiary population, Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, and ACO participants' Medicare Parts A and B FFS revenue. For one, this approach ensures CMS' timely determination of final repayment amount estimates for ACOs required to establish a repayment mechanism arrangement prior to the start of a new agreement period under a two-sided model, or prior to start of the upcoming performance year under a two-sided model (for ACOs transitioning from a one-sided to a two-sided model along the BASIC track's glide path). Second, under this approach, the data used to determine repayment mechanism amounts is consistent with the data used in making other determinations during the application cycle and annual change request cycle, including determination of whether an ACO is categorized as a low revenue ACO or high revenue ACO.

In accordance with § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period in accordance with § 425.204(f), based on the certified ACO participant list for the relevant performance year. We explained that in annually recalculating ACOs' repayment mechanism amounts we use the same methodology that applies when calculating the expenditure-based amount and revenue-based amount in accordance with § 425.204(f)(4)(ii), which governs the initial repayment mechanism amount calculation that is performed for the first year of an agreement period in which an ACO is required to obtain a repayment mechanism. That is, in recalculating the repayment amount we determine the assigned beneficiary population, Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, and ACO participants' Medicare Parts A and B FFS revenue, for the most recent calendar year for which 12 months of data are available.

In the CY 2022 PFS proposed rule, we proposed to modify the methodology for the annual repayment mechanism amount recalculation. Specifically, we proposed to determine the number of assigned beneficiaries that is used as a multiplier in step 3 of the expenditure-based amount and revenue-based amount calculations, based on more recently available assignment data, rather than using a population projected to be assigned to the ACO based on historical data (that is, for the most recent calendar year for which 12 months of data are available). In determining the number of beneficiaries used as a multiplier in the recalculation estimate, we proposed to determine the size of the ACO's assigned population based on the number of beneficiaries assigned to the ACO at the beginning of the performance year, as specified under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or paragraph (a)(3)(i) (for ACOs under prospective assignment). This population of assigned beneficiaries is specified in the ACO's initial assignment list report for the performance year. For all ACOs, this population is identified based on an assignment window that is offset from the calendar year (that is, from October 1 through September 30 prior to the start of the performance year), and which is the basis for determining prospective assignment for the performance year. Under the proposed approach, which uses more recent assignment data in determining the recalculation estimate, we would not apply an assignment growth factor as a multiplier for the population size since we would no longer be using historical data to project the size of the ACO's assigned population. We explained our belief that this proposed approach would help ensure the recalculated repayment mechanism amounts account for an ACO's composition as reflected in the size of its assigned population for the performance year for which the recalculated amount relates, and thereby provide more accurate recalculated amounts.

We explained in the CY 2022 PFS proposed rule that we anticipated performing the annual recalculation of the repayment mechanism amounts shortly before or shortly after the start of the new performance year. We stated that under the proposed approach, CMS would perform the recalculation of the repayment mechanism once the initial assignment list report is available, which is typically delivered to ACOs in the early winter (around mid-December), prior to the start of the relevant future performance year. We also noted that under the existing

[120] We divide the total Medicare Parts A and B FFS revenue by the number of assigned beneficiaries determined in step 1, as opposed to the number of beneficiaries that is the basis for determining FFS revenues in step 2, in order for the expenditure-based and revenue-based per capita amounts to be calculated on the same basis.

approach and the proposed approach to determining the assigned population used as a multiplier in the annual recalculation of the repayment mechanism amounts, the effects on ACO's amounts are varied, resulting in relatively higher or lower amounts depending on the change in the size of the population.

In annually recalculating the repayment mechanism amount under the proposed approach, we would follow the previously described steps for calculating the expenditure-based amount and revenue-based amount, except that the number of beneficiaries used as a multiplier in step 3 of the calculations would be based on the population that will be assigned to the ACO for the next performance year, rather than the relevant historical calendar year. Since we are using a recently identified assigned population, we would not apply an assignment growth factor as a multiplier for the population size in step 1 (as previously described). In step 3 of the expenditure-based amount calculation, we would calculate the product of the total number of assigned beneficiaries specified in the ACO's initial assignment list report for the relevant future performance year, and the estimated per capita FFS expenditures determined for the relevant historical calendar year (determined according to step 2). In step 3 of the revenue-based amount calculation, we would calculate the product of the total number of assigned beneficiaries specified within the ACO's initial assignment list report for the relevant future performance year, and the estimated per capita FFS revenues of ACO participants determined for the relevant historical calendar year (determined according to step 2).

In the CY 2022 PFS proposed rule (86 FR 39285 and 39286), we provided two examples to illustrate the calculation and recalculation of the repayment mechanism amounts after the proposals, if finalized, would become effective on January 1, 2022. The first example involved an ACO applying to enter a two-sided model for an agreement period beginning on January 1, 2022. For such an ACO, we stated that we would calculate the repayment mechanism amount during the application cycle which occurs during CY 2021. During this time, CY 2020 is the most recent calendar year for which 12 months of data are available and is the relevant historical calendar year for purposes of calculating the repayment mechanism amount. In this example, the proposed approach to identifying the assigned beneficiary population, Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, and ACO participants' Medicare Parts A and B FFS revenue used within these calculations would be consistent with our current operational approach. This first example provides greater specificity about the repayment mechanism amount calculations than is outlined in the existing regulations at § 425.204(f)(4)(ii), including a description of how CMS identifies the number of beneficiaries used as a multiplier in these calculations.

In step 1 of the expenditure-based amount and revenue-based amount calculations, we would identify the beneficiaries that would have been assigned to the ACO for CY 2020, determined based on the ACO participant list for performance year 2022 submitted with the ACO's application, and determined using preliminary prospective assignment with retrospective reconciliation. That is, we would determine assignment based on the 12-month assignment window from January 1, 2020, through December 31, 2020.[121] We would multiply the number of such beneficiaries by an assignment growth factor.

In step 2 of the expenditure-based amount calculation, we would calculate total Medicare Parts A and B FFS expenditures incurred in CY 2020 by the beneficiaries determined under step 1 to be assigned to the ACO for CY 2020. In step 2 of the revenue-based amount calculation, we would calculate ACO participants' total Medicare Parts A and B FFS revenue, based on claims for services furnished to any beneficiary by ACO participants during CY 2020. We would determine the estimated per capita FFS expenditures, and the estimated per capita FFS revenues of ACO participants, by dividing the CY 2020 dollar amounts by the number of assigned beneficiaries for CY 2020 (determined in accordance with step 1) before the assignment growth factor is applied. We would multiply the resulting numbers by a dollar trend factor.

In step 3 of the expenditure-based amount calculation, the number of assigned beneficiaries for CY 2020 determined under step 1 would be multiplied by the estimated per capita FFS expenditures determined for CY 2020 in accordance with step 2. In step 3 of the revenue-based amount calculation, the number of assigned beneficiaries for CY 2020 determined under step 1 would be multiplied by the estimated per capita Medicare FFS revenues of ACO participants determined for CY 2020 in accordance with step 2.

In step 4, we would calculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage. Under the existing regulation, the applicable percentage is 1 percent under the expenditure-based amount calculation, and 2 percent under the revenue-based amount calculation. As described in section III.J.3.b.(1) of this final rule, under the policies we are finalizing, the applicable percentages will be one-half percent under the expenditure-based amount calculation, and 1 percent under the revenue-based amount calculation.

Our second example illustrated how we would perform the annual recalculation of the repayment mechanism amount for performance year 2022 under the proposed policy.

In step 1 of both the expenditure-based amount and revenue-based amount calculations, we use a similar method for identifying the CY 2020 assigned population as described in the first example. That is, we would identify the beneficiaries that would have been assigned to the ACO for CY 2020, determined based on the ACO's certified ACO participant list for performance year 2022, and determined using preliminary prospective assignment with retrospective reconciliation. Again, we would determine assignment based on the 12-month assignment window from January 1, 2020, through December 31, 2020. Unlike in our first example, we would not multiply the number of such beneficiaries by an assignment growth factor.

In step 2 of the expenditure-based amount calculation, we would calculate total Medicare Parts A and B FFS expenditures incurred in CY 2020 by the beneficiaries CMS determined under step 1 would have been assigned to the ACO for CY 2020. In step 2 of the revenue-based amount calculation, we would calculate ACO participants' total Medicare Parts A and B FFS revenue, based on claims for services furnished to any beneficiary by ACO participants during CY 2020, using the ACO's certified ACO participant list for performance year 2022. We would determine the estimated per capita FFS expenditures, and the estimated per capita FFS revenues of ACO participants, by dividing the CY 2020

[121] Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #9, February 2021), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-0.*

dollar amounts by the number of assigned beneficiaries for CY 2020 (determined in accordance with step 1, which does not apply an assignment growth factor). We would then multiply the resulting number by a dollar trend factor.

In step 3, we would not use the number of assigned beneficiaries as determined under step 1. Rather, we would identify the total number of assigned beneficiaries specified in the ACO's initial assignment list report for performance year 2022. This population of assigned beneficiaries would be the population identified based on the assignment window from October 1, 2020 through September 30, 2021,[122] and which would be the basis for determining prospective assignment for performance year 2022. Assignment would be determined based on the ACO's certified ACO participant list for performance year 2022. In step 3 of the expenditure-based amount calculation, the number of assigned beneficiaries for performance year 2022 would be multiplied by the estimated per capita FFS expenditures determined for CY 2020 in accordance with step 2. In step 3 of the revenue-based amount calculation, the number of assigned beneficiaries for performance year 2022 would be multiplied by the estimated per capita FFS revenues determined for CY 2020 in accordance with step 2.

In step 4, we would recalculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage. Under the policies we are finalizing in this rule, the applicable percentages will be one-half percent under the expenditure-based amount calculation, and 1 percent under the revenue-based amount calculation.

We proposed to modify § 425.204(f)(4)(ii) to more clearly specify the assigned population used as a multiplier in calculating the repayment mechanism amount. Under the existing regulation text at § 425.204(f)(4)(ii)(A), the potential repayment mechanism amount is a specified percentage of total per capita Medicare Parts A and B FFS expenditures ''for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.'' We proposed to amend paragraph (f)(4)(ii)(A) to refer to a specified percentage of total per capita Medicare Parts A and B FFS expenditures ''for the ACO's assigned beneficiaries, based on expenditures *and the number of assigned beneficiaries* for the most recent calendar year for which 12 months of data are available'' (emphasis added to reflect revised text).

Under the existing regulation text at § 425.204(f)(4)(ii)(B), the potential repayment mechanism amount is a specified percentage of total Medicare Parts A and B FFS revenue ''of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.'' We proposed to amend paragraph (f)(4)(ii)(B) to refer to a specified percentage of total Medicare Parts A and B FFS revenue ''of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, *and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available*'' (emphasis added to reflect revised text).

We also proposed technical and conforming changes to the introductory text of § 425.204(f)(4)(iii). We propose to remove as unnecessary and irrelevant the text specifying that the provision applies for agreement periods beginning on or after July 1, 2019. We proposed to revise the introductory text for clarity to specify that CMS will recalculate the ACO's repayment mechanism amount ''for'' the second and each subsequent performance year in the agreement period, rather than ''before'' the second and each subsequent performance year in the agreement period. We proposed to make a conforming change to the introductory text of § 425.204(f)(4)(iii) to specify that CMS' recalculation of the ACO's repayment mechanism amount would be in accordance with § 425.204(f)(4)(ii) based on the certified ACO participant list for the relevant performance year, ''except that the number of assigned beneficiaries used in the calculations would be the number of beneficiaries assigned to the ACO at the beginning of the relevant performance year under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3)(i) (for ACOs under prospective assignment).''

We proposed that these modifications would be effective and applicable on January 1, 2022. We explained that if finalized as proposed, these policies would be used in the following manner: (1) In determining required repayment mechanism amounts for ACOs establishing a repayment mechanism arrangement to support their participation in a two-sided model beginning with performance year 2022, and in subsequent performance years; (2) in making annual repayment mechanism amount recalculations for performance year 2022 and subsequent performance years; and (3) determining whether an eligible ACO has a one-time opportunity to decrease the amount of its repayment mechanism amount as described in section III.J.3.b.(3) of the CY 2022 PFS proposed rule (refer to section III.J.3.b.(3) of this final rule).

We received public comments on the proposals on the population of assigned beneficiaries used in calculating and recalculating repayment mechanism amounts. The following is a summary of the comments we received and our responses.

Comment: Commenters generally expressed support for CMS' proposals for how to identify the number of assigned beneficiaries used in the repayment mechanism amount calculation and in the annual repayment mechanism amount recalculation.

Response: We appreciate the commenters' support for our proposals.

After consideration of public comments, we are finalizing as proposed to amend the regulations at §§ 425.204(f)(4)(ii) and (iii) to specify how we identify the number of assigned beneficiaries used in calculating and recalculating the repayment mechanism amount (respectively). Further, we received no public comments on our proposed technical and conforming changes to the introductory text of § 425.204(f)(4)(iii), and therefore, are finalizing these changes as proposed. We refer readers to the detailed descriptions of these proposals as restated in this section of this final rule.

(3) Optional One-Time Repayment Mechanism Decrease for Eligible ACOs

As described in the CY 2022 PFS proposed rule (86 FR 39286 and 39287), we proposed to allow certain ACOs a one-time opportunity to decrease the amount of their repayment mechanisms. This proposed optional one-time repayment mechanism decrease was in connection with the proposal for lowering the repayment mechanism amounts specified in the CY 2022 PFS proposed rule (86 FR 39280 through 39283) and in section III.J.3.b.(1) of this final rule. We explained that the purpose of this proposal is to let any ACO that established a repayment mechanism to support its participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to decrease its repayment mechanism amount before it seeks to renew its agreement under the new proposed policy, which if finalized, would otherwise be the first opportunity for the ACO to reduce its repayment

[122] We note there was an inadvertent error in the prospective assignment window described in the CY 2022 PFS proposed rule (86 FR 39286), which we are correcting within this final rule, for clarity.

mechanism amount. Along these lines, the one-time decrease would also avoid unnecessary burden that could result if ACOs seek to terminate their participation agreements early and apply to re-enter the program in order to reduce their required repayment mechanism amounts.

We explained that if the proposed repayment mechanism amount policies are finalized and become effective and applicable on January 1, 2022, we would use the revised methodology for calculating repayment mechanism amounts (specified in the CY 2022 PFS proposed rule, 86 FR 39280 through 39283, and in section III.J.3.b.(1) of this final rule) to determine repayment mechanism amounts for ACOs establishing a repayment mechanism to support their participation in a two-sided model beginning with performance year 2022. Therefore, ACOs entering a two-sided model for an agreement period beginning on January 1, 2022, and ACOs with an earlier start date participating in the BASIC track's glide path and entering a two-sided model starting on January 1, 2022, would have repayment mechanism amounts determined according to the proposed amount calculation methodology, if finalized. Therefore, such ACOs would not need or be eligible for the proposed one-time opportunity to decrease the amount of their repayment mechanism.

Under this proposal, an eligible ACO that established a repayment mechanism to support its participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, may elect to decrease the amount of its repayment mechanism if the recalculated repayment mechanism amount for performance year 2022 is less than the existing repayment mechanism amount. To determine if an ACO is eligible to lower its repayment mechanism amount, we proposed to compare the ACO's existing repayment mechanism amount with the recalculated amount of the ACO's repayment mechanism based on its certified ACO participant list for performance year 2022, calculated in accordance with § 425.204(f)(4)(iii) (including any modifications finalized with CY 2022 PFS rulemaking to the recalculation methodology which would be effective and applicable January 1, 2022). If the recalculated repayment mechanism amount for performance year 2022 is less than the existing repayment mechanism amount, the ACO would be eligible to decrease the amount of its repayment mechanism to the recalculated amount. Under this approach, we would permit a one-time decrease in the repayment mechanism amount even for relatively small differences in dollar amounts.

We proposed that CMS would notify the ACO in writing that the ACO may elect to decrease the amount of its repayment mechanism. We explained that if the proposal became final, we anticipated that we would notify an ACO of its opportunity to reduce its repayment mechanism amount after the start of performance year 2022. We also proposed that an ACO must submit such election, and revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. We expected that the deadline for submitting the election and revised repayment documentation would be 30 days from the date of the written notice from CMS, although we recognized that there may be circumstances that necessitate a longer timeframe. CMS would review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

We proposed to amend § 425.204 to add paragraph (f)(4)(v) to establish the policy and relevant procedure that would allow eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to lower the amount of their repayment mechanism arrangements.

We received public comments on the proposed optional one-time repayment mechanism decrease for eligible ACOs. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the proposed approach that provides a one-time opportunity for eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to decrease the amount of their existing repayment mechanisms if their recalculated amount for performance year 2022 is less than their existing repayment mechanism amount. Some commenters explained their belief that it would be fair to permit such ACOs to decrease the amount of their repayment mechanisms.

Response: We appreciate the commenters' support for the proposal. As described in section III.J.3.b.(1) of this final rule, we are finalizing our proposal to reduce by one-half the percentages used in the methodology for calculating repayment mechanism amounts for ACOs. We continue to believe the proposed one-time decrease opportunity could avoid unnecessary burden on ACOs from having to maintain their existing repayment mechanism at a potentially higher amount until they seek to renew their agreement, or in the event they would seek to terminate their participation agreements early and apply to re-enter the program in order to reduce their required repayment mechanism amounts.

Comment: One commenter urged that CMS promptly allow reimbursement for any ACOs that have overpaid escrow once this proposal is made final.

Response: As we interpret the comment, we believe the commenter is concerned about the procedure by which an ACO would obtain the excess funds held in its escrow account. If an ACO with an existing repayment mechanism in the form of escrow account is permitted to decrease the amount of its repayment mechanism, and if the ACO elects to so decrease the amount of funds in its escrow account, CMS will instruct the escrow agent to disburse to the ACO any funds above the new minimum required amount. These returned funds would include accrued interest.

After consideration of public comments, we are finalizing as proposed to amend § 425.204 to add paragraph (f)(4)(v)(A) to establish the policy that would allow eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to lower the amount of their repayment mechanism arrangements. We received no public comments on the proposed procedures for eligible ACOs to make such election to decrease the amount of their repayment mechanism. Therefore, we are finalizing as proposed to amend § 425.204 to add paragraph (f)(4)(v)(B) specifying that CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism. We are also finalizing as proposed the policy that the ACO must submit such election, and revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. We will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

(4) Threshold for Increasing Repayment Mechanism Amounts

In accordance with § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount. Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS approval documentation that the amount of its repayment mechanism has been increased to the amount specified by CMS.

In establishing the annual repayment mechanism amount recalculation policy in earlier rulemaking (83 FR 67930), we explained the purpose of this approach was to address changes in the ACO's composition of ACO participant TINs and the individuals who bill through the participant TINs over the course of an agreement period and to ensure the adequacy of an ACO's repayment mechanism. In establishing the annual recalculation policy (83 FR 67932), we explained that a threshold of 50 percent or $1,000,000 would likely require an increased repayment mechanism amount only for ACOs that had the largest changes in their estimated repayment mechanism value (the top 5 to 10 percent of ACOs). We believed this approach would minimize an ACO's administrative burden and financial institution fees while adjusting for meaningful changes in repayment mechanism amounts that would help protect the Medicare Trust Funds.

As described in the CY 2022 PFS proposed rule (86 FR 39287), we continue to believe that the annual repayment mechanism amount recalculation serves an important function in identifying the need for repayment mechanism increases when an ACO's composition changes. Such changes could result in higher expenditures for the ACO's assigned beneficiaries, higher ACO participant revenue, or a larger assigned beneficiary population. Each of these changes could increase the amount of potential shared losses for an ACO under a two-sided model.

We stated in the proposed rule that, based on our operational experience with the recalculation policy, we have found that ACOs whose recalculated repayment mechanism amount is at least 50 percent higher than their existing amount, but less than $1,000,000 more, tend to be low revenue ACOs with relatively smaller existing repayment mechanism amounts, typically less than $300,000. We recognized that it is burdensome for ACOs to modify repayment mechanism arrangements to revise the amount of the repayment mechanism. These modifications are time consuming to arrange, and can result in additional fees charged by financial institutions for ACOs to modify their arrangements, in addition to requiring ACOs to set aside additional funds (such as with escrow accounts). We explained our belief that the burden for these ACOs to increase their repayment mechanism amounts is disproportional to the benefit CMS receives by having access to additional repayment mechanism arrangement funds to support repayment of losses.

In light of our proposal to reduce repayment mechanism amounts, we revisited the thresholds that would require an increase in an ACO's repayment mechanism amount upon annual recalculation in accordance with § 425.204(f)(4)(iii). We were concerned that if we finalized our proposal to reduce repayment mechanism amounts, applying the existing 50 percent threshold to a lower repayment mechanism amount would be more burdensome for ACOs because they would be required to amend their repayment mechanisms to reflect relatively smaller increases in their repayment mechanism amounts, which would be even more disproportional to the benefit received by CMS.

In the CY 2022 PFS proposed rule (86 FR 39287), we explained our belief that requiring an increase in the repayment mechanism amount if the recalculated amount for the performance year is at least $1,000,000 greater than the existing amount balances our interest in ensuring the repayment mechanism amount accounts for significant changes in an ACO's composition during its agreement period, while avoiding burdensome repayment mechanism modifications for relatively small dollar amounts. Therefore, we proposed to amend the regulations at § 425.204(f)(4)(iii)(A) to remove the 50 percent threshold from the annual repayment mechanism increase threshold, such that if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least $1,000,000, we will notify the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount. We anticipated this approach would reduce the number of ACOs required to annually increase their repayment mechanism amounts and would further simplify the repayment mechanism amount calculations.

As specified in the CY 2022 PFS proposed rule (86 FR 39288), we proposed that this modification would be effective and applicable on January 1, 2022. We explained that the revised threshold (if finalized) would be used in determining required repayment mechanism increases for performance year 2022, and subsequent performance years.

We received public comments on the proposed revision to the threshold for determining whether an increase in the repayment mechanism amount is required during the ACO's agreement period. The following is a summary of the comments we received and our responses.

Comment: Commenters generally expressed support for CMS' proposal to modify the threshold for increasing an ACO's repayment mechanism amount during its agreement period by removing the 50 percent threshold, and instead require ACOs to increase their repayment mechanism amount if the recalculated amount is at least $1,000,000 greater than the existing amount.

Some commenters indicated that this approach would minimize administrative burdens for ACOs, such as by reducing administrative complexity, and minimize the financial costs for ACOs of participating in the Shared Savings Program. Several commenters explained that this proposed approach would allow ACOs to focus their limited time and resources on care coordination interventions as opposed to unnecessary administrative requirements.

Response: We agree with commenters that this approach could reduce administrative burden and financial costs on ACOs.

After consideration of public comments, we are finalizing our proposal to amend the regulations at § 425.204(f)(4)(iii)(A) to remove the 50 percent threshold from the annual repayment mechanism increase threshold, such that if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least $1,000,000, we will notify the ACO in writing that the amount of its repayment mechanism

must be increased to the recalculated repayment mechanism amount.

4. Reducing Shared Savings Program Application Burden

a. Background

To participate in the Shared Savings Program, a prospective ACO must submit an application and certify that it satisfies all the eligibility and other requirements of the Shared Savings Program, including regulatory requirements to disclose prior participation. Under § 425.204(b), an ACO must disclose in its Shared Savings Program application whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Shared Savings Program under the same or a different name or is related to or affiliated with another Shared Savings Program ACO, and if the related participation agreement was terminated voluntarily or involuntarily.

The application evaluation criteria for renewing and re-entering ACOs are designed to prevent an ACO with a history of poor performance or noncompliance with the Shared Savings Program regulations from participating in the program. Under § 425.224(b), we determine whether to approve an application based on an evaluation of several criteria, including the following: (1) Whether the ACO has a history of noncompliance with the program's requirements, including a failure to meet the quality performance standard; (2) the ACO's history of financial performance; (3) whether an ACO under a two-sided model failed to repay shared losses owed to the program; and (4) whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to perform poorly or to be terminated in a prior application cycle.

Additionally, under § 425.204(c)(6), all applicants, including initial, renewing, and re-entering applicants, must submit as part of the application process and upon request by CMS, documents demonstrating that their ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. Currently, such documents must include a sample or form agreement and the first and signature pages of each executed ACO participant agreement. In some instances, we may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. The ACO is also required to certify that each of its ACO participant agreements meet all Shared Savings Program requirements in 42 CFR part 425. Additionally, under § 425.116(c), we require an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application, participation agreement renewal process, and when making additions to its list of ACO participants in accordance with § 425.118. The agreements may be submitted in the form and manner specified under § 425.204(c)(6) or as otherwise specified by CMS.

In conducting Shared Savings Program application reviews, we have found that the document submission requirements in §§ 425.204(b) and (c)(6), and 425.116(c) substantially increase applicant burden without lending significant value to our review of an organization's application to confirm that the ACO meets all the eligibility requirements for participation. As described in the CY 2022 PFS proposed rule, we proposed specific policy refinements aimed at reducing administrative burden during the application process.

b. Revisions

In the CY 2022 PFS proposed rule, we proposed to modify § 425.204(b) so that the prior participation disclosure requirement is prescribed only at the request of CMS during the application process—rather than as a mandatory submission with the ACO's initial or renewal application. We stated that, in accordance with § 425.224(b), we will continue to review an ACO's history of compliance with Shared Savings Program regulations, and quality and financial performance results and, when appropriate, request additional information from an ACO regarding prior participation.

We also proposed to modify § 425.204(c)(6) to remove provisions requiring an ACO to submit sample ACO participant agreements during the application process. Under this proposal, sample ACO participant agreements and the first and signature pages of each executed ACO participant agreement would need to be submitted during the application process only if requested by CMS, rather than as a mandatory submission with the ACO's initial or renewal application. The ACO must continue to certify that all ACO participant agreements comply with the regulatory requirements of the Shared Savings Program, and CMS retains the discretion to request ACO participant agreement documentation at any time during an agreement period.

In addition, we proposed to modify § 425.116(c) to remove provisions requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application or participation agreement renewal process. We stated that we would retain the requirement that an ACO must submit an executed ACO participant agreement for new ACO participants that it requests to add to its list of ACO participants.

We stated in the proposed rule that we believe these three proposals will collectively reduce the administrative and programmatic burden for ACOs significantly, and without sacrificing program integrity. We reinforced that ACOs are responsible for ensuring that their ACO participant agreements meet Shared Savings Program requirements.

We received several comments on our proposals aimed at reducing burden during the Shared Savings Program application process. Commenters were generally supportive of CMS' efforts to reduce administrative burden for ACOs during the application process noting that the proposed changes would continue to ensure program integrity, greatly reduce administrative burden and control programmatic costs, and increase participation among ACOs. We describe the proposals and respond to comments below.

(1) Prior Participation Requirement (§ 425.204(b))

In the CY 2022 PFS proposed rule, we proposed to modify § 425.204(b) so that the prior participation disclosure requirement is prescribed only at the request of CMS, rather than as a mandatory submission with the ACO's initial or renewal application. During the application cycle and for the purposes of evaluating program eligibility, we already determine prior participation for initial and re-entering ACO applicants by reviewing ACO and ACO participant-level information. We screen all ACO applicants, initial ACOs and re-entering ACOs, to determine if they have participated in the Shared Savings Program, including if their prior participation agreement was terminated early (voluntarily or involuntarily). We also identify initial ACOs as re-entering ACOs if greater than 50 percent of their ACO participants were included on the ACO participant list, under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date (§ 425.20), in order to hold these ACOs accountable for their ACO participants' experience with the program.

Additionally, all ACO participants and ACO providers/suppliers undergo a

rigorous screening process during the application cycle (and throughout the agreement period, if approved to participate in the program) to ensure they meet certain program requirements. CMS' screening processes are protective of the program and provide CMS with eligibility information about individual ACO participants including: Medicare-enrollment status (§ 425.20); program integrity history (§ 425.305(a)); any participation in other Medicare shared savings initiatives (§ 425.114); and participation in other Shared Savings Program ACOs, including whether the ACO participant submitted claims used in beneficiary assignment (§ 425.306). These robust application screening processes for ACO participants and ACO providers/suppliers provide necessary information about ACOs and individual ACO participants.

We proposed to revise § 425.204(b) to provide that, upon request by CMS during the application cycle, the ACO must submit information regarding prior participation in the Shared Savings Program by the ACO, its ACO participants, or its ACO providers/suppliers, including such information as may be necessary for CMS to determine whether to approve an ACO's application in accordance with § 425.224(b). As described in the CY 2022 PFS proposed rule (86 FR 39289), to ensure future compliance we may request additional information from an ACO concerning its prior participation or the prior participation of their ACO participants or its ACO providers/suppliers. In that case, we would require the ACO to include in its response assurances describing how they will remain in compliance with program requirements—particularly as to the quality performance standard and financial performance—while completing the full term of the participation agreement. In conjunction with the robust evaluation criteria of § 425.224(b) for renewing and re-entering ACOs, and the application screening processes for ACO participants and providers/suppliers, we believe CMS can effectively evaluate an ACO's prior participation and determine its suitability to participate in the program without requiring ACOs to self-identify prior participation under § 425.204(b), including the cause of termination (if any), and what safeguards have been put into place.

The following is a summary of the comments we received and our responses.

Comment: Commenters unanimously supported the proposed change to the Shared Savings Program application process to eliminate the requirement for an ACO to inform CMS about past participation, but to make this information available upon CMS request, and confirmed CMS' belief that this refinement would reduce program burden during the application cycle without sacrificing program integrity.

Response: We appreciate the commenters for their support of this proposal.

After consideration of the public comments, we are finalizing without modification the proposed change to § 425.204(b) so that the prior participation disclosure requirement is prescribed only at the request of CMS, rather than as a mandatory submission with the ACO's initial or renewal application.

(2) Submission of Sample Agreements (§ 425.204(c)(6))

In the CY 2022 PFS proposed rule, we proposed to revise § 425.204(c)(6) to require an ACO to submit sample or form ACO participant agreement documents during the application cycle only upon request by CMS. As stated in the proposed rule, we review sample agreements to ensure they contain the language required under § 425.116. However, it is ultimately the ACO's responsibility to ensure that all of its ACO participant agreements comply with the Shared Savings Program requirements. We also noted our concerns that CMS review of sample participant agreements gave the incorrect impression that CMS had determined that an agreement met all regulatory requirements.

We explained our belief that removing the requirement at § 425.204(c)(6) to submit sample agreements reduces administrative burden on both ACOs and CMS in the submission and reviewing of sample agreements. Under our proposal, we retained the ability to request ACO sample participant agreements during the application cycle and at any point during an agreement period. We also noted that we do not expect to routinely make such requests during the application cycle, but that such requests could be particularly useful in cases where an ACO has a history of noncompliance with § 425.116 or other program requirements.

Under our proposal, we retained the requirement in § 425.204(c)(6) that the ACO must certify that each of its ACO participant agreements comply with the requirements of the Shared Savings Program. We explained that we believe this modification to § 425.204(c)(6) more clearly prescribes that the ACO is ultimately responsible for compliance with all program requirements.

The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported CMS' proposal to reduce the frequency and circumstances under which ACOs must submit sample ACO participant agreements to CMS and noted that this policy refinement reduces administrative burden during the application process.

Response: We appreciate the commenters' support.

Comment: Several commenters suggested alternative proposals to those outlined in the proposed rule. One commenter noted that the proposed changes would place a tremendous burden on ACOs, and therefore, opposed the policy change, recommending that CMS continue with compliance checks through the application process and submission of signed participant agreements. One commenter suggested permitting ACOs to request a CMS review of their sample ACO participant agreements prior to the ACO participant list change request review cycle. This commenter noted that an ACO-requested review and subsequent CMS approval of the sample agreement would mitigate ACO concerns that an agreement could be deemed noncompliant after submission of any executed agreements. Another commenter requested CMS to provide tools to help ACOs create agreements that comply with Shared Savings Program requirements.

Response: We thank the commenters and understand ACOs' concern for ensuring program compliance with respect to ACO participant agreements. However, we continue to believe that the proposed policy will uphold program integrity while easing administrative burden. We acknowledge that submission of documentation will impose some administrative burden for those ACOs that receive such a request. But because ACOs will no longer be required to submit the documentation routinely, the overall administrative burden to ACOs is reduced. Each year CMS will continue to oversee the application processes and when warranted, request appropriate documentation from an ACO to determine compliance with Shared Savings program requirements.

When CMS chooses to request sample ACO participant agreements, we will review them for compliance with § 425.116, but we reiterate that each ACO is responsible for ensuring that all of their ACO participant agreements are compliant with § 425.116 and all other applicable laws and regulations. Any

CMS review of ACO participant agreements is limited only to determining compliance with one or more specific Shared Savings Program requirements and does not preclude CMS, HHS, or any other Federal or State agency from enforcing any applicable laws and regulations.

CMS is not a party to ACO participant agreements, which may include other terms and conditions beyond those that are required in the regulation. Additionally, based on our 9 years of program experience, we have found it is no longer necessary to go through this extensive sample agreement review process. We have utilized our experience to develop guidance for ACOs intended to assist with crafting their ACO participant agreements in compliance with our regulations. Specifically, before, during, and after the Shared Savings Program application cycle and/or performance year, CMS makes guidance documents (at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications*) and technical assistance resources available to ACOs (through assigned ACO Coordinators and the Shared Savings Program Helpdesk for email inquiries) requesting help with any questions and/or concerns that allow ACOs to receive timely responses to their questions.

After considering the public comments, we are finalizing without modification the proposed revision to § 425.204(c)(6) to require an ACO to submit sample or form ACO participant agreement documents during the application cycle only upon request by CMS.

(3) Submission of Executed Participant Agreements (§ 425.116(c))

We proposed to modify § 425.116(c) to remove language requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application and during the participation agreement renewal process. We explained that the submission of agreements at the time of initial application is governed by § 425.204(c)(6) and does not need to be addressed in § 425.116(c). We further explained that, unless there have been amendments to an ACO participant agreement, we would not need to collect for a second time executed ACO participant agreements with ACO participants who are actively participating in an ACO at the time it is applying to renew its participation agreement with the program.

We proposed to retain the remainder of § 425.116(c), which requires an ACO to submit ACO participant agreements when requesting additions to their ACO participant list in accordance with § 425.118 and specifies that the agreements may be submitted in the form and manner specified under § 425.204(c)(6). We noted that although ACOs may request additions to an ACO participant list at specified times during a performance year, all approved ACO participant list additions become effective on January 1 of the following performance year (§ 425.118(b)(1)(ii)). We stated that we continue to find value in reviewing executed ACO participant agreements in these circumstances. ACO participant additions may take the form of an initial applicant or renewing ACO submitting proposed ACO participants (that may or may not have participated with another ACO), or a currently participating ACO adding proposed participants (that may or may not be participating with another ACO) to their ACO participant list. Collecting executed agreements (which may include collecting only the first and signature page(s) under § 425.204(c)(6)) for additions to an ACO's participant list provides CMS with evidence that the ACO and the participant are each aware of the agreement and are participating together in the Shared Savings Program. If CMS needs to review executed participant agreements other than when ACOs are adding to their list of ACO participants, CMS can request them at that time under § 425.204(c)(6) or under its audit authority in accordance with § 425.314.

The following is a summary of the comments we received and our responses.

Comment: All commenters supported CMS' proposal to reduce the frequency with which ACOs must submit executed ACO participant agreements to CMS. One commenter noted that this proposed modification was appreciated because the work involved is time consuming and duplicative. Another commenter contended that re-executing agreements for all existing ACO participants at the time of a renewal application is particularly difficult for large ACOs and appreciated the proposed policy change.

Response: We appreciate the commenters' support for this proposal and wish to clarify that renewal or early renewal applicants entering into a new Shared Savings Program agreement period are not required to submit a newly executed ACO participant agreement for any ACO participant with which the ACO already has an ACO participant agreement if that ACO participant will continue to participate in the ACO during the new agreement period. When renewal or early renewal applicants indicate that an existing ACO participant will continue to participate in the ACO during the new agreement period, the ACO has the option to either submit a newly executed ACO participant agreement or to resubmit the existing ACO participant agreement executed by the ACO and the ACO participant. In either case, the agreement must meet the Shared Savings Program requirements under § 425.116.

Comment: A few commenters suggested other burden reduction changes to the ACO application process that were outside the scope of this rulemaking. These commenters suggested that CMS extend the deadline for ACOs to add participants and to provide ACOs direct access to PECOS so that they can manage participant agreements directly in the CMS database.

Response: Comments of this nature are beyond the scope of the policies discussed in the CY 2022 PFS proposed rule and are not being addressed in this final rule.

After considering the public comments, we are finalizing without change our proposal to amend § 425.116(c) to remove language requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application and during the participation agreement renewal process.

In summary, we are finalizing without change our proposal to modify section § 425.204(b) regarding the disclosure of prior participation information. Specifically, under this final rule, an ACO will be obligated to submit prior participation information only at the request of CMS during the application process. We are finalizing without change our proposal to modify § 425.204(c)(6) regarding the submission of sample ACO participant agreements during the application process. Specifically, under this final rule, an ACO will obligated to submit such documents only upon the request of CMS. Lastly, we are finalizing without change our proposal to modify § 425.116(c) by removing language requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application or participation agreement renewal process. Under this final rule, an ACO is obligated to submit an executed ACO participant agreement only for those ACO participants that the ACO seeks to add to its list of ACO participants.

5. Beneficiary Information Notices for ACOs With Prospective Assignment

a. Background

To ensure full transparency between Shared Savings Program ACOs and the beneficiaries they serve, § 425.312(a)(1) provides that an ACO must ensure that Medicare FFS beneficiaries are notified about all of the following: (1) That its ACO providers/suppliers are participating in the Shared Savings Program; (2) the beneficiary's opportunity to decline claims data sharing; and (3) the beneficiary's ability to, and the process by which, he or she may identify or change identification of the individual he or she designated as their primary clinician for purposes of voluntary alignment. Under § 425.312(a)(2)(i), we require this information to be furnished by an ACO participant posting signs in its facilities and, in settings in which beneficiaries receive primary care services, making standardized written notices available upon request.

In the December 2018 final rule, we specified at § 425.312(a)(2)(ii) that, during the performance year beginning on July 1, 2019 and each subsequent performance year, the information must also be furnished by an ACO or ACO participant providing each beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS. While we continued to encourage ACO participants to distribute the notice to beneficiaries at the point of care to address any beneficiary questions or concerns, the flexibility was granted so that an ACO or its ACO participants could distribute beneficiary notifications through electronic transmission (such as email) or mail. We note that, regardless of the method of notification used, CMS may review evidence related to the dissemination of the beneficiary information notice at any time under its audit authority in accordance with § 425.314.

We believe the modifications made to the beneficiary notification requirements in the December 2018 final rule help empower beneficiary choice, support beneficiary engagement, improve transparency, and ensure that beneficiaries are informed about the program and how it may affect their care and the use of their data. In making the decision to provide a CMS-approved template, we aimed to make the notification a comprehensive resource that compiled information about the program and what participation in the program means for beneficiary care. In addition, we believed that the availability of CMS-approved beneficiary notification templates would mitigate the potential for administrative and operational burden on providers.

b. Revisions

In considering the several different iterations of the beneficiary notice requirement over the history of the program,[123] we have concluded that the current requirement to provide beneficiary notifications prior to or at the first primary care visit of the performance year is overly broad with respect to ACOs that have selected the prospective assignment methodology. Such ACOs are currently required to provide the beneficiary notice to beneficiaries who will never be assigned to the ACO for the performance year.

As noted in the CY 2022 PFS proposed rule, the purpose of the beneficiary notification is to empower beneficiaries, encourage beneficiary engagement, and improve transparency. For an ACO participating under the prospective assignment methodology, as described in § 425.400(a)(3), all of the ACO's beneficiaries are assigned at the beginning of the performance year. Under § 425.704(d)(1)(ii), such ACOs may request beneficiary identifiable claims data only for FFS beneficiaries that appear on the ACOs' prospective assignment list at the beginning of the performance year and who have not opted out of data sharing. Beneficiaries who are not assigned at the beginning of the performance year to an ACO that has selected prospective assignment will never be assigned to the ACO during the relevant performance year and will not be subject to data sharing with the ACO. In short, such beneficiaries have no need to receive any information about the Shared Savings Program during the performance year. Therefore, as stated in the CY 2022 PFS proposed rule, we believe that it causes unnecessary confusion for beneficiaries to receive the notice if they are not prospectively assigned to an ACO because the notice describes details that will not apply to them (for example, information on data sharing and the SNF 3-day rule waiver).

In contrast, for ACOs under preliminarily prospective assignment with retrospective reconciliation, the preliminary prospective assignment list provided to the ACO at the beginning of the performance year does not include all FFS beneficiaries who may ultimately be assigned to the ACO. As such, we continue to believe all FFS beneficiaries receiving primary care services from ACO providers and/or suppliers participating in ACOs that have selected preliminary prospective assignment with retrospective reconciliation should receive the notice. This ensures that all beneficiaries ultimately assigned to the ACO will be informed of their right to decline data sharing.

In the CY 2022 PFS proposed rule, we proposed to amend § 425.312(a)(2) to set forth different beneficiary notification obligations depending on the assignment methodology selected by the ACO. Specifically, we proposed at § 425.312(a)(2)(ii) to provide that, in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide the standardized written beneficiary notice to each FFS beneficiary prior to or at the first primary care visit of the performance year. We proposed to add at § 425.312(a)(2)(iii) that, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary prior to or at the first primary care visit of the performance year.

In the CY 2022 PFS proposed rule, we stated that we continue to believe that the requirement to provide the beneficiary information notice is important to empowering beneficiaries and providing important information about their care, but we also understand that the current requirement of disseminating the beneficiary information notice annually may have the potential to be overly burdensome to ACOs and/or their ACO participants. We solicited comment from stakeholders on whether we should modify the frequency with which the beneficiary information notice must be furnished, for example, by reducing the frequency of the existing requirement from annually to once per agreement period.

We received public comments on our proposal to eliminate the requirement for ACOs that have selected the prospective assignment methodology to provide the beneficiary information notice to beneficiaries who are not prospectively assigned, and therefore, to whom it would not affect. The following is a summary of the comments we received and our responses.

[123] We have made several revisions to the beneficiary notification provisions over time. Refer to the November 2011 final rule, 76 FR 67802, 67945 through 67946 (establishing the requirement for beneficiary notifications). Refer to the June 2015 final rule, 80 FR 32692, 32740 through 32743 (establishing requirements for ACO to use a CMS-approved template for beneficiary notifications, allowing ACOs to obtain claims data for beneficiaries, and establishing an avenue for beneficiaries to opt out of data-sharing).

Comment: Many commenters supported the proposal to amend the beneficiary notification requirement such that ACOs that have selected prospective assignment do not have to send notification to beneficiaries who are not prospectively assigned to them.

Response: We appreciate the commenters' support.

Comment: Many commenters advocated that CMS remove the obligation for ACOs to furnish standardized written beneficiary information notices. These commenters stated that the requirement to provide written beneficiary notices is redundant and imposes an unnecessary burden on ACOs. The commenters stated that the same effect is achieved by providing notice via in-office posters, the Medicare & You handbook, and/or after-visit summaries. Some commenters shared that if CMS believes it is necessary to inform patients about ACO goals and objectives using methods other than the posted notices that are already a requirement of the Shared Savings Program, that CMS should provide such notifications. The commenters noted that if CMS furnished such notifications, beneficiaries would not receive notifications from multiple ACOs, which would reduce the cost and burden currently placed on ACOs.

Response: While we appreciate commenters' feedback, we decline to eliminate the requirement that ACOs furnish the standardized written beneficiary notifications required under § 425.312. For several reasons, we continue to believe that it is important for ACOs to furnish these notifications. First, such notices provide important information to beneficiaries about their care and serve to improve transparency. For example, the standardized written notice informs a beneficiary that CMS may share the beneficiary's claims data with the ACO and that the beneficiary can prevent such claims data sharing by following instructions provided in the notice. In the absence of such notification, a beneficiary may incorrectly assume that there is no difference between receiving care from an ACO participant and receiving care from a provider or supplier that is not participating in an ACO. Second, the standardized written notices provide an opportunity for direct engagement of the beneficiary with the ACO or an ACO participant, thereby serving to strengthen the beneficiary's relationship with the ACO and ACO participants from whom the beneficiary may receive care. Because the notice is furnished by the ACO or an ACO participant, it is qualitatively different from a notice furnished by CMS. For this reason, we decline to accept the commenters' suggestion that CMS furnish the required beneficiary notifications.

We do not agree with the commenters' assertion that the requirement to provide written beneficiary notices is redundant and that the same effect is achieved by providing notice via in-office posters, the Medicare & You handbook, or ''after-visit summaries.'' We note that ''after-visit summaries'' are not required by our regulations and are therefore not a reliable mechanism for ensuring that beneficiaries receive the required information. Although posters and the Medicare & You handbook may be a sufficient notification mechanism for some beneficiaries, not all beneficiaries will read the posters or the Medicare & You handbook. Moreover, the information contained in the Medicare & You handbook cannot be as complete as the information that must be included in the standardized written notices required under § 425.312(a)(2). For example, the Medicare & You handbook would not identify the specific ACO with which CMS may share the beneficiary's claims data. Written notifications distributed directly to beneficiaries by ACOs and ACO participants offer an additional avenue for ensuring that more beneficiaries are aware of their healthcare provider's participation in an ACO, the claims data that CMS may share with the ACO, the opportunity to prevent such claims data sharing, and the opportunity to designate a particular practitioner for purposes of voluntary alignment to the ACO. Simply put, the standardized written beneficiary notices are not redundant; rather, they are one of multiple notice mechanisms that together ensure that beneficiaries are likely to receive and understand comprehensive information regarding the significance of receiving care from a provider or supplier participating in the Shared Savings Program.

We appreciate the commenters' desire to reduce the burden on ACOs by eliminating the chance of a beneficiary receiving notices from multiple ACOs. We note that under this final rule, a beneficiary aligned to an ACO that has selected prospective assignment will not receive notifications from multiple ACOs.

We received public comments on whether we should modify the frequency with which the beneficiary information notice must be furnished, for example, by reducing the frequency of the existing requirement from annually to once per agreement period. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for reducing the frequency of the beneficiary information notice to once per agreement period. Commenters related that requiring ACOs to notify beneficiaries annually when there have been no programmatic changes can cause unnecessary confusion and burden on patients. Some commenters also suggested modifying the language within the notice to be plainer and more beneficiary-friendly. Additionally, commenters noted that removing the annual requirement would significantly reduce burden on ACOs, both administratively with paperwork, and financially, in terms of expenses and resources.

Response: We appreciate the commenters for the feedback. We will consider this information in future rulemaking.

After consideration of public comments, we are finalizing the proposed policy without modification. Accordingly, we are finalizing the amendment of § 425.312(a)(2) to set forth different beneficiary notification obligations depending on the assignment methodology selected by the ACO. Specifically, we will finalize our proposal at § 425.312(a)(2)(ii) to provide that, in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide the standardized written beneficiary notice to each FFS beneficiary prior to or at the first primary care visit of the performance year. We will also finalize our proposal to add at § 425.312(a)(2)(iii) that, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary prior to or at the first primary care visit of the performance year.

6. Comments on Considerations Related to the Use of Regional FFS Expenditures and the Risk Adjustment Methodology in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark

a. Background on the Shared Savings Program Benchmarking Methodology

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using

the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. The benchmark shall be reset at the start of each agreement period. In addition to the statutory benchmarking methodology established in section 1899(d) of the Act, section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and that the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

In the November 2011 final rule establishing the Shared Savings Program, we adopted policies for establishing, updating, and resetting the benchmark at § 425.602. The Shared Savings Program's regulations have since evolved to include different benchmarking methodologies, including modifications to § 425.602, and the addition of separate benchmarking policies for ACOs entering a second or subsequent agreement period at § 425.603. Benchmarking policies applicable to all ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, are specified in § 425.601. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; and December 2018 final rule, 83 FR 68005 through 68030).

For details on the benchmarking calculations, we refer readers to the regulations at 42 CFR part 425, subpart G, as well as the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #9, February 2021), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-0.*

In section III.J.6 of the CY 2022 PFS proposed rule (86 FR 39291 through 39295), we summarized select aspects of the Shared Savings Program's benchmarking methodology and related concerns that have been expressed by ACOs and other stakeholders. We specified some considerations based on our initial analyses of these issues, and solicited comment on considerations that may inform future policy developments. However, we noted that we are still in the process of monitoring program calculations based on the initial performance years of experience under the new participation options and program modifications that were adopted as part of the Pathways to Success rulemaking and are applicable for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, including changes to the benchmarking methodology (finalized in the December 2018 final rule (83 FR 67816)). In addition, we also specified that we are monitoring the impact of any anomalies in Medicare FFS expenditures and healthcare utilization by Medicare FFS beneficiaries resulting from the PHE for COVID–19, which we anticipate could further inform our considerations of future modifications to Shared Savings Program benchmarking policies (see for example, discussion in the CY 2021 PFS final rule, 85 FR 84770 through 84785).

We appreciate commenters' careful consideration of these issues, as reflected in the public comments we received about the current Shared Savings Program benchmarking methodology, and the potential alternative benchmarking approaches described in the proposed rule. In this section of this final rule, we review the comment solicitations, and summarize the comments received. We appreciate the ongoing dialogue between CMS, ACOs and other program stakeholders on considerations for improving the Shared Savings Program's benchmarking policies. Because we sought comments on these issues for purposes of informing future rulemaking and did not propose any changes to the Shared Savings Program's benchmarking methodology, we decline at this time to provide detailed responses to the commenters' suggestions and concerns. However, we will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies. We will propose any specific policy changes in future notice and comment rulemaking.

b. Comments on Calculation of the Regional Adjustment and Blended National-Regional Growth Rates for Trending and Updating the Benchmark

In the CY 2022 PFS proposed rule (86 FR 39291 through 39294), we discussed some of our considerations based on our initial analyses of stakeholders' concerns about the methodology for calculating regional FFS expenditures used in certain benchmark calculations, specifically the regional adjustment and the blended national-regional growth rates used in trending and updating the benchmark. We explained that we were investigating these concerns and performing additional simulations. We solicited comments on these considerations and other related issues, as well as suggested approaches to modifying the program's benchmarking methodology, which could inform future rulemaking.

We received public comments on the alternative benchmarking methodologies discussed in the proposed rule. The following is a summary of the comment solicitations, the comments we received and our responses.

(1) Overview of Benchmarking Policies Using Regional FFS Expenditures

As we described in the CY 2022 PFS proposed rule, in calculating the historical benchmark, we use historical expenditures for the ACO's assigned beneficiaries, as well as factors based on regional FFS expenditures, factors based on national FFS expenditures, and factors based on a blend of national and regional FFS expenditures. As we have described in earlier rulemaking, incorporating regional expenditures into benchmark calculations makes the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region (see for example, 81 FR 37950, 37951 and 37955). We have also acknowledged in earlier rulemaking that the incorporation of factors based on regional FFS expenditures into ACO benchmarks will have varying effects on ACOs depending on each organization's individual circumstances (see for example, 81 FR 37950, 37954 through 37957, and 81 FR 37975 through 37977; and 83 FR 67816, 68017 and 68026).

In accordance with § 425.601(a)(8), we adjust historical benchmark expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's historical benchmark amount

(referred to herein as the ''regional adjustment''). The percentage that is applied in calculating the regional adjustment is determined in accordance with § 425.601(f) and depends on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment, according to the phase-in schedule of the applicable weights. CMS caps the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to ±5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3.

In accordance with § 425.601(a)(5), in establishing and resetting an ACO's benchmark, CMS trends forward expenditures for each benchmark year (BY1 and BY2) to BY3 dollars using a blend of national and regional growth rates, making separate calculations for each Medicare enrollment type. Similarly, in accordance with § 425.601(b), CMS updates the historical benchmark annually for each year of the agreement period using a blend of national and regional growth rates between BY3 and the performance year. As described in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt this policy under which we update the historical benchmark using a blend of national and regional growth rates, rather than the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act. CMS accounts for an ACO's penetration in its region when calculating the national-regional blended growth rates, by placing a higher weight on the national component of the blend and a lower weight on the regional component as the ACO's penetration in its region increases.

In determining regional FFS expenditures, CMS uses average county FFS expenditures for assignable beneficiaries, including the ACO's assigned beneficiaries, in each county in the ACO's regional service area for the 12-month calendar year corresponding to the relevant benchmark or performance year.[124, 125] CMS weights these county-level FFS expenditure amounts by the proportion of the ACO's assigned beneficiaries residing in each county, with all calculations performed separately by Medicare enrollment type. Refer to § 425.601(c) (calculating county expenditures) and (d) (calculating regional expenditures).

As described in the CY 2022 PFS proposed rule (86 FR 39292), ACOs and other program stakeholders have expressed concerns with the approach to determining regional FFS expenditures using a population of assignable beneficiaries that includes the ACO's assigned beneficiaries, including with respect to the impact on the calculation of the regional adjustment and the blended national-regional growth rate used to trend and update an ACO's historical benchmark, suggesting this policy results in relatively lower benchmarks for ACOs, particularly ACOs with high market penetration in their regional service area, which may tend to be ACOs located in rural areas.[126] For example, the National Association of ACOs' (NAACOS') summary ''Fixing the Rural Glitch'' explains its belief that by including the costs of all beneficiaries in the regional adjustment—both those assigned to the ACO and those who are not—CMS penalizes an ACO for reducing costs relative to its regional competitors. That is, as an ACO reduces the costs of its own assigned beneficiaries, it also reduces the average regional costs. According to NAACOS, this will ultimately reduce savings for efficient ACOs in all areas, but the effect may be most dramatic for rural ACOs because they will tend to care for a greater portion of their region's total beneficiary population than an urban ACO.[127] As another example, a stakeholder suggests that incorporating factors based on regional FFS expenditures into the Shared Savings Program's benchmarking methodology systemically penalizes ACOs with a large market share when they reduce costs, leading to disparate payments to ACOs with identical performance.[128] ACOs and other program stakeholders have suggested that CMS remove the effects of the ACO's own performance from factors based on regional FFS expenditures, such as by excluding an ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures.[129] Other alternatives that have been suggested to address these concerns include capping an ACO's penetration in the region at 50 percent by Medicare enrollment type, or expanding the ACO's region.[130] In recent years, legislative changes have been introduced, which if enacted would require the removal of the ACO's assigned beneficiaries from regional expenditure calculations.[131] [132] In the CY 2022 PFS proposed rule, we expressed our appreciation for ACOs and other program stakeholders bringing their concerns, and suggested alternatives, to our attention. We stated that we had begun to analyze these concerns about the use of factors based on regional FFS expenditures in

[124] Assignable beneficiary, as defined in § 425.20, means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

[125] The ACO's regional service area, as defined in § 425.20, means all counties where one or more beneficiaries assigned to the ACO reside.

[126] See for example the CY 2021 PFS final rule, summarizing commenters' concerns about the program's benchmarking methodology received in response to modifications to Shared Savings Program policies that were adopted in the May 8, 2020 COVID–19 IFC to address the impact of the PHE for COVID–19, although we noted these comments went beyond the modifications to the program's regulations established in that IFC (85 FR 84783 through 84785).

[127] See NAACOS, Fixing the Rural Glitch, available at *https://www.naacos.com/assets/docs/pdf/2021/RuralGlitchExplainer.pdf.*

[128] Aledade, ''Opportunities for 2022 Improvements to MSSP ACOs in the Physician Fee Schedule'' (June 2021), provided as a document during E.O. 12866 Meeting (CMS–1751), available at *https://mobile.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0938-AU42&meetingId=49323&acronym=0938-HHS/CMS.*

[129] See for example, 85 FR 84784; see also, NAACOS, Fixing the Rural Glitch, available at *https://www.naacos.com/assets/docs/pdf/2021/RuralGlitchExplainer.pdf.*

[130] See for example, Aledade, ''Opportunities for 2022 Improvements to MSSP ACOs in the Physician Fee Schedule'' (June 2021), provided as a document during E.O. 12866 Meeting (CMS–1751), available at *https://mobile.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0938-AU42&meetingId=49323&acronym=0938-HHS/CMS.*

[131] See S.2648—Rural ACO Improvement Act, 116th Congress (2019–2020), available at *https://www.congress.gov/bill/116th-congress/senate-bill/2648/text* (including a provision on Exclusion Of Assigned Beneficiaries In Certain Circumstances Including Determination Of Regional Adjustments), and H.R. 5212—Accountable Care in Rural America Act, 116th Congress (2019–2020), available at *https://www.congress.gov/bill/116th-congress/house-bill/5212/text.*

[132] See also, Letter from NAACOS et al., to Representatives Arrington, DelBene, Kelly, Bera, O'Halleran, Sewell, Dunn and Gooden (June 15, 2021), describing the introduction of H.R. 3746, the Accountable Care in Rural America Act. Available at *https://www.naacos.com/naacos-and-12-others-write-congress-in-support-of-the-accountable-care-in-rural-america-act--h-r--3746-.* H.R. 3746—117th Congress (2021–2022), available at *https://www.congress.gov/bill/117th-congress/house-bill/3746/text?r=58&s=1.*

calculating ACO benchmarks, and to consider possible modifications to the Shared Savings Program's benchmarking methodology to ensure the sustainability of the program's financial models. We noted that any such modifications would need to be adopted through notice and comment rulemaking.

The following is a summary of the public comments we received and our response.

Comment: Several commenters, including MedPAC, did not support amending the Shared Savings Program benchmarking methodology to remove an ACO's assigned beneficiaries from the assignable beneficiary population used in determining regional FFS expenditures. These commenters noted that the balance of current Shared Savings Program incentives already tends to favor ACOs that are efficient within their region (that is, historically low-spending ACOs) and this imbalance would be exacerbated by removing an ACO's assigned beneficiary expenditures from its benchmark. Among other factors, these commenters noted that such an approach could create a situation that would reward low-spending ACOs without improving their efficiency of care and would reduce incentives for participation among high spending ACOs (including ACOs serving high-spending beneficiaries in a region, or operating in high cost or high need areas) that the commenters stated were likely to have the greatest opportunity for efficiency improvements. One commenter indicated that an approach that removes the ACO's assigned beneficiaries from benchmark calculations may advantage experienced ACOs that are already successful in lowering spending for their assigned population, more so than new ACOs. This commenter also explained that in circumstances where an ACO's beneficiaries are removed and the remaining population for the benchmark calculation is healthier or utilizing fewer health care services, the ACO will be left to compete against an unattainable benchmark.

Some comments pointed to the need for further clarity from CMS on the impact of removing the ACO's assigned beneficiaries from the assignable population used to determine regional FFS expenditures. A commenter stated that they were unsure how they would be impacted (positively or negatively) by an approach that would reduce the influence of an ACO's assigned beneficiaries on regional expenditure calculations, and recommended CMS propose and allow time for response to any such alternative policies. A few commenters suggested that ACOs that include physicians or facilities providing specialist care might be negatively impacted as these health care providers serve patients with high costs of care and requested that CMS provide more information about the potential impacts on these ACOs.

Many commenters who responded to the comment solicitation favored CMS making regulatory changes to remove ACO-assigned beneficiaries from the regional reference population used in the current benchmarking methodology, raising concerns about the impact of the existing approach to calculating regional expenditures more broadly or specifically with respect to the regional adjustment or the blended national-regional factors used to trend and update the benchmark. Most commenters favoring this approach called for the changes to be made as soon as possible, with some commenters suggesting that CMS finalize a policy change in this final rule. A commenter requested that the changes be made retroactively, calling on CMS to re-calculate shared savings and losses from prior years and to pay additional shared savings to ACOs that were negatively affected by the current policy. While noting it was important to address calculation of regional FFS expenditures in the Shared Savings Program, several commenters recommended that CMS also review methodologies used in existing and developing Innovation Center models to ensure they appropriately account for an APM participant's regional presence.

Some commenters described the current policy on calculating regional expenditures as penalizing ACOs when they reduce costs by also reducing the regional costs against which the ACO is compared. Commenters suggested that this can hinder an ACO's ability to generate savings and earn shared savings. A commenter suggested the policy would reduce the financial incentives for ACOs to fund critical care improvement initiatives that are fundamental to total cost of care reduction. The same commenter noted that ACOs could ultimately face shared losses even if they have the same performance as a prior year in which they achieved savings due to continually decreasing benchmarks. Some commenters stressed that removing the ACO's assigned beneficiaries from the regional reference population was important for creating more fair and accurate benchmarks and a level playing field for ACOs which, in turn, would help the Shared Savings Program to attract and retain participants. Some commenters noted that accurate and reliable benchmarking is critical for the long-term success of the Shared Savings Program and APMs more generally.

Many commenters maintained that the current approach to determining regional FFS expenditures particularly disadvantages rural ACOs or ACOs with high market penetration in their regional service areas, which may tend to be ACOs operating in rural areas. Some commenters referred to the issue as the ''rural glitch''. Several commenters described this aspect of the Shared Savings Program's benchmarking methodology as creating a value-based care equity issue, because it systematically disadvantages ACOs in rural areas by making it harder for them to achieve savings even when they improve quality and reduce costs on par with their counterparts in urban areas. Several commenters underscored the importance of and urgency for CMS to remove ACO assigned beneficiary costs from the regional factors used in Shared Savings Program benchmarking to create sustainability for value-based care in rural communities. More specifically, a commenter suggested that CMS should take this approach to allow Medicare patients in rural areas to have the same or similar ability to access providers participating in innovative delivery system models as their urban counterparts.

While acknowledging the potential impact on rural ACOs, some commenters noted that the current policy also adversely affects many suburban and urban ACOs. A few commenters described the current policy as penalizing ACOs that are successful or the most efficient providers in their market.

Some commenters indicated their support for the Value in Health Care Act of 2021,[133] particularly regarding the removal of ACO assigned beneficiaries from the methodology for calculating the regional expenditures used to establish, adjust and update the benchmark. A commenter suggested CMS support another piece of legislation, the Accountable Care in Rural America Act,[134] to address exclusion of ACO assigned beneficiaries from the methodology for calculating regional expenditures. At least one commenter explained that while they have endorsed legislation aimed at fixing the ''rural glitch'', they believe

[133] Refer to H.R. 4587—117th Congress (2021–2022), available at *https://www.congress.gov/bill/117th-congress/house-bill/4587/text.*

[134] Refer to H.R. 3746—117th Congress (2021–2022), available at *https://www.congress.gov/bill/117th-congress/house-bill/3746/text?r=58&s=1.*

that it is fully within CMS' authority to fix this issue through rulemaking.

Response: We will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies and will propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking.

(2) Methodology for Removing ACO Assigned Beneficiaries From Regional FFS Expenditures

As we explained in the CY 2022 PFS proposed rule (86 FR 39292 and 39293), there may be several possible approaches that we could consider for removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations, which would vary in the degree of additional program calculations and the level of complexity. As we described in the proposed rule, we simulated the impact of removing an ACO's assigned beneficiaries from the regional expenditure calculations using an approach that would pose relatively limited operational burden and would leverage data elements already computed under the current benchmarking methodology. This approach relies on the premise that per capita risk-adjusted regional FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of per capita risk-adjusted FFS expenditures for the ACO's assigned beneficiaries (b) and per capita risk-adjusted FFS expenditures for assignable beneficiaries in the region who are not assigned to the ACO (c), where the weight on (b) is the ACO's regional market share [135] and the weight on (c) is one minus the ACO's regional market share. Shown as an equation this is:

(a) = [(b) × (ACO's regional market share)] + [(c) × (1 − ACO's regional market share)].

Thus, to remove the ACO's assigned beneficiaries from the regional expenditure calculation, we would insert the applicable values into the above equation and solve for (c) by rearranging the equation as follows:

(c) = {(a) − [(b) × (ACO's regional market share)]}/(1 − ACO's regional market share).

[135] What is referred to here as the ''ACO's regional market share'' is the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO, which is the weight that it is applied to the national component of the national-regional blend under § 425.601(a)(5)(iv) and (v).

By using such ACO- and regional-level values, this approach, performed separately by Medicare enrollment type, would avoid the need to calculate individualized ACO county-level risk-adjusted expenditures. We solicited comment on the approach we outlined, or alternative approaches to calculating regional FFS expenditures without an ACO's assigned beneficiaries. In particular, we solicited comment on specific approaches that would strike the balance of achieving the desired outcome of removing the ACO's assigned beneficiaries from program calculations without introducing an inordinate amount of operational and administrative complexity such that the steps and data included in the calculations can be understood by ACOs and other program stakeholders, and the potential for calculation errors is minimized.

As we explained in the CY 2022 PFS proposed rule (86 FR 39293), we performed initial simulations, for a subset of Shared Savings Program ACOs, using data for the 6-month performance year starting on July 1, 2019 (sometimes referred to as performance year 2019A), for which expenditures were determined based on expenditures for CY 2019, to observe the effects of potential modifications to the benchmarking methodology. In performing these simulations, we used the aforementioned approach for removing expenditures for the ACO's assigned beneficiaries from the calculation of regional FFS expenditures, by removing the impact of an ACO's assigned beneficiaries from the assignable population as weighted by the ACO's regional market share. Specifically, we simulated the effects on the per capita updated benchmark of several alternate policies that would remove an ACO's assigned beneficiaries from regional expenditures used to trend and update the benchmark (either alone or as part of a national-regional blend) or from regional expenditures used to calculate the regional adjustment, or from both. When looking at average impacts by quintile of the ACO's penetration in its regional service area (that is, market share) and rural or non-rural status, the various alternatives resulted in estimated increases in the updated benchmark by amounts ranging from 0.1 percent to 1.4 percent, with ACOs with higher market shares tending to see slightly higher average increases than ACOs with lower market shares and rural ACOs seeing slightly higher average increases than non-rural ACOs. We also observed that some ACOs experienced decreases in their benchmark amounts, ranging from −0.02 percent to −1.5 percent under these simulations of alternate benchmarking policies. We noted that additional analysis would be needed to consider the impact of such policies on a broader set of ACOs participating in the Shared Savings Program, including ACOs that did not participate in a 6-month performance year from July 1, 2019, through December 31, 2019. We solicited comment on this estimated range of impacts on ACO benchmark values, and on the potential mixed effects on ACOs that could result from modifications to the benchmarking methodology.

In the CY 2022 PFS proposed rule (86 FR 39293), we explained our belief that in considering alternative benchmarking methodologies to address ACOs' penetration in their regional service areas it would be important to consider what would constitute heavy penetration by an ACO in its regional service area, and the extent to which market penetration should be considered in benchmark calculations. Based on preliminary analysis of data for CY 2019 using performance year 2021 ACO Participant Lists for all ACOs participating in the program as of January 1, 2021, the median ACO regional market share was approximately 16.2 percent, with a minimum of 0.9 percent and a maximum of 59.2 percent. Further, 90 percent of ACOs had a regional market share of less than 37.8 percent, and 80 percent of ACOs had a regional market share of less than 29.3 percent. Accordingly, we solicited comment on what would constitute heavy penetration in the ACO's regional service area and how removing the ACO's assigned beneficiaries from regional calculations, dependent on the level of penetration, could either increase or decrease the ACO's benchmark. We also solicited comment on approaches that could strike a balance between adjusting program policies to address impacts on the potentially few ACOs that are heavily penetrated in their regional service area while maintaining stability for most ACOs that have relatively low penetration in their regional service area.

The following is a summary of the public comments we received and our response.

Comment: Some commenters addressed the question of how to remove an ACO's assigned beneficiaries from the reference population used in calculating factors based on regional FFS expenditures. A few commenters directly addressed the formula CMS

presented in the CY 2022 PFS proposed rule, appearing to support the potential approach for performing this exclusion. Some commenters indicated CMS' mathematical approach was ''directionally correct'', relatively simple, and works well in nearly every case while using data that CMS already produces. One commenter appreciated the transparency of the approach laid out by CMS but sought further clarification on whether the time period for measuring the ACO's market share would be the same period used to calculate expenditures.

Several commenters addressed CMS' analyses simulating the effect of removing an ACOs' assigned beneficiaries from regional expenditure calculations on ACO benchmarks. A few commenters noted that CMS showed a range of results, both positive and negative, but did not state how many ACOs would benefit versus be harmed. By their own analysis, a commenter found that nearly 80 percent of ACOs would benefit and that there was no consistent pattern among ACOs that would benefit versus those that would be harmed. Another commenter expressed their belief that CMS' analysis made it clear that the current benchmarking methodology could be made more fair. A commenter remarked that CMS' simulations found that removing each ACO's assigned beneficiaries would slightly increase the average benchmark, even for ACOs with low market share or those in urban areas. This commenter surmised that the ACOs that saw negative effects were likely to be historically high-spending ACOs. Another commenter responding to CMS' simulation results recommended that CMS set a cap on the adjustment to the benchmark for ACOs that would be harmed.

Some commenters addressed the issue of how to identify the population of Medicare FFS beneficiaries to remove from the assignable population used to determine regional FFS expenditures. Several commenters generally supported excluding ACO assigned beneficiaries from the regional reference population but did not clarify whether they preferred to see only an ACO's own beneficiaries removed or all ACO assigned beneficiaries. Suggestions from other commenters included removing all of a respective region's ACO-assigned beneficiaries, or beneficiaries attributed to all Medicare ACO initiatives, including the Global and Professional Direct Contracting Model. However, commenters acknowledged the possibility that the remaining beneficiary population could be too small, which, as a commenter indicated, could lead to significant variability in the regional component of the benchmark.

Some commenters responded directly to CMS' request for comment on what would constitute heavy penetration by an ACO in its regional service area, and the extent to which market penetration should be considered in benchmark calculations. A commenter recommended that CMS set the high penetration mark at 30 percent, but did not provide specific suggestions for how this penetration level might be incorporated into the Shared Savings Program's benchmarking methodology. Some commenters discussed using 50 percent market share as a threshold in certain benchmark calculations. MedPAC noted that CMS found relatively few Shared Savings Program ACOs with high market share, which was consistent with its own analyses and believed that this relatively small number of ACOs with high market penetration is not enough to warrant a change in policy of this magnitude. MedPAC also noted that the current blended national-regional trend factor reasonably attempts to address high ACO market shares and recommended that, like the existing blend, any changes in policy should attempt to avoid imposing a market share threshold or ''cliff.''

Response: We will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies and will propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking.

(3) Unintended Consequences of Removing ACO Assigned Beneficiaries From Regional Calculations, and Identifying Other Needed Modifications

In the CY 2022 PFS proposed rule (86 FR 39293 and 39294), we solicited comment on the following considerations, and other possible unintended consequences that could result from removing an individual ACO's assigned beneficiaries from regional calculations.

- Would this approach create incentives for ACOs to have assigned beneficiaries who are healthier than the remaining comparison population that is the basis for benchmark factors based on regional FFS expenditures (so as to yield a higher benchmark), which could lead ACOs to seek out healthier beneficiaries and avoid at-risk or higher-cost beneficiaries?

++ Would this approach incent the formation of large ACOs within a particular market to obtain the most competitive benchmarks resulting in market consolidation, and discourage participation by relatively smaller ACOs, thus increasing costs for the Medicare Trust Funds if CMS pays larger amounts of shared savings to ACOs that have consolidated to take advantage of the ability to attract more low-cost beneficiaries in their region?

++ Would a change in the regional benchmarking methodology encourage ACOs to avoid at-risk or higher-cost beneficiaries and potentially exacerbate inequities in access to health care?

- We solicited comment on the potential for negative impacts on ACOs that serve larger proportions of medically complex beneficiaries, such as ACOs whose assigned beneficiary populations include larger proportions of beneficiaries who are medically complex and cared for in ambulatory or home-based settings or who reside in long term care facilities, resulting from an approach that removes the ACO's assigned beneficiaries from the assignable beneficiary population used to determine regional FFS expenditures. Would such an approach yield a benchmark so low that such ACOs have little incentive to participate in the Shared Savings Program?
- Would removing an individual ACO's assigned beneficiaries result in regional FFS expenditures based on very small populations, thus introducing significant variability into regional FFS expenditure trends used in benchmark calculations?

Additionally, we solicited comment on whether removal of an ACO's assigned beneficiaries from regional FFS expenditure calculations would bring about a need to remove ACO assigned beneficiaries from other Shared Savings Program financial calculations based on a broader Medicare population, including factors based on national FFS expenditures, which are used in calculating blended national and regional expenditure trend and update factors, truncation points used in calculating benchmark and performance year expenditures, and the 5 percent cap on the regional adjustment.

The following is a summary of the public comments we received and our response.

Comment: Commenters offered differing perspectives on the potential unintended consequences that could result from an approach that would remove ACO assigned beneficiaries from the regional FFS expenditure calculations including the following:

- Several commenters expressed the belief that removing ACO assigned beneficiaries from regional FFS expenditure calculations would

penalize ACOs serving medically complex, high cost patients in a region. A commenter noted that this approach could result in such ACOs leaving the Shared Savings Program or could be a deterrent to entry for future ACOs. Another commenter suggested that ACOs would be incentivized to avoid growth and expansion of services into high risk, high cost, high need areas, regardless of whether they are rural or urban, citing evidence for this phenomenon published in *Health Affairs.*[136]

• Several commenters expressed concern that the policy would create increased incentives for patient selection or ''cherry picking''. Another commenter disagreed, stating they did not believe that removing an ACO's assigned beneficiaries would create any of the unintended consequences CMS has contemplated, including cherry-picking healthier beneficiaries. Several other commenters also believed the likelihood of ACOs avoiding high-risk patients if ACO assigned beneficiaries are removed from the regional reference population is quite low and is outweighed by their concerns about the other effects of the existing policy. Commenters noted various safeguards or guardrails, such as provider choice among patients and risk adjustment, are already built into the framework of the Shared Savings Program to help to prevent ACOs from purposefully avoiding certain populations.

• One commenter expressed concerns about potential market consolidation effects, while a few other commenters explained that while there has been increased consolidation in recent years across the healthcare industry, there is not strong evidence showing ACOs are driving this change. A few other commenters also expressed the belief that a change in policy regarding the calculation of regional expenditures would not lead to provider consolidation, but would increase participation in ACOs in rural markets, expanding access to coordinated care and encouraging alternative payment model participation across the country.

• MedPAC expressed concern that the population used to determine regional FFS expenditures would become less comparable with the ACO's assigned population as the ACO's regional market share increases, even after risk adjustment, citing evidence from a 2009 evaluation of the Physician Group Practice (PGP) demonstration[137] (a predecessor to the Shared Savings Program). Several other commenters believed that concerns about small reference populations resulting from removing ACO-assigned beneficiaries is an issue for a minority of ACOs, such as those serving dual eligible Medicare and Medicaid beneficiaries, ESRD beneficiaries, and other high-risk beneficiary groups. The commenters suggested that, in these cases, CMS should consider expanding the regional service area to include assignable beneficiaries in adjoining counties or increasing the number of years included in the calculation of regional expenditures to improve the stability of the regional adjustment. Another commenter acknowledged that there are concerns about extreme differences between the ACO population and non-ACO population that risk adjustment does not handle well, but that these considerations affect only a small fraction of ACOs and can be addressed by expanding the definition of the region to include contiguous counties.

Response: We will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies and will propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking.

(4) Alternative Approaches to Determining Regional FFS Expenditures and Alternative Benchmarking Methodologies

In the CY 2022 PFS proposed rule (86 FR 39294), we solicited comment on using other approaches to calculating benchmarks under the Shared Savings Program. In particular, we solicited comment on alternatives to determining regional FFS expenditures that would reduce the influence of an ACO's assigned beneficiaries on regional expenditure calculations, such as basing these expenditures on a larger geographic area, including using State-level data, Core-Based Statistical Area (CBSA)-level data, or a combination of data for these larger geographic areas and county-level data (such as blended county/State regional expenditures). We also solicited comment on alternative benchmarking methodologies that may incorporate data sources other than Medicare FFS expenditure trends, such as by incorporating factors based on Medicare Advantage rates, or other published trends.

We also solicited comment on considerations related to the potential use of our authority under section 1899(i)(3) of the Act to implement suggested modifications to the benchmarking methodology, in particular alternative approaches to updating the historical benchmark or other alternative benchmarking methodologies that diverge from the requirements of section 1899(d)(1)(B)(ii) of the Act, since to do so we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures.

The following is a summary of the public comments we received and our response.

Comment: Commenters suggested a number of alternative approaches for addressing the impact of an ACO's own performance on its benchmark or countering the potentially adverse effects of removing the ACO's assigned beneficiaries from regional expenditure calculations including:

• Several commenters suggested that CMS should expand the definition of regional service area in cases where ACO market penetration is high, with some of those commenters suggesting this would mitigate concerns about the reference population being too small after removing the ACO's assigned beneficiaries. Some commenters specifically called for using a threshold of 50 percent market penetration in such an approach. For example, a commenter recommended expanding the ACO's regional service area to include all contiguous counties when an ACO's assigned beneficiary population in a county exceeds 50 percent, with allowances for alternate thresholds to be used in certain special cases, such as: When the ACO's regional service area includes very small counties to expand the ACO's regional service area to include the contiguous counties; when an ACO represents more than 50 percent of a combined statistical area, to use national inflation in place of regional inflation; or when there are significant risk score differences between assigned and non-assigned beneficiaries, to consider using a lower threshold for expanding the ACO's regional service area to include contiguous counties, such as a threshold of at least 30 percent or higher, instead of 50 percent.

• One commenter, concerned about the potential for ''cherry-picking'', suggested using geographic units smaller than counties to define an

[136] Citing Markovitz AA, et al. Risk Adjustment In Medicare ACO Program Deters Coding Increases But May Lead ACOs To Drop High-Risk Beneficiaries. Health Affairs. February 2019. Available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05407.*

[137] Citing Secretary of Health and Human Services, Report to Congress, Physician Group Practice Demonstration Evaluation Report. 2009. Available at *https://innovation.cms.gov/files/reports/pgp-rtc-sept.pdf.*

ACO's regional service area as these geographic units may be more socio-economically homogenous; alternatively, the commenter suggested maintaining a county-level definition of region, but adjusting the benchmarking process to adequately account for beneficiary social, functional, and clinical risk factors and to provide an upward financial adjustment for ACOs serving these higher cost populations. Along a similar vein, several commenters encouraged CMS to explore further ways to stratify benchmarks based on patient risk factors, such as to set separate benchmarks for certain high-cost patients.

- MedPAC suggested modifications to both the national and regional components of the blended national-regional trend factors. MedPAC also suggested that CMS alter the calculation of regional spending in the trend factor by extending the ACO's regional service area to a larger market area (for example, CBSAs, health service areas, or hospital referral regions) in lieu of excluding ACO assigned beneficiaries from regional expenditure calculations. Based on its own analysis, MedPAC concluded that expanding an ACO's regional service area would help to reduce an ACO's influence on its regional benchmark calculation without explicitly favoring certain categories of ACOs (for example, historically low-spending ACOs). MedPAC also suggested that the national portion of the blended national-regional trend factor could be standardized for average wages or adjusted to reflect local wage and geographic practice indices.
- Some commenters suggesting removal of ACO assigned beneficiaries from the regional reference population also suggested that CMS use a regional-only trend rather than a national trend or a blended national-regional trend in establishing and updating the ACO's benchmark. These commenters explained that the use of a blended trend factor often over-emphasizes the national trend component for high market share ACOs and that this is especially problematic during the COVID–19 pandemic because the national trend does not reflect important local market dynamics that vary across the country. Specifically, these commenters noted that in 2020 regional spending decreased by 10 percent or more in some markets, while remaining relatively ''flat'' in other markets. These commenters concluded that ACOs in COVID–19 ''hot spots'' likely have higher costs than the overall nation, and therefore, using the national trend as part of the benchmarking methodology is detrimental and unfair to these ACOs as it does not reflect the pandemic's effect on costs in their regions. Another commenter generally suggested that CMS adjust blended national-regional growth rates to account for ACOs in COVID–19 ''hot spots'', but did not provide details describing such an approach.
- Several commenters suggested that CMS consider approaches being used in Innovation Center models. Several commenters suggested CMS use an approach under the Shared Savings Program similar to the approach used in the Direct Contracting Model to adjust benchmarks based on regional FFS expenditures. For example, MedPAC specifically suggested that ACOs selecting prospective assignment be offered a trend factor that is set prospectively prior to the start of the performance year and developed utilizing the local and national estimates in the rate book developed for the Direct Contracting model. In its comments, MedPAC underscored that any changes that CMS considers making to the benchmarking methodology should enhance incentives for care improvement and avoid penalizing ACOs with assigned beneficiary populations that are more complex and costly than the ACO's regional average. Several commenters suggested that CMS establish additional benchmark options based on patient population and clinical need, especially for complex patient populations, referring to the approaches used under the Primary Care First Seriously Ill Population model and Direct Contracting model High Needs track.
- One commenter suggested that CMS take the following approach to incentivize participation and retention among ACOs, regardless of their initial efficiency relative to their region: (1) Continue to have ACOs move to increased (50 percent to 100 percent) regional weighting over time; (2) For ACOs more efficient (lower spending) than their region, apply only positive regional adjustments; (3) For ACOs less efficient (higher spending) than their region, allow for purely historical benchmarks until the ACO moves below the regional average.
- Several commenters expressed concerns about use of 2020 and 2021 data in establishing ACO historical benchmarks because of the impact of the COVID–19 PHE on expenditures. One commenter suggested that CMS waive the requirement in § 425.601 that the benchmark is established or reset using data from the three most recent years prior to the start of the agreement period, and instead utilize data from 2017, 2018 and 2019 to establish or reset benchmarks for agreement periods that begin on January 1, 2022. This commenter suggested that CMS could alternatively offer ACOs with agreement periods beginning January 1, 2022, the option to choose use of benchmark year data either from 2019, 2020 and 2021 or from 2017, 2018 and 2019. Another commenter suggested CMS adjust how performance years 2020 and 2021 will be weighted in the calculation of financial benchmarks for future agreement periods.

Response: We will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies and will propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking.

For reference, as noted in the CY 2022 PFS proposed rule (86 FR 39294), for each calendar year, CMS releases two public use files (PUFs): (1) County-level Aggregate Expenditure and Risk Score Data on Assignable Beneficiaries PUF, and (2) Number of ACO Assigned Beneficiaries by County PUF. These files are available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/SSP_Benchmark.* Stakeholders may find this data helpful to inform their further consideration of these issues.

c. Comments on the Shared Savings Program's Risk Adjustment Methodology

In the CY 2022 PFS proposed rule (86 FR 39294 and 39295), we discussed stakeholders' concerns about the methodology for risk adjusting the ACO's historical benchmark each performance year during its agreement period, and we sought comment on approaches to potentially address these concerns, and some related considerations. The following is a summary of the comment solicitations, the comments we received and our response.

As described in the CY 2022 PFS proposed rule, we take into account changes in severity and case mix of the ACO's assigned beneficiary population when establishing the benchmark and also in adjusting the benchmark each performance year. In accordance with § 425.601(a)(3), in establishing the benchmark, we adjust expenditures for changes in severity and case mix using prospective HCC risk scores. Under § 425.601(a)(10), we further adjust the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned

beneficiary population between BY3 and the performance year (refer to § 425.601(a)(10); § 425.605(a)(1), (a)(2); § 425.610(a)(2), (a)(3)). In making this risk adjustment, we make separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). We use CMS–HCC prospective risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period. This cap is the maximum increase in risk scores allowed for each agreement period, such that any positive adjustments between BY3 and any performance year in the agreement period cannot be larger than 3 percent. That is, the risk ratios (ratio of performance year risk score to the BY3 risk score) applied to historical benchmark expenditures to capture changes in health status between BY3 and the performance year will never be higher than 1.030 for any performance year over the course of the agreement period. This cap is applied separately for the population of beneficiaries in each Medicare enrollment type.[138]

ACOs and other stakeholders have expressed concerns that the program's methodology for capping any increase in the risk adjustment to the historical benchmark, such that any positive adjustment between benchmark year 3 and any performance year in the agreement period cannot be larger than 3 percent, does not account for risk score growth in the ACO's regional service area, and thereby penalizes ACOs.[139] [140] In earlier rulemaking, commenters indicated that the 3 percent cap on risk score increases is especially problematic for ACOs whose regional service area includes a population of beneficiaries whose risk scores rise more than the cap. A commenter encouraged CMS to adopt a policy of applying a cap on risk score growth after accounting for regional increase in risk scores (85 FR 84784).

In the CY 2022 PFS proposed rule, we solicited comment on the following issues related to the risk adjustment methodology—

- Approaches, generally, to improving the risk adjustment methodology for the Shared Savings Program, and specifically for ACOs with medically-complex, high-cost beneficiaries.
- Approaches to risk adjustment that would balance the need for accurate and complete coding, while protecting against incentivizing coding intensity initiatives by ACO participants and ACO providers/suppliers (which may be even more problematic for ACOs with high penetration in their region) that increase risk score growth above the existing 3 percent cap.
- Alternate approaches that would increase the cap on an ACO's risk score growth in relation to risk score growth in the ACO's regional service area, such as:

++ Allowing the ACO risk score growth cap to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area. In this alternate approach, the percentage applied would be equal to 1 minus the ACO's regional market share. This approach would raise the existing cap while limiting the ability for ACOs with high penetration in their region to increase their cap by engaging in coding intensity initiatives that raise the regional risk score.

++ Setting the ACO risk score growth cap at some level between the existing 3 percent risk score cap and the regional risk score growth, which would account for a portion of the regional risk score growth that exceeds the current cap.

- The potential interactions between policies to remove assigned beneficiaries from the assignable beneficiary population used to calculate regional FFS expenditures and growth rates (as described elsewhere in this section of this final rule), and policies addressing regional risk score growth.

Comment: Several commenters responding to the comment solicitation on the Shared Savings Program's risk adjustment methodology explained that risk adjustment is an important aspect of setting fair ACO benchmarks and evaluating expenditures during the performance year. The commenters noted that accurate risk adjustment should remove or minimize differences in health and other risk factors that impact performance but are outside the ACO's control.

MedPAC indicated that the existing risk adjustment approach may be effective in balancing a number of considerations. MedPAC expects that changes in an ACO's population health status would be accounted for by the CMS–HCC model, and the current 3 percent potential increase to benchmarks—in addition to being susceptible to rewarding ACOs for coding—would likely cover anomalies when ACO populations have deteriorating health status. Another commenter expressed the belief that, while not perfect, the CMS–HCC model used in the Shared Savings Program is known to providers and does a decent job of capturing the risk of Medicare FFS beneficiaries.

Many commenters remain concerned about the existing risk adjustment methodology under which there is a 3 percent cap on positive adjustments resulting from risk score increases over the ACO's 5-year agreement period, and many of these commenters also expressed concern about the absence of a cap (or floor) on negative adjustments to account for risk score decreases. Several commenters believe the current approach is unfair to ACOs and inadequate, indicating that risk adjustment caps may be somewhat reasonable in the early years of a 5-year agreement period, but not in the later years of the agreement period. One commenter noted that freezing risk scores over 5 years could create a constant struggle against a population's outdated risk score (calculated several years earlier) for which ACOs are at financial risk. The commenter also explained that CMS has already recognized the necessity of shorter-term caps on risk and price adjustments, referring to the Bundled Payments for Care Improvement initiative (trend factor variation capped on a quarter-over-quarter basis) and the Next Generation ACO model (risk scores capped at 3 percent over 2 years). Some commenters referred to an analysis by CMS described in earlier rulemaking which indicated that 32 percent of ACOs would have a risk ratio greater than 1.03 for the aged/dual eligible enrollment type over 5 years. According to some of these commenters, this analysis demonstrates that the current 3 percent cap is not appropriately set as it limits risk score growth for more than just outliers. With respect to a cap on risk score decreases, a few commenters noted that CMS had previously been hesitant to introduce such a cap out of concern about creating a gaming opportunity for ACOs. It appears that these commenters may have been

[138] Refer to the December 2018 final rule (83 FR 68007 through 68013), section on ''Risk Adjustment Methodology for Adjusting Historical Benchmark Each Performance Year''. See also, the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #9, February 2021), section 3.6, available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-0.*

[139] 85 FR 84783 through 84785.

[140] Aledade, ''Opportunities for 2022 Improvements to MSSP ACOs in the Physician Fee Schedule'' (June 2021), provided as a document during E.O. 12866 Meeting (CMS–1751), available at *https://mobile.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0938-AU42&meetingId=49323&acronym=0938-HHS/CMS.*

referring to the discussion in the December 2018 final rule (83 FR 68010 and 68011), in which CMS explained that it shared the concerns raised by some commenters that capping risk score decreases would encourage favorable risk selection, such that ACOs might seek to attract low-cost beneficiaries or avoid high-cost beneficiaries in order to lower their performance year expenditures without any corresponding adjustment to their benchmark due to the cap on negative risk adjustments. These commenters believed that CMS has other tools for monitoring for potential gaming, such as continuing to monitor voluntary alignment, but they did not explain how such monitoring would address CMS' concerns about capping risk score decreases.

Some commenters raised particular concerns about the current risk adjustment policy in light of the PHE for COVID–19. Several commenters raised concerns regarding the application of a 3 percent cap on risk score increases over the ACO's 5-year agreement period and the lack of a floor for risk score decreases given the widespread and unparalleled effects of the PHE for COVID–19. A few commenters indicated their expectation that most ACOs' risk scores for 2021 will be extremely low as providers were unable to capture many beneficiaries' HCCs due to reduced patient volume in 2020. They explained that if in-person patient volume resumes in 2021, 2022, and beyond, ACOs will likely have a significant increase in risk scores simply because patients are once again receiving care in physicians' offices. One commenter suggested that beneficiaries may also have worse health status due to delayed diagnosis and delay in seeking care, providing the example of hospitals noting significant increases in case mix index (CMI) for hospitalized patients related to these delays. Several commenters suggested that more ACOs will be subject to the existing 3 percent cap under these circumstances. One commenter noted that the current risk adjustment methodology could penalize ACOs for patients' need to stay in the safety of their homes during the pandemic. Another commenter indicated that ACOs could be forced to exit the Shared Savings Program as a result.

Many commenters also remained concerned that the current policy places a cap on the ACO's risk score growth but does not restrict regional risk score growth. Commenters noted that this penalizes ACOs in markets where a region's risk score growth exceeds the cap. To illustrate this, some commenters gave the example of a case where both the ACO's risk score and the regional risk score grow by 6 percent. In this circumstance, the benchmark would be reduced by 3 percent, despite the fact that the ACO's risk score growth matched that of the region. Several commenters provided examples based on 2020 data, noting that the average risk ratio for counties above 1.03 was 1.042 in the aged/non-dual eligible population and was 1.055 in the dual eligible population, indicating a larger negative impact for this more vulnerable population. One commenter suggested that higher risk score growth at the county level is due to underlying population changes and once a county diverges from the national average it will continue in that direction without reversion to the mean. As a result, the commenter suggested that the problem of these negative impacts would continue unless CMS modifies the risk adjustment methodology using the approach described in the CY 2022 PFS proposed rule, which would allow the ACO risk score growth cap to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area. Another commenter suggested that by including a cap on the ACO's risk score, but not on risk score growth for the region, CMS is creating new incentives that run counter to the original purpose of CMS–HCC risk adjustment, which the commenter believed is to level the playing field and remove disincentives for treating high cost patients. Several commenters indicated that the increased variation in risk scores introduced by the COVID–19 pandemic has further demonstrated the impact of the 3 percent cap on risk score growth in reducing ACO benchmarks, when risk score growth in the ACO's region exceeds the ACO's risk score growth. MedPAC did not appear to support aligning ACO and regional risk score growth out of concern that this would effectively reward ACOs for greater coding intensity in their region, particularly for those with higher market share.

Several commenters suggested that the existing policy is also driving inequity and may disadvantage ACOs that serve more vulnerable populations or beneficiaries with complex medical needs. Some commenters explained that beneficiaries who are in the disabled and the aged/dual eligible Medicare enrollment types are, in most combinations, more than twice as likely to have risk score growth above the cap as those who are in the aged/non-dual eligible category. Some commenters indicated that due to a variety of factors, such as sample size and volatility, the rates at which Medicare enrollment types are subject to the 3 percent cap on risk score growth are often significantly different. A commenter explained that there can also be significant risk score volatility when the high-risk patient population is small. As a result of these factors, some commenters explained that the current approach may disadvantage ACOs that serve more vulnerable populations (such as ACOs composed of community health centers), or ACOs that serve a disproportionate number of dual eligible patients needing complex services (such as ACOs based around an academic medical center). A commenter stated that there currently exists a disincentive for ACOs to take on certain vulnerable populations, such as beneficiaries with ESRD or who need SNF-level care. However, another commenter noted that the current model has some protections for ACOs that experience a disproportionate increase in the medical complexity of their population, highlighting that the current risk adjustment method makes separate adjustments for assigned beneficiaries in each enrollment type, which allows ACOs to increase the proportion of their ESRD, dual eligible, and disabled populations without being affected by the 3 percent cap.

Commenters seemed to offer differing perspectives on CMS' concerns about creating incentives for coding initiatives including:

- MedPAC expressed support for CMS' considerable caution in this area, noting that population-based models can be highly susceptible to coding incentives and that the Shared Savings Program does not include a retrospective coding adjustment to offset these incentives. MedPAC recommended that CMS should address the underlying incentives for coding intensity and the accuracy of risk adjustment before considering any policy that would increase the risk score growth cap.
- One commenter that was supportive of the approach CMS described in the CY 2022 PFS proposed rule, under which an ACO's risk score growth cap would be allowed to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area, believed this approach would continue to insulate CMS from coding intensity.
- One commenter stated that capping positive risk score growth at 3 percent over the 5-year agreement period, while intended to limit incentives for coding intensity, has the effect of harming

ACOs that provide care and services to beneficiaries with complex medical needs, and suggested that this approach does not adequately account for changes in beneficiaries' disease burden over time. Another commenter stated that CMS should abolish the policy of capping year-over-year risk-score growth, as CMS does not want ACOs to ''cherry pick'' patients or avoid providing care to high-risk, high-cost beneficiaries. The commenter explained its belief that by encouraging ACOs to properly code the risk of their beneficiary population, CMS would help to ensure ACOs will have necessary resources to invest in infrastructure and serve higher-risk patients more effectively.

- A few commenters explained that the current methodology of normalizing risk adjustment in a region can penalize ACOs that have been coding accurately and whose beneficiaries maintain the same health status over the course of the ACO's agreement period. Under this scenario, an ACO could see a decrease in its risk score if others in its region increase their coding intensity. The commenters indicated that this issue is further exacerbated for ACOs that include a large number of specialists, since they have fewer opportunities to increase their risk score, but did not explain why they believed this to be the case.

Commenters suggested a variety of alternative approaches to risk adjusting historical benchmarks each performance year during the ACO's agreement period, including the suggestions summarized below.

Response: We will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies and will propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking.

Comment: Commenters also offered suggestions related to the following issues:

Suggestions for capping positive/negative risk score adjustments included the following:

- Many commenters suggested that CMS increase the cap on risk score growth during an ACO's 5-year agreement period to no less than 5 percent and implement a floor of no greater than negative 5 percent for risk score decreases. A commenter requested that CMS consider applying a cap on risk score growth of 10 percent over 5 years.
- Several commenters suggested that CMS should consider temporarily removing or increasing the 3 percent cap following an anomalous year, such as 2020, during which risk scores were impacted by the COVID–19 pandemic.
- A commenter suggested that CMS implement a floor on the risk score, adjust for the effects of COVID–19, and apply a cap on risk score increases, if any, that is the same for all Medicare populations, including Medicare Advantage.
- Some commenters encouraged CMS to cap the aggregate risk ratio across Medicare enrollment types. They indicated that this would be more fair because the rates at which Medicare enrollment types are subject to the 3 percent cap on risk score growth are often significantly different, due to a variety of factors, such as sample size and volatility.
- A commenter recommended that, at a minimum, CMS should increase the cap on risk score growth for high-risk populations (specifically, ESRD, aged/dual eligible and disabled), to ensure vulnerable beneficiaries are better served by Shared Savings Program ACOs.

Suggestions for addressing differences in risk score growth between the ACO and the ACO's regional service area included the following:

- A few commenters noted their support for modifying the risk adjustment methodology to enable the risk score growth cap to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area, with a commenter explicitly citing the approach described in the proposed rule in which the percentage applied to the difference would equal 1 minus the ACO's market share. The commenter, who believes this change should be applied retroactively to at least performance year 2021, explained that removing an ACO's assigned beneficiaries from its regional trend would simplify the equation because an ACO could no longer impact its regional risk score.
- Some commenters suggested more generally that CMS align the use of a risk adjustment cap for the ACO and its region by applying a consistent capping policy to both. Some commenters also called for this approach to be applied retroactively beginning with performance year 2021. A number of the commenters who supported aligning ACO and regional risk score growth caps also called for increasing the cap on positive risk score adjustments and applying a cap on negative risk score adjustments.

Other suggestions related to Shared Savings Program risk adjustment included the following:

- MedPAC recommended that CMS use 2 years of diagnostic data for risk adjustment as permitted under the 21st Century Cures Act, which they believe would improve the accuracy of coefficients estimated with FFS data and reduce year-to-year variation in beneficiary risk scores, along with reducing the administrative burden for ACO participants related to HCC documentation. MedPAC further suggested that CMS should only consider changes to the 3 percent cap after making this suggested change and after observing the effect of the phase-in from 2020 to 2022 of the Alternative Payment Condition Count (APCC) CMS–HCC risk adjustment model, which they noted was designed to improve the accuracy of risk adjustment for high-spending beneficiaries.
- Several commenters suggested that CMS adopt a single (standardized) approach for measuring the health status of a population across Medicare Advantage and Medicare ACO initiatives. Some commenters suggested, for example, that CMS recalibrate the risk adjustment methodology across all Medicare programs and models by updating the HCC Model to use ICD–10 codes to improve accuracy, refining HCC diagnoses, and incorporating social determinants of health. Several commenters suggested that, at a minimum, CMS should align the risk adjustment methodology used in the Shared Savings Program's ENHANCED track with Medicare Advantage. Another commenter suggested that CMS examine the risk adjustment methodology in general and analyze how fairly it is applied within both Medicare Advantage and traditional Medicare.
- Several commenters encouraged CMS to consider including social risk factors in the risk adjustment models used for ACO benchmarking. A commenter suggested this could be an incentive for ACOs to improve social risk and demographic data collection. Another commenter suggested that including factors related to a patient's background (for example, sociodemographic status, language, and post-discharge support structure) in the risk-adjustment methodology could reduce barriers to more robust participation by safety net hospitals.
- A few commenters encouraged CMS to examine coding patterns on a local/regional level and to employ a more ''veracious'' approach to calculating coding intensity adjustment factors that considers the increasing prevalence of chronic disease in a region, noting that the current Shared Savings Program risk adjustment methodology attributes all

growth in risk scores beyond demographic risk entirely to coding intensity when populations may instead be increasingly chronically ill or have a different burden of illness between the baseline population and the attributed population.

- A commenter encouraged CMS to explore ways to implement the Innovation Center's concurrent HCC risk adjustment model in the Shared Savings Program, explaining that such models are better able to predict costs for populations with high disease burden or who are otherwise seriously ill, as they can better capture a rapid deterioration in health in the current year, such as through the occurrence of acute episodes that are difficult to predict or prevent (for example, heart attacks).
- Several commenters suggested that CMS avoid establishing a risk adjustment methodology that creates adverse incentives for practices to select or avoid certain beneficiaries based on their health risk status. A commenter detailed a combination of policies to achieve this, including some that related to ACO and regional risk score caps. Specifically, the commenter recommended: Establishing a risk adjustment cap that accounts for the size of the ACO's assigned beneficiary population (in recognition of the fact that a smaller assigned beneficiary population will be more volatile in terms of utilization and costs and may not be comparable risk-wise to other ACOs in the region); considering an ACO's assigned beneficiary population break-down across dual eligible and non-dual eligible beneficiaries when calculating the cap; capping the reference population risk score in the same way that the ACO population risk score is capped prior to normalizing; considering the proportion of vulnerable populations a given ACO serves; and looking to the Innovation Center's risk adjustment methodologies, and applying promising practices as appropriate in the Shared Savings Program.
- A commenter suggested that CMS consider applying a frailty adjustment in the Shared Savings Program risk adjustment methodology such as is used in the PACE program.
- A commenter suggested that CMS consider excluding unforeseeably expensive Part B drugs from Shared Savings Program benchmark and performance year expenditure calculations, or otherwise accommodating these costs. The commenter explained that pharmaceuticals represent an area of rapid technological improvement that has increasingly been accompanied by extremely high acquisition costs. As a result, the commenter believed that these products create cost imbalances between benchmark and performance periods that are not sufficiently addressed through risk adjustment.

Response: We will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies and will propose any specific policy changes, if deemed appropriate, in future notice and comment rulemaking.

K. Medicare Ground Ambulance Data Collection System

1. Background on Ambulance Services

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments at § 414.610(c)(5)(i) are: (1) A 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments at sections 1834(l)(12)(A) and (13)(A) of the Act and § 414.610 are: (1) A 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in ''super rural'' areas. Section 50203(a)(1) and (2) of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, February 9, 2018) includes an extension of the temporary add-on payments through December 31, 2022.

Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirements for the Ground Ambulance Providers and Suppliers To Submit Cost and Other Information

Section 50203(b) of the BBA of 2018 added paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Section 1834(l)(17)(B)(i) of the Act requires the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system. Section 1834(l)(17)(D) of the Act requires that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. Section 1834(l)(17)(F) of the Act requires that no later than March 15, 2023 and as determined necessary by MedPAC, MedPAC must submit a report to Congress on the information submitted by the ground ambulance providers and suppliers through the data collection system on the adequacy of payments for ground ambulance services and geographic variations in the cost of furnishing such services.

In the CY 2020 PFS final rule (84 FR 62864 through 62897), we implemented section 1834(l)(17) of the Act and codified regulations governing data

reporting by ground ambulance providers and suppliers (referred collectively as ''ground ambulance organizations'') at §§ 414.601, 414.605, 414.610(c)(9), and 414.626. In the CY 2020 PFS final rule (84 FR 62863 through 629897), we finalized a data collection system that collects detailed information on ground ambulance provider and supplier characteristics including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare Ground Ambulance Data Collection Instrument, via a web-based system. This instrument includes the specific questions that will be asked of ground ambulance organizations about the total service volume, costs, and revenue associated with a provider or supplier's entire ground ambulance organization in such a way that MedPAC could use to calculate an average cost per ground ambulance transport. In the CY 2022 PFS proposed rule (86 FR 39295), we referred the reader to our CY 2020 PFS final rule (84 FR 62863 through 62897) for more specifics on the establishment of the Medicare Ground Ambulance Data Collection System.

3. Revisions to the Medicare Ground Ambulance Data Collection Instrument

As described in the CY 2020 PFS final rule (84 FR 62867), the Medicare Ground Ambulance Data Collection Instrument uses screening questions and skip patterns so that it is applicable to all ground ambulance organizations regardless of their size, scope of operations and services offered, and structure. We stated that we believe this approach is easier to navigate and less time consuming to complete than a cost report template or instrument and that it minimizes respondent burden by directing ground ambulance organizations to only view and respond to questions that apply to their specific type of organization, all while still collecting the information required in sections 1834(l)(17)(A) of the Act.

The CY 2020 PFS final rule provided a detailed overview of the elements of the data collection instrument, including questions to collect information on costs, revenues, utilization (which CMS defines for the purposes of the data collection instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations. Table 38 includes a high-level summary of the 13 sections of the Medicare Ground Ambulance Data Collection Instrument.

TABLE 38: Components for the Data Collection Instrument

Component (Data Collection Instrument Section)	Broad Description
General Survey Instructions (1)	Information on background and motivation for data collection, instructions for navigating the instrument, and links for questions and other resources.
Ground Ambulance Organization Characteristics (2-4)	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground Ambulance Service Volume (5) and Service Mix (6)	Number of responses and transports, level of services reported by HCPCS code.
Costs (7-12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Hours and costs associated with EMTs, administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; annual cost of ownership, insurance, maintenance, and utilities.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual cost of ownership; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the data collection instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

We continue to receive ad hoc questions and feedback related to the Medicare Ground Ambulance Data Collection System and the Medicare Ground Ambulance Data Collection Instrument via three primary channels. First, we receive email and other communication from ground ambulance organizations via the CMS Ambulance Data Collection email inbox (*AmbulanceDataCollection@cms.hhs.gov*) and through other channels (for example, inquiries sent by organizations to Medicare Administrative Contractors (MACs) and then forwarded to CMS). These emails and other communications often include questions seeking clarification of instrument questions and their applicability to specific ground ambulance organization scenarios and context. We continue to update a Medicare Ground Ambulance Data Collection System Frequently Asked Questions (FAQ) document with answers to commonly asked questions. This document is available on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.* Through review of

questions and feedback, we have identified some instances where a clarification to the instrument language itself will likely be more useful and less burdensome to respondents than having to respond with reference to the FAQ document. Second, our contractor also asked a small number of ground ambulance organizations to complete and provide feedback on a paper version of the Medicare Ground Ambulance Data Collection Instrument. This feedback was helpful to identify some additional opportunities for clarification. Third, we continue to identify opportunities to clarify instructions and correct a small number of typos as we work to develop the web-based, programmed version of the Medicare Ground Ambulance Data Collection Instrument.

Based on information that we received via the three sources described above, in the CY 2022 PFS proposed rule (86 FR 39296), we proposed the following changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument. The changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

We received public comments on our overall changes and clarifications to the Medicare Ground Ambulance Data Collection System. The following is a summary of the comments we received and our responses.

Comment: Some commenters noted their general support for our proposed modifications to the Medicare Ground Ambulance Data Collection System. A commenter stated that its member organizations are appreciative of CMS' previous solicitation of stakeholder feedback in the development of the survey tool. A commenter supported CMS efforts to provide and update the Frequently Asked Questions (FAQ) for the Medicare Ground Ambulance Data Collection document and ongoing efforts to create clarity around this system. However, this commenter stated that the process is still complex and cumbersome and may prevent compliance from ground ambulance organizations. A commenter supported the agency collecting information on ground ambulance cost, revenue, utilization and other information, however, the commenter reminded CMS that this data is for purposes of assessing the adequacy of Medicare payments for ground ambulance services and that any data collected that are not directly for this purpose would be improper and not add value to this purpose and intent.

Response: We appreciate the overall support for the changes and clarifications to the Medicare Ground Ambulance Data Collection System. The data collected through the Medicare Ground Ambulance Data Collection System will provide us with the necessary information needed to determine the adequacy of Medicare payment rates for ground ambulance services and geographic variations in the costs of furnishing such services, as well as the data MedPAC needs to prepare its statutorily-required report to Congress. We have attempted to limit the complexity and administrative burden of the Medicare Ground Ambulance Data Collection System as much as possible while ensuring that the collected data satisfy these statutory requirements.

a. Change to the Shared Services Questions in Section 2 (Organizational Characteristics)

One component of the data collection instrument is ground ambulance organization characteristics, which is information regarding the identity of the organization and respondent(s) service area, ownership, response time, and other characteristics (84 FR 62871 through 62875). One characteristic on which we sought information is organization type, including whether costs are shared with fire or police response or health care delivery operations (84 FR 62871). The instrument contains a number of questions that are relevant to the issue of shared costs.

Section 2, Question 7 asks ''Which category best describes your ground ambulance operation?'' and allows respondents to select one of the following options:

(a) Fire department-based; (b) Police or other public safety department-based (including all-hazards public safety organizations); (c) Government stand-alone emergency medical services (EMS) agency; (d) Hospital or other Medicare provider of services (such as skilled nursing facility); (e) Independent/proprietary organization primarily providing EMS services; (f) Independent/proprietary organization primarily providing non-emergency services; or (g) Other (please specify).

Section 2, Question 8 subsequently requests respondents answering a, b, or d to Question 7 to ''confirm that your ground ambulance operation shares operational costs, such as building space or personnel, with these other operations.'' Section 2, Question 9 asks ''Does your ground ambulance operation share any operational costs, such as building space or personnel, with one of the following,'' offering respondents the following options: (a) A fire department (not presented if the response to Section 2, Question 7 is ''a''); (b) A police or other public safety department (not presented if the response to Section 2, Question 7 is ''b''); (c) A hospital or other Medicare provider of services (such as a skilled nursing facility) (not presented if the response to Section 2, Question 7 is ''d''); (d) Another healthcare organization (excluding hospitals, skilled nursing facilities, or other Medicare provider of services); (e) Another healthcare organization (excluding hospitals, skilled nursing facilities, or other Medicare provider of services); (f) Other (specify).

Collectively, the purpose of these three questions is to collect information on whether a portion of organizations' costs and revenues may be related to services or operations other than providing ground ambulance services. When this occurs, ground ambulance organizations are presented with additional instructions specifying how they should report costs and revenues associated with providing ground ambulance services rather than these other services or operations.

Based on feedback from ground ambulance organizations, we believe the specific wording of Section 2, Question 9 may be confusing. The question asks respondents whether they share operational costs with ''one of the following,'' implying respondents are limited to a single response, even though in some cases respondents may wish to select multiple responses. Furthermore, ground ambulance organizations may have difficulty interpreting the phrase ''share any operational costs.'' We received questions from some ground ambulance organizations asking whether renting space from a fire department qualified as a ''shared operational cost.'' The intent of the question was to ask about shared ownership and accounting, not renting facility space, sharing a physical space with a separate organization, or similar business and logistical arrangements.

In the CY PFS 2022 proposed rule (86 FR 39297), we proposed to revise Section 2, Question 9, to read, ''Does your organization provide any of the following services or operations (select all that apply)?'' retaining the current response options. This proposed change clarifies that the intent of Section 2, Question 9 is to collect information on services or operations provided by the sampled organization. We solicited comments on our proposal regarding reporting shared services.

We did not receive public comments on this proposal. Therefore, we are finalizing our proposal to revise Section

2, Question 9 to read, ''Does your organization provide any of the following services or operations (select all that apply)?'' retaining the current response options.

b. Change to Average Trip Time Question

We stated that the area served by ambulance organizations is an important characteristic and finalized a policy to collect information on the geographic area served by each ambulance organization in Section 3 of the data collection instrument (84 FR 62875). We included questions related to average trip time in primary and secondary service areas (questions 3 and 6 of Section 3) that were important to understand how geographic distance between the ground ambulance organization's facilities and patients affects costs (84 FR 62873).

Section 3 (Service Area), Questions 3 and 6 in the instrument ask ground ambulance organizations to report their ''average trip time'' using a set of categorical time ranges (for example, 30–60 minutes). These questions define average trip time as ''the time the ambulance leaves the station to when that ambulance is available to take another call.'' Based on feedback from ground ambulance organizations, we believe this definition may be confusing in cases where an ambulance responds to a call from a location other than the station (for example, while en route to another call, from a standby event, or from a hospital). Based on the literal wording of the question, it is not clear whether and if so, how ground ambulance organizations should report trip times for responses not originating at a station when responding to this question, leading to potentially missing or biased data.

In the CY 2022 PFS proposed rule (86 FR 39297), we proposed that this question be revised to ask for ''average time on task'' defined as ''from the time an ambulance begins its response to the time when the ambulance is available to respond to another call (that is, time on task)'' to better capture interfacility transfers and situations when an ambulance is already out and responds from a site other than the central station. We believe this change in the wording of the question will be clearer to respondents and will result in higher-quality reported data. We solicited comments on our proposal to change the definition of the average trip time.

We received public comments on our proposal to revise the average trip time question. The following is a summary of the comments we received and our responses.

Comment: A commenter indicated that time on task could be difficult to calculate for many organizations. The commenter provided an example where an ambulance transports a patient to the hospital and while returning to the station, the ambulance crew is assigned to another call. In this example, the crew may not have completed the patient care report for the first call, so accurately documenting time on task will prove to be difficult.

Response: We recognize that not all ground ambulance organization may track time on task as proposed. However, we heard from some ground ambulance organizations that the initial question wording requesting for ''average trip time'' would be problematic for other reasons. Specifically, our initial definition of ''average trip time'' only applied to situations where the ambulance left from a station. We believe that this change will provide ground ambulance organizations with greater flexibility to report information regarding the active time for their ambulance crews.

After consideration of public comments, we are finalizing our proposed revision to the average trip time question to request for ''average time on task'' defined as ''from the time an ambulance begins its response to the time when the ambulance is available to respond to another call (that is, time on task)'' to better capture interfacility transfers and situations when an ambulance is already out and responds from a site other than the central station.

c. Change to Secondary Service Area Instructions

In Section 3, Question 4 instructions define the secondary service area for an organization as ''outside [its] primary service area, but one where [it] regularly provide[s] services through mutual or auto-aid arrangements. The instruction directs organizations to ''not include areas where [they] provide services only under exceptional circumstances.'' We were notified that some ground ambulance organizations are unsure how to report areas where they (a) did have mutual or auto-aid arrangements in place, which aligns with the definition of secondary service area in the instructions, but where (b) they responded to calls only very rarely, for example once a year, which could be considered an ''exceptional circumstance'' and ignored for reporting per the instruction.

Although the instructions leave the determination of whether an organization has a secondary service area at the discretion of the sampled ground ambulance organization, we believe that some organizations may benefit from a rule of thumb or example to help assess whether they should or should not report a ZIP code as being part of their secondary service area. In the CY 2022 PFS proposed rule (86 FR 39297), we proposed to add the following text to the Section 3, Question 4 instructions: ''Some, but not all, ground ambulance organizations regularly provide service outside of their primary service area, for example through mutual or auto-aid agreements with nearby municipalities. If this applies to your organization, please report areas that are outside your primary service area but where you regularly provide services as part of your secondary service area. You do not need to report areas where you provide services very rarely or only under exceptional circumstances (for example, when participating in coordinated national or State responses to disasters or mass casualty events). Use your judgment as to whether your organization regularly serves a secondary service area. For example, you may choose to consider ZIP codes outside your primary service area but where you had 5 or more responses during the data collection period as part of your secondary service area if you believe these transports have a significant impact on your organization's costs.'' Even with this added text, ground ambulance organizations could still determine whether they do or do not have a secondary service area for the purposes of reporting in the Medicare Ground Ambulance Data Collection System. We solicited comments on our proposal to revise the secondary service area instructions.

We received a public comment on our proposal to revise the secondary service area instructions. The following is a summary of the comment we received and our response.

Comment: A commenter supported our proposed change to the instructions in this section of the Medicare Ground Ambulance Data Collection Instrument. This commenter stated that many of their primary service areas do not follow strict county boundary lines or ZIP code designations so the commenter requested that CMS provide additional language to clarify how ambulance organizations designate primary service areas when the service area is based on the needs of the population.

Response: We appreciate the commenter's support for the proposed change. In the instrument, we define primary service area as the set of ZIP codes in which the ground ambulance organization is exclusively or primarily

responsible for providing service at one or more levels (that is, Basic Life Support (BLS) or Advanced Life Support (ALS)) and in which it is highly likely that the majority of the organization's transport pickups occur. We appreciate the commenter's point that ground ambulance organizations' approaches to determining their primary service area may differ. While not all primary service areas will align cleanly with ZIP code boundaries, we chose to select a single, uniform, ZIP code-based approach for ground ambulance organizations to report service areas in order to minimize burden and ensure the collected information is useful for analysis as noted in the CY 2020 PFS final rule (84 FR 62874). We will continue to provide education and give opportunities to organizations to ask questions regarding the Medicare Ground Ambulance Data Collection Instrument, including the instructions for reporting service areas.

After consideration of public comments, we are finalizing our change to the secondary service area instructions as proposed.

d. Change to the 90th Percentile Emergency Response Time

Section 4 (Emergency Response Time), Question 3 asks ground ambulance organizations to report the 90th percentile emergency response time, which the question defines as the time separating the quickest 90 percent of responses from the longest 10 percent of responses. The intent of the question was to collect information to help CMS understand the difference between average response times and atypical ''outlier'' response time. In the CY 2020 PFS proposed rule (84 FR 40688), we proposed to include a question on average response time. As we noted in the CY 2020 PFS final rule (84 FR 62873), several commenters to the CY 2020 PFS proposed rule recommended requesting ground ambulance organizations to provide 90th percentile response time rather than or in addition to the average response time. The commenters believed 90th percentile response time is a more accurate indicator of ambulance services capabilities and quality. The commenters stated that the average time has too wide a range for error, since roughly half of responses are quicker/slower than average. The commenters further stated that using average response time also tends to flatten the data, which means the fastest and slowest organizations did not stand out as much. In response to these comments (84 FR 62874), we finalized an additional question to the instrument requesting ground ambulance organizations responding to emergency calls for service to report their 90th percentile response time.

Based on feedback from ground ambulance organizations that we have received on this question since we finalized the instrument, we believe most ground ambulance organizations will find it challenging to interpret this question and report the requested information. Several ground ambulance organizations have indicated that they would misinterpret this question, describing a shorter 90th percentile emergency response time compared to average response time, which, while mathematically possible, is not the intent as we were interested in characterizing outlier emergency responses with unusually long response times.

Thus, in the CY PFS 2022 proposed rule (86 FR 39298), we proposed to revise the question to state: ''what is your best estimate of the share of responses (enter percentage) that take more than twice as long as the average response time as reported in the prior question?'' We believe this will be an easier question for ground ambulance organizations to understand. The goal of this question is to help CMS understand whether the organization has some response times that are much longer than its typical response time. Although the question language will be different, the reported information will still help CMS understand the extent to which a small number of emergency responses may be substantially longer than the average response for each organization. We solicited comments on our proposal to revise the question to ask respondents to report the share of responses with more than twice the average response time instead of their 90th percentile emergency response time.

We did not receive public comments on this proposal, and therefore, we are finalizing our proposal to revise the question to state: ''what is your best estimate of the share of responses (enter percentage) that take more than twice as long as the average response time as reported in the prior question?''.

e. Change To Reporting Paid Ambulance Transports

In the CY 2020 PFS final rule (84 FR 62876 through 62877), we established a series of questions in the data collection instrument to collect data on the volume and the mix of services, including paid ground ambulance transports, that is, ground ambulance transports where the ambulance provider or supplier was paid for a billed amount in part or in full. The general instructions for Section 5 (Ground Ambulance Service Volume) note: ''A paid ground ambulance transport refers to a ground ambulance transport for which your organization has been paid in full or in part by a payer and/or patient only. Depending on how your organization collects data, you may report (a) the number of transports furnished during the data collection period that were also paid during the data collection period, or (b) the number of transports paid during the data collection period even if some transports occurred prior to the data collection period.'' Furthermore, Section 5, Question 7 asks respondents, ''what was the total number of paid ground ambulance transports in calendar year 202X [or fill fiscal year as appropriate], across all payer types and regardless of the level of service or geography? (Enter number).''

Based on questions and feedback from ground ambulance organizations that we have received since we finalized the instrument, we believe respondents may have different interpretations of this question, which could lead to inconsistent reported data, including the reported total ground ambulance transports during the data collection period (Section 5, Question 6). The intent of this question was to capture the reported number of ground ambulance transports during the data collection period, provided such transports were paid by the time the information was prepared for reporting to CMS. We did not intend for organizations to report the total number of ground ambulance transports for which they received the payment itself during the data collection period.

We recognize that there is a temporal disconnect between when services are provided and when initial and final payment may be received. In order to standardize the information that is reported by all ground ambulance organizations, and to align the reported information on the number of responses and transports during the data collection period with information reported on the number of paid transports, we proposed in the CY 2022 PFS proposed rule (86 FR 39298) to clarify Section 5, Question 7 to ask ''Of the ground ambulance transports your organization provided in calendar year 202X [or fill fiscal year as appropriate], how many were paid (either in part or in full) across all payer types and regardless of the level of service or geography by the time you are reporting data to CMS?''

We recognize that the ''runout period,'' that is, the time from when services are provided to the time when data is being analyzed, will be short and

variable across organizations, particularly for transports towards the end of organizations' data collection periods. Despite this limitation, we believe this approach is preferable to alternatives where (a) respondents have variable interpretations of Section 5, Question 7 and (b) where respondents are asked to report the number of transports for which payment was received during the data collection period, even if the transports for which payment was received happened prior to the data collection period. In the latter case, the number of paid ground ambulance transports could not be directly compared to the number of total ground ambulance transports reported in Section 5, Question 6.

We also proposed to revise the general instructions in Section 5 to delete the following text as it will no longer be relevant: ''Depending on how your organization collects data, you may report (a) the number of transports furnished during the data collection period that were also paid during the data collection period, or (b) the number of transports paid during the data collection period even if some transports occurred prior to the data collection period''

We solicited comments on our proposal to revise reporting paid ground ambulance transports.

We received a public comment on our proposal to revise reporting paid ground ambulance transports. The following is a summary of the comment we received and our response.

Comment: A commenter supported our proposed change in the instructions for reporting paid ambulance transports but requested clarification on whether the ''transports provided'' during the period refers to the date of service or another period.

Response: Our proposal specifies that the transports in question must have been furnished (that is, with dates of service) during the data collection period and paid at least through the end of the data collection period and potentially through the date on which the ground ambulance organization reports the required information via the Medicare Ground Ambulance Data Collection System.

After consideration of public comments, we are finalizing our revised instructions in Section 5 of the instrument as proposed.

f. Change to Questions Related to Labor Hours

Section 7 (Labor Costs) of the data collection instrument asks respondents to report compensation and hours worked for ground ambulance staff. The instrument currently requests respondents to report, separately for each staff category: Total compensation, total hours worked inclusive of all responsibilities, and total hours worked unrelated to either ground ambulance or public safety responsibilities. The rationale for requesting total compensation and hours, even if these include compensation and hours for activities other than those related to ground ambulance services, was to preserve the ability to compare compensation between organizations and to external benchmarks such as Bureau of Labor Statistics data. The last item, total hours worked unrelated to either ground ambulance or public safety responsibilities, can be subtracted from overall total hours worked related to ground ambulance and public safety responsibilities combined, and further allocation could separate ground ambulance time and compensation from public safety time and compensation for fire and other public safety-based ground ambulance organizations.

Based on questions received by ground ambulance organizations since we finalized the instrument and feedback through testing on Section 7 questions, we learned that some ground ambulance organizations may misinterpret the Section 7 questions. Specifically, we believe some organizations may assume the question is requesting for hours ''related'' rather than ''unrelated'' to ground ambulance or public safety responsibilities given the focus of the data collection effort, despite instructions to the contrary. Relatedly, we were notified that some organizations were confused that the Section 7 questions did not provide an opportunity to report total hours worked related to ground ambulance responsibilities, which they assumed was an unintentional omission from the instrument.

In the CY 2022 PFS proposed rule (86 FR 39299), we proposed to change the instructions in Section 7 to request respondents to report hours worked on different activities in such a way that the sum of hours worked across different activities equals total hours worked annually. We believe this approach will be easier for respondents to understand and estimate, resulting in less burden for respondents and higher quality reported information.

For stand-alone ground ambulance organizations, we proposed to request respondents to report each of the following per staff category: (a.) Total annual compensation; (b.) Total hours worked annually; (c.) Total hours worked annually related to ground ambulance operations; and (d.) Total hours worked annually related to all other responsibilities. With this change, the instructions in Section 7 will note that ''total hours worked annually related to ground ambulance operations'' plus ''total hours worked annually related to all other responsibilities'' should equal ''total hours worked annually.''

For fire department or other public safety-based ground ambulance organizations, we proposed to request respondents to report each of the following per staff category: (a.) Total annual compensation; (b.) Total hours worked annually; (c.) Total hours worked annually related to ground ambulance operations; (d.) Total hours worked annually related to fire, police, or other public safety operations; and (e.) Total hours worked annually related to all other responsibilities The Section 7 instructions will note that the sum of total hours worked related to ground ambulance operations; fire, police, or other public safety operations; and all other responsibilities should equal total hours worked annually. We solicited comments on our proposal to revise the labor hours.

We did not receive public comments on this proposal, and therefore, we are finalizing the revised questions and instructions in Section 7 of the Medicare Ground Ambulance Data Collection Instrument as proposed.

g. Change to Instructions Related to Facility, Vehicle, and Equipment Certain Expenses

In the CY 2020 PFS final rule (84 FR 62882 through 62886), we finalized policies to collect cost information related to facilities, vehicles, and other equipment, consumables and supplies. The purpose of Sections 8 (Facilities Costs), 9 (Vehicles Costs), and 10 (Equipment, Consumable, and Supply Costs) in the instrument is to collect total expenses during the data collection period related to facilities, vehicles, and equipment and supplies, respectively. Based on feedback from ground ambulance organizations that we have received since we finalized the instrument, we are concerned that some respondents, particularly those that do not currently depreciate facilities, vehicles, and/or equipment for accounting purposes, may not be sure where to report some components of total expenses in these categories. Although we believe most ground ambulance organizations depreciate facilities, vehicles, and capital medical equipment, we were notified that some ground ambulance organizations do not depreciate these items in their regular accounting practices. Upon a review of

the instrument, we found that the instructions and opportunities to report costs for organizations using a cash basis for accounting were inconsistent across Sections 8, 9, and 10 of the instrument. In some instances, ground ambulance organizations are requested to report annual depreciation expenses only, without a clear question related to expenses should the organization not regularly depreciate a certain category of asset. In other cases, there are questions requesting respondents to report annual expenses other than annual depreciation expenses, but the instructions provide incomplete guidance on what expenses are in scope.

We considered several factors when developing our proposals to address these inconsistencies. Overall, the purpose of the questions in Sections 8, 9, and 10 is to collect comprehensive information on total expenses related to facilities, vehicles, and equipment and supplies during the organizations' data collection periods. We believe the primary purpose of changes and clarifications to questions in this section should be to ensure all expenses are reported from both organizations that do and do not depreciate facilities, vehicles, and equipment for accounting purposes. We understand that allowing organizations flexibility to report cost information using their current accounting approach will reduce burden. The instructions to the instrument currently state: ''In general, you will be able to report information collected under your organization's current accounting practices. We understand that some ground ambulance organizations use accrual-basis accounting while others use cash-basis accounting.'' We continue to believe this is the correct approach, and that alternatives will impose considerable additional burden on ground ambulance organizations.

We considered several broad alternatives on how to report facility, vehicle, and equipment expenses in Sections 8, 9, and 10. One option is to require all organizations to calculate and report depreciation for facilities, vehicles, and equipment using a standardized approach. Although this will increase burden for respondents, potentially significantly for organizations that do not currently calculate depreciation, it will result in the most standardized information being submitted to CMS and the fewest changes to the layout of the instrument. Another option will be to retain the current structure of the instrument but provide more detailed instructions on how organizations that do and do not depreciate facilities, vehicles, and equipment should report information. A third option is to add new screening questions to the instrument asking individually whether the organization depreciates facilities, vehicles, and equipment. The responses to these screening questions could be used to tailor the instructions, table headings, and question text later in the instrument to avoid confusion.

After considering these options, in the CY PFS 2022 proposed rule (86 FR 39300), we proposed to add screening questions to the instrument asking individually whether the organization depreciates facilities, vehicles, and equipment. We believe this will not substantively affect response burden for organizations and may in some cases reduce burden by clarifying what and how information on expenses must be reported in Sections 8, 9, and 10.

There are two specific places in Sections 8 and 9 in the instrument where we believe the instructions on how to report annual expenses may not be clear. First, Section 8.2, Question 1 asks respondents to report annual expenses for each facility that they report as being related to their ground ambulance operation in Section 8.1, Question 3. Section 8.2, Question 1 is a table with columns for ''annual lease or rental costs,'' ''annual depreciation expenses,'' and ''annual mortgage, bond interest, and other costs of ownership.'' Although the instructions note ''do not report depreciation if your organization does not capitalize facilities for accounting purposes,'' it is not immediately clear where organizations that do not capitalize facilities should report expenses if the facility is owned outright (for example, in cases where a facility is acquired during the data collection period).

Second, Section 9.1, Question 5 and Section 9.2, Question 5 are tables where respondents report costs associated with individual vehicles. Both tables currently ask, ''What was the annual depreciation expense for this vehicle?'' Although the instructions note ''for owned vehicles, do not report depreciation if your organization accounts for vehicles on a cash basis,'' the instructions do not indicate where expenses for vehicles purchased during the data collection period should be reported by organizations that do not capitalize vehicles for accounting purposes.

We considered several options to clarify the instructions in Sections 8 and 9 specifically. One option is to preserve current table structures and item numbers in both sections while providing additional written instructions. We believe that although this will minimize disruption to the layout of the instrument, it will also do the least to address potential confusion around these questions. Another option is to add new columns in Sections 8 and 9 for facilities and vehicles purchased outright during the data collection period for organizations that do not depreciate these expenses. We proposed to add an additional column for clarity, but noted that if the screening questions are added as described above not all columns will appear for all respondents, particularly given our proposal to add screening questions related to reporting expenses in Sections 8 and 9.

We also believe there are specific instructions in Section 10 that may not be clear. Section 10.1, Question 1 and Section 10.2, Question 1 request respondents to report ''annual depreciation expenses'' for medical and non-medical capital equipment, respectively. The Section 10 instructions note ''do not report depreciation if your organization uses a cash basis for accounting'' and that ''for capital expenditures, medical and non-medical equipment, most organizations will amortize costs over the life of the good'' but do not specify that organizations that do not depreciate medical or non-medical equipment should skip these questions and report expenses for equipment acquired during the data collection period in Section 10.1, Question 3, and Section 10.2, Question 3 instead.

We considered several options to clarify the instructions in Section 10 specifically. One option is to clarify in the instructions that organizations that do not depreciate medical or non-medical equipment should skip Section 10.1, Question 1 and Section 10.2, Question 1 and report expenses for equipment acquired during the data collection period in Section 10.1, Question 3, and Section 10.2, Question 3 instead. Although this will involve the least change to the instrument, we will lose the ability to distinguish between expenses for the kinds of equipment that most ground ambulance organizations depreciate for organizations reporting in this way. Another option is to change the instructions for Section 10.1, Question 1 and Section 10.2, Question 1 to refer to broad types of equipment that are typically considered capital medical and non-medical equipment, and then request respondents to report relevant annual expenses for qualifying equipment in these questions, regardless of whether the expenses are annual depreciation expenses or purchase costs (for organizations not calculating depreciation). We proposed to request

organizations that do not depreciate equipment to report expenses associated with purchasing equipment in Section 10.1, Question 1 and Section 10.2, Question 1. This option will preserve our and MedPAC's ability to separately analyze these expenses. We solicited comment on these alternatives to address instructions related to facility, vehicle, and equipment expenses.

We did not receive public comments on our proposed changes to the instructions related to facility, vehicle, and equipment certain expenses in Sections 8, 9, and 10 of the instrument, and therefore, we are finalizing these changes as proposed.

h. Changes to Questions Related to National Provider Identifier's (NPIs) Under Broader Parent Organizations

Some ground ambulance NPIs are part of broader parent organization companies that own and/or operate multiple ground ambulance NPIs. Section 2, Question 2 asks, ''Did your organization use more than one NPI to bill Medicare for ground ambulance services during the data collection period?'' Based on feedback from ground ambulance organizations that we have received since we finalized the instrument, we were notified that the use of ''organization'' in this question is potentially confusing because it is not clear whether the term applies to the organization sampled to report information to the Medicare Ground Ambulance Data Collection System (which, by definition, is an individual NPI) or to a broader ''parent organization.'' In the CY 2022 PFS proposed rule (86 FR 39300), we proposed clarifying the question to ask ''Is this NPI part of a larger 'parent organization' that owns or operates multiple NPIs billing for ground ambulance services?'' We also proposed to clarify the wording of the follow-up instruction for organizations that answer ''yes'' to this question. The follow-up instruction currently reads, ''You are being asked to complete this instrument and enter data only for the following NPI: [pre-populate number].'' Because very large parent organizations may have several NPIs sampled and a single or small number of staff collecting and reporting data for multiple NPIs, we proposed to revise the text to read, ''You are being asked to complete this instrument and enter data separately for each sampled NPI. The following questions refer only to the following NPI: [pre-populate number].''

The instrument requests these organizations to report an allocated share of parent organization expenses at the end of most sections of the instrument. For example, Question 3 in Section 7.2 on paid administration, facilities, and medical director staff costs asks, ''Please report the allocated portion of administrative labor costs incurred at the level of the parent organization/central office of this NPI based on your organization's approach for allocating costs to specific NPIs. (Enter dollar amount.)''

There are four sections in the instrument that lack similar questions: Section 7.1 (Paid EMT/Response Staff Compensation and Hours Worked), Section 7.3 (Volunteer Labor), Section 9.1 (Ground Ambulance Vehicle Costs), and Section 10.1 (Medical Equipment/Supplies). Without these questions, total reported costs may be biased downward for NPIs that are part of broader parent organizations. We proposed to add questions like the one reproduced above to the end of these four sections for completeness. The text will be the same as the above except for replacing ''EMT/response staff labor costs,'' ''costs associated with volunteer labor,'' ''ground ambulance vehicle costs,'' and ''medical equipment and supply costs'' for ''administrative labor costs'' in the respective sections.

Relatedly, for completeness, we proposed to clarify in the instructions for Section 12 (Total Cost), Question 1, that organizations part of broader parent organizations should include an allocated portion of parent organization (or ''central office'') costs when reporting their total costs in this question. We solicited comments on our proposal to address questions related to NPIs under broader parent organizations.

We did not receive public comments on our proposed changes to questions related to NPIs under broader parent organizations, and therefore, we are finalizing these changes as proposed.

i. Other Clarifications to the Medicare Ground Ambulance Data Collection Instrument

In the CY 2022 PFS proposed rule, (86 FR 39301), we proposed the following 11 additional clarifications and updates to the instrument.

i. Replacing all first-person language (for example, ''we'') with third-person language (for example, ''CMS'') throughout the instrument for editorial consistency.

ii. Section 2, Question 17: There is a typo where this question referred to itself rather than, as is implied by the ordering and framing of the question, the prior item. The question currently asks, ''other than what was reported in item 17 . . . ,'' when it should read, ''other than what was reported in item 16 . . .''.

iii. Section 3, Question 2: This question currently asks, ''are you the primary emergency ambulance provider . . . ,'' using ''provider'' more colloquially than elsewhere in the instrument where the same word is sometimes used to differentiate between Medicare providers of service and Medicare suppliers. We proposed to reword this question to read, ''are you the primary emergency ambulance organization . . .''

iv. Section 4, Questions 1 and 2 Clarification: The question currently defines response time as ''the time from when the call comes in to when the ambulance or another EMS response vehicle arrives on the scene.'' We proposed clarifying this definition to say ''the time from when the call comes in to dispatch to when the ambulance or another EMS response vehicle arrives on the scene.'' Relatedly, for Section 4, Question 2, we proposed adding a second answer option for this question that reads, ''From the time our organization receives a call from dispatch to the time the ambulance or other EMS vehicle is at the scene.'' Respondents would still have the option to write-in their own response in Section 4, Question 2, if neither of the pre-programmed options apply to their organization.

v. Section 5, Question 3a. Clarification: This question requests respondents to report the percentage of ground ambulance responses that involve a non-transporting agency and the percentage of ground ambulance transports in which the non-transporting agency continues to provide medical care in the ambulance during a transport. Based on feedback from ground ambulance organizations that we have received since we finalized the instrument, we believe many organizations do not currently track this data and will not easily be able to begin tracking it. We proposed clarifying this question to note that estimated percentages are acceptable, as they are in response to certain other questions in the instrument (where noted). We specifically proposed to edit Section 5 question 3a. to read: ''What is your best estimate of the percentage of total ground ambulance responses that involved a non-transporting agency? (Enter percentage)''

vi. Section 7.1 Instruction Clarification: We proposed clarifying ''You will report on these staff in a different section'' to ''You will report on these staff in a later section'' to make it clear that the opportunity to report on

these staff follows the current instruction.

vii. Sections 7.1 and 7.2 Instruction Clarification: We proposed to add ''employer payroll taxes'' as an additional example of a component contributing to total compensation, without altering any of the definitions or other instructions in these sections.

viii. Section 7.2, Question 3 Clarification: We proposed adding a clarification warning for respondents not to consider labor that was reported elsewhere when responding to this question.

ix. Section 7.3, Question 4 Clarification: We proposed adding a clarification that medical director volunteer hours do not contribute to this response and a reminder that they are reported separately below (Section 7.3, Question 5).

x. Section 10 Instructions: We proposed to correct a typo in the instructions where the instrument describes ''operation expenses'' rather than ''operating expenses'' as intended.

xi. Section 13, Question 3 Clarification: Based on the instructions for this question, organizations may report revenue from specific payers that include patient cost-sharing amounts. To ensure patient cost-sharing is not reported twice, we recommended clarifying the item in the chart that currently reads, ''Patient self-pay (amount patients pay for deductibles, coinsurance, etc.) to read, ''Patient self-pay (cash payment and the amount patients paid for deductibles, coinsurance, and other cost-sharing only if not reported in a row above.)'' We solicited comments on these clarifications and updates to the instrument.

We received public comments on these clarifications and updates to the instrument. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposed clarification to Section 5, Question 3a regarding reporting the percentage of ground ambulance responses that involve a non-transporting agency. A commenter expressed their appreciation for a policy that can promote simplicity and efficiency of data collection and reporting. A commenter supported the clarification and noted that information on joint responses is difficult to track and collect.

Response: We appreciate the commenters' support.

Comment: A commenter supported our proposed clarification for Section 5, Question 3a, but recommended that CMS maintain strict expectations for respondents to provide accurate estimates in this response, noting a common scenario in which a ground ambulance provider or supplier utilizes an ALS provider or supplier from a non-transport agency to continue caring for the patient during transportation. According to the commenter, this common scenario forces the non-transport agency to assume the labor and equipment costs associated with the ALS provider or supplier while an ALS level 1 reimbursement is paid to the ground ambulance provider or supplier that provided the medically necessary ground ambulance transport. The commenter stated that this information is crucial in demonstrating the need for CMS to provide reimbursement to all agencies involved in caring for Medicare beneficiaries. The commenter suggested that CMS make these responses publicly accessible in addition to all other data reported in a timely fashion.

Response: While we appreciate the importance of joint responses in determining expenses for all contributing ground ambulance organizations and other services, the Medicare Ground Ambulance Data Collection Instrument currently does not collect detailed information on the number of services with joint responses of different types. Instead, our approach is to question broadly whether the ground ambulance organization collecting and reporting data participates in joint responses and, if so, which general types of labor and other inputs are involved.

Comment: A commenter supported our proposed clarifications to Section 13, Question 3 on reporting revenue, stating that this is a helpful clarification for reporting organizations to distinguish between patient self-pay types.

Response: We appreciate the commenter's support.

After consideration of public comments, we are finalizing all the clarifications as proposed.

4. Collection and Reporting of Information Under the Data Collection System

In the CY 2020 PFS final rule (84 FR 62893), we finalized our sampling proposals to implement a 25 percent stratified sample in each of the first 4 years of data collection and codified the representative sample approach at § 414.626(c). CMS' sampling approach is designed to result in representative samples of ground ambulance organizations in terms of key characteristics including provider versus supplier status, service area population density, volume of transports, and ownership category. The selected ground ambulance organizations for year 1 and year 2 have already been listed on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.*

In the CY 2020 PFS final rule (84 FR 62894), we finalized the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or the organization's annual accounting period that begins during the data collection year when an organization has an annual accounting period (such as a fiscal year) that differs from the calendar year and the organization elects to collect and report data over this period rather than the calendar year. We also finalized our proposal to require organizations to report data during a 5-month data reporting period starting immediately following the end of the data collection period. The data collection and reporting requirements for selected ground ambulance organizations were codified at § 414.626(b).

As part of the Medicare Ground Ambulance Data Collection System, sampled ground ambulance organizations will report information to CMS using a web-based version of a data collection instrument that is posted on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.* We are currently developing the Medicare Ground Ambulance Data Collection System and stated in the CY 2020 PFS final rule (84 FR 62867) that the web-based survey would be available before the start of the first data reporting period to allow time for users to register, receive their secure login information, and receive training from CMS on how to use the system.

Due to the COVID–19 public health emergency (PHE), we issued two blanket waivers (May 5, 2020 and November 25, 2020) to delay the data collection and data reporting periods under the Medicare Ground Ambulance Data Collection System. The first waiver delayed the data collection period and data reporting period for selected year 1 ground ambulance organizations and the second waiver delayed the data collection periods and data reporting periods for selected year 1 and year 2 ground ambulance organizations.

This revised modification has been issued on page 32 in the following document: *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.* Specifically, we modified the data collection period and data reporting

period, as defined at § 414.626(a), for ground ambulance organizations (as defined at § 414.605) that were selected by CMS under § 414.626(c) to collect data beginning between January 1, 2020 and December 31, 2020 (year 1) and for ground ambulance organizations that were selected to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) for purposes of complying with the data reporting requirements described at § 414.626.

Under this modification, these ground ambulance organizations will select a new continuous 12-month data collection period (organizations may choose a collection period aligning with the calendar year or the organization's fiscal year) that begins between January 1, 2022 and December 31, 2022, to collect data necessary to complete the Medicare Ground Ambulance Data Collection Instrument during their selected data collection period, and submit a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to their selected data collection period. We modified this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020–2021 so that they can focus on their operations and patient care during the COVID–19 PHE. We stated, when the blanket waiver was granted, in the COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document (page 63 of this document: *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*) that CMS will not allow an option to continue with their current data collection period because the data collected in 2020 and 2021 during the PHE may not be reflective of typical costs and revenues associated with providing ground ambulance services.

As a result of the COVID–19 delay, ground ambulance organizations selected in year 1, 2, and 3 will have the same data collection periods beginning between January 1, 2022 and December 31, 2022 and will have the same data reporting periods beginning between January 1, 2023 and December 31, 2023. In the CY 2020 PFS final rule (84 FR 62893), we finalized our sampling proposals to implement a 25 percent stratified sample in each of the 4 years of data collection. Prior to the delay, we anticipated approximately equal shares of ground ambulance organizations will collect and report data in 4 consecutive periods. However, as a result of the delays, there will now be approximately 75 percent of the ground ambulance organizations that will have data collection periods that start in the same year and subsequently will have data reporting periods starting in the same year. Later, a final 25 percent sample of ground ambulance organizations in year 4 will collect and report data.

When finalizing our policies in regard to ground ambulance collection and reporting of data, we did not intend to have approximately 75 percent of ground ambulance organizations collect and report data at the same time. To provide MedPAC with the data needed for analysis, acknowledging that due to the COVID–19 delay there will be a delay in CMS providing that data, we believe that we should revise the data collection period and data reporting period for selected ground ambulance organizations in year 3.

Accordingly, in the CY 2022 PFS proposed rule (86 FR 39302), we proposed to revise the data collection period beginning between January 1, 2022 and December 31, 2022 and data reporting period beginning between January 1, 2023 and December 31, 2023 for selected ground ambulance organizations in year 3. Under this proposal, there will be a new data collection period beginning between January 1, 2023 and December 31, 2023 and a new reporting period beginning between January 1, 2024 and December 31, 2024 for selected ground ambulance organizations in year 3. With this proposal, we plan to do the sample in 2022 for selected ground ambulance organizations in year 3 rather than the current plan in 2021. The main advantage of delaying the year 3 sample is that the selected organizations would be more representative of the organizations actually collecting beginning in 2023 and reporting beginning in 2024. The longer the delay between sampling and the data collection and data reporting, the more changes in the industry (for example, NPIs ceasing ground ambulance or all operations). This timeline will align with the data collection period and data reporting period requirements for selected ground ambulance organizations in year 4. As a result, there will be approximately 50 percent of ground ambulance organizations selected in year 1 and 2 with data reporting periods beginning between January 1, 2023 and December 31, 2023 and approximately 50 percent of ground ambulance organizations selected in year 3 and 4 with data reporting periods beginning between January 1, 2024 and December 31, 2024.

Due to the delay caused by the PHE for COVID–19, we examined the possibility of extending the data reporting to encompass 4 years as planned instead of 2 years. We concluded that it will not be feasible to extend the data reporting period over 4 years. Extending the data reporting to encompass 4 years will further delay MedPAC receiving the data required to analyze for its report to Congress, which is required to be submitted by March 15, 2023. The sampling for year 1 and year 2 selected ground ambulance organizations has already been completed and the lists for the selected ground ambulance organizations in year 1 and year 2 are posted on the CMS website.

With this proposal, more data will be collected in 2023 as there will hopefully be more distance from the peak of the COVID–19 pandemic. Thus, it is our hope that 2023 will be even more reflective of a typical year of costs for ground ambulance organizations than 2022. As the course of the pandemic continues to evolve, we believe that our proposal provides a potential for more even distribution of data over 2 years for comparison by MedPAC. We solicited comments on our proposal to revise the data collection period and data reporting period for ground ambulance organizations selected in year 3.

We received public comments on our proposal to revise the data collection period and data reporting period for ground ambulance organizations selected in year 3. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposed changes to the data collection period and data reporting periods for selected ground ambulance organizations in year 3. A commenter stated that the proposal to align the timeline for selected ground ambulance organizations in Years 1 and 2, and Years 3 and 4 is an appropriate response to the disruption that the pandemic caused with respect to the ground ambulance data collection and recognizes CMS' efforts to prevent further delays. This commenter stated that the proposed adjusted timeframe will provide their organization enough time to build up the appropriate collection tools and processes, and will allow for a smooth transition for submitting the required data.

A commenter supported the data collection timeline as proposed and stated that it is important that assessments of the adequacy of ground ambulance payments not be based on data that reflects anomalous, temporary trends in utilization and costs caused by a global pandemic. The commenter stated that to the extent that these anomalous trends might still be occurring in 2022, the commenter

concurs with CMS' caution about using 2022 data because it could bias analyses of the geographic variation in costs and the adequacy of Medicare's ground ambulance payments.

A commenter supported the proposal and stated that while their organization appreciated the need to delay the data collection process due to the PHE for COVID–19, the commenter is concerned that further delays will prevent MedPAC from having the data needed to produce their report to Congress.

A commenter supported the delays to the ground ambulance data collection because their members were on the frontlines of responding to the pandemic, however, the commenter does not support collapsing the Congressionally mandated 4 years of data collection into 2 years. The commenter stated that the proposed timeline is problematic given that CMS did not beta test the Medicare Ground Ambulance Data Collection System and according to the commenter, the first year of the data collection is likely to be fraught with confusion and errors, despite CMS and its contractor's best efforts to address as many questions as possible before the data collection is fielded. This commenter recommended a 4-year timeline: Data collection period in 2022 and data reporting period in 2023 for selected ground ambulance organizations already selected in year 1; data collection period in 2023 and data reporting period in 2024 for selected ground ambulance organizations already selected in year 2, data collection period in 2024 and data reporting period in 2025 for selected ground ambulance organizations in year 3 and data collection period in 2025 and data reporting period in 2026 for selected ground ambulance organizations in year 4. The commenter suggested a 12-month data reporting period rather than a 5-month data reporting period that begins the day after the last day of the ground ambulance organization's data collection period. This commenter noted that MedPAC may not have time to complete their analysis and report on either the proposed timeline or the commenter's recommended timeline. However, the commenter stated that its approach would allow for timing that mirrors what the authorizing statute requires and it also would meet CMS stated goal that the data collected be ''more reflective of a typical year of costs for ground ambulance organizations'' than data collected during the turbulent of the pandemic, which continues to rage during this fourth surge with the Delta variant.

Response: We appreciate the feedback on our proposed changes to the data collection period and data reporting period for selected ground ambulance organizations in year 3. As several commenters noted, we are keenly aware of the tension between the need to begin collecting data and the challenges and threats to generalizability of collecting data through the ongoing pandemic and PHE. Our proposal attempts to strike a balance between these two considerations. Under our proposal, information will be collected from fewer organizations during data collection periods starting in 2022, and from more organizations during data collection periods starting in 2023. Delaying data collection and reporting for more ground ambulance organizations, or stretching the data collection period and data reporting period over a 4-year period, will result in a longer delay before information is collected from all ground ambulance organizations. We are therefore not accepting the commenter's recommended 4-year timeline. We plan to conduct beta testing on the Medicare Ground Ambulance Data Collection System prior to data reporting in the system.

After consideration of public comments, we are finalizing our proposal for a new data collection period beginning between January 1, 2023 and December 31, 2023 and a new data reporting period beginning between January 1, 2024 and December 31, 2024 for selected ground ambulance organizations in year 3. With this proposal, we plan to do the sample in 2022 for selected ground ambulance organizations in year 3 rather than the current plan in 2021.

5. Change to the Notification Process for Selected Ground Ambulance Organizations Required to Report

In the CY 2020 PFS final rule, we codified our notification process at § 414.626(c)(3) and (b)(1). We stated at § 414.626(c)(3) that CMS will notify an eligible ground ambulance organization that it has been selected to report data for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data by posting a list of selected organizations on the CMS web page and providing written notification to each selected ground ambulance organization via email or U.S. mail.

The Medicare Administrative Contractor (MAC) is responsible for providing written notifications to the selected ground ambulance organizations in their service area. We codified their role at § 414.626(b)(1) which states that within 30 days of the date we notify a ground ambulance organization that it has been selected to report data under this section, the ground ambulance must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to the ground ambulance organization's Medicare Administrative Contractor.

In the CY 2022 PFS proposed rule (86 FR 39303), we proposed to make a technical revision to § 414.626(b)(1) to state that the selected ground ambulance organization provide the start date of the data collection period to CMS or its contractor instead of the Medicare Administrator Contractor. This change will provide CMS with flexibility to have the MACs or other contracted entities provide written notifications and collect information from the selected ground ambulance organizations. If we find the response rate is low, having the flexibility to contract with other entities that could employ additional outreach resources may be useful. This revision will not preclude CMS from including the MACs in the notification process. We also proposed to correct a typographical error at § 414.626(b)(1), which currently states ''a ground ambulance must select a data collection period'' to read ''a ground ambulance organization must select a data collection period.'' We solicited comments on our technical revisions to the citation at § 414.626(b)(1).

We did not receive public comments on this proposal, and therefore, we are finalizing it as proposed.

6. Payment Reduction for Failure to Report

Section 1834(l)(17)(D)(i) of the Act requires that beginning January 1, 2022, subject to clause (ii), the Secretary reduce the payments made to a ground ambulance organizations under section 1834(l)(17) of the Act for the applicable period by 10 percent if the ground ambulance organization is required to submit data under the data collection system with respect to a data collection period under the data collection period and does not sufficiently submit such data.

We stated in the CY 2020 PFS final rule (84 FR 62895) that we would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than the date that is 3 months following the date that the ground ambulance organization's data reporting period ends. In this final rule, we provided examples of when the determination will be made based on calendar year and fiscal year data collection period

beginning in 2020. Due to the delay caused by the PHE for COVID–19, we did not receive data collected in 2020. We will begin to follow this timeline to make a determination that the ground ambulance organization is subject to the 10 percent payment reduction when data collected in 2022 is required to be reported in 2023 for selected ground ambulance organizations in year 1 and year 2.

For example, if a selected ground ambulance organization's data collection period is based on a calendar year, that is, January 1, 2022 through December 31, 2022, we will allow a ground ambulance organization 5 months to report the data collected during the data collection period. For this example, the data reporting period for this organization is January 1, 2023 to May 31, 2023. We will make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than August 31, 2023. With this timeframe, we will apply the 10 percent reduction in payments, if applicable (no hardship exemption or informal review is granted), for ambulance services provided between January 1, 2024 and December 31, 2024.

As another example, if a selected ground ambulance organization's data collection period is based on a fiscal year, that is, October 1, 2022 through September 30, 2023, we will allow a ground ambulance organization 5 months to report the data collected during the data collection period. For this example, the data reporting period for this organization is October 1, 2023 to February 28, 2024, we will make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than June 1, 2024. With this timeframe, we will apply the 10 percent reduction in payments, if applicable (no hardship exemption or informal review is granted), for ambulance services provided between January 1, 2025 and December 31, 2025.

Comment: A commenter supported aligning the timelines for the application of penalties for not reporting data with our new timelines for data collection and reporting.

Response: We appreciate the commenter's support.

7. Public Availability of Data

We stated in the CY 2020 PFS final rule (84 FR 62897), the data will be made available to the public through posting on our website at least every 2 years and we will post the summary results by the last quarter of 2022. We codified the public availability at § 414.626(f), which states: (f) Public availability of data. Beginning in 2022, and at least once every 2 years thereafter, we will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

Due to the COVID–19 delay, in the CY 2022 PFS proposed rule (86 FR 39303), we proposed to revise § 414.626(f) to state that we will make the data collected under § 414.626 publicly available beginning in 2024. We solicited comments on our proposal to revise the timeline when the public availability of data will begin.

We received a public comment on our proposal to revise the timeline when the public availability of data will begin. The following is a summary of the comment we received and our response.

Comment: A commenter stated that it would provide greater transparency if CMS were to release data annually rather than waiting until 2024 for the first release. The commenter stated that this would be similar to cost reporting data or other data files released for other healthcare entities that are also released annually and that it would be important for the public to have access to the data that will be used by MedPAC for their analysis.

Response: In the CY 2020 PFS final rule (84 FR 62897), we finalized our proposals for public availability of the data including to post on our website a report that includes summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable. The data above will be made available to the public through posting on our website at least every 2 years. We do not plan on releasing information collected via the Medicare Ground Ambulance Data Collection Instrument in precisely the same way that cost reporting data is released but intend to post as much data as possible, including summary statistics describing the data reported by subgroups of respondents, while protecting the confidentiality of the respondents.

After consideration of public comments, we are finalizing the proposal as proposed.

L. Medicare Diabetes Prevention Program (MDPP)

The Medicare Diabetes Prevention Program (MDPP) expanded model is a structured intervention that aims to prevent or delay onset of type 2 diabetes among eligible Medicare beneficiaries diagnosed with pre-diabetes. The MDPP expanded model is an expansion of duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested through a Round One Health Care Innovation Award. MDPP services are furnished in community and health care settings by organizations that enroll in Medicare as MDPP suppliers, a new supplier type, even if they have an existing Medicare enrollment as another supplier type. MDPP services furnished under the MDPP expanded model are covered as an additional preventive service with no cost-sharing under Medicare. Eligible organizations seeking to furnish MDPP services began enrolling in Medicare as MDPP suppliers on January 1, 2018, and began furnishing MDPP services on April 1, 2018.

We proposed to amend our regulation at § 410.79 to preclude the provision of ongoing maintenance sessions unless the MDPP beneficiary has started his or her first core session on or before December 31, 2021. In addition, we proposed to amend § 414.84(b) and (c) to update the amount of the performance payments for the core sessions and core maintenance sessions and ongoing maintenance sessions (where applicable) to be consistent with our proposal. We proposed that this change apply to all MDPP beneficiaries starting the MDPP set of services on or after January 1, 2022. Additionally, we proposed to amend § 424.205(b) to add a provision to waive the provider enrollment Medicare application fee for all organizations enrolling in Medicare as MDPP suppliers that submit an application on or after January 1, 2022. Finally, we proposed to make a conforming amendment to § 424.502 to remove a reference to the CMS–20134 from the definition of ''institutional provider.'' (In accordance with § 424.514, institutional providers generally must pay the enrollment application fee.)

We do not anticipate that the changes will impact our ability to complete an evaluation of the MDPP expanded model, but the evaluation will consider the changes we finalize. The evaluation will continue to use beneficiary-level Diabetes Prevention Recognition Program (DPRP) encounter data and program data furnished by the Centers for Disease Control and Prevention (CDC) in combination with Medicare claims data to analyze the long-term utilization of services by beneficiaries who have received the MDPP set of services. We will use these data as planned to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without

reducing the quality of care, or improve the quality of care and reduce spending.

While we acknowledge that additional changes will likely be needed in the future to improve access to MDPP, we anticipate that the programmatic adjustments finalized in this rule are likely to result in more MDPP suppliers, increased beneficiary access to MDPP services, and an ongoing reduction of the incidence of diabetes in eligible Medicare beneficiaries, in both urban and rural communities. We believe that the three changes that we are finalizing in this rule will make MDPP more attractive to potential suppliers by addressing consistent stakeholder comments about MDPP underpayment and the length of the MDPP service period, as well as more manageable for MDPP beneficiaries by reducing their commitment to MDPP to 1 year. We anticipate that removing the Medicare enrollment fee for suppliers, providing larger payments up front to suppliers, and paying more for attendance-only achievements will result in more organizations enrolling as MDPP suppliers and MDPP suppliers will be able to more consistently implement sustainable programs which will increase the availability of the MDPP set of services to more beneficiaries. Stakeholders have suggested that a payment structure that provides higher payments later in the set of services and places too much emphasis on weight-loss requirements disincentivizes MDPP suppliers from providing services to underserved populations who may be less successful at achieving the weight-loss goals. We believe that by providing larger payments up front and paying more for attendance-only achievements we will remove the potential disincentives and improve accessibility to underserved populations who may face barriers to weight-loss. We anticipate that these changes will increase beneficiary access to MDPP services in rural areas and it may have a positive impact on more equitable access to the service.

1. Changes to § 410.79(b), (c), and (e)

We proposed to amend certain MDPP expanded model policies previously finalized in the CY 2017 PFS final rule (81 FR 80459 through 80475 and 80552 through 80558), the CY 2018 PFS final rule (82 FR 34157 through 34158), and the CY 2021 PFS final rule 85 FR 50074). Previous rules established policies related to the set of MDPP services, beneficiary eligibility criteria, reimbursement structure, and supplier enrollment requirements and compliance standards.

MDPP has experienced challenges recruiting suppliers to participate in the expanded model, which has limited beneficiary access to the preventive services offered under the expanded model. Existing and prospective suppliers have reported that the length of the set of MDPP services and the payment timing and amounts have made implementation and operation of MDPP burdensome and has hindered participation. Currently, MDPP suppliers are required to offer up to 2 years of MDPP services to eligible MDPP beneficiaries. The MDPP set of services, as defined in § 410.79(b), consists of at least 16 sessions offered during the core sessions phase (Months 1–6), monthly maintenance sessions offered during the core maintenance sessions phase (Months 7–12) (collectively the ''core sessions phase''), and additional monthly sessions offered during the ongoing maintenance sessions phase (Months 13–24) for eligible beneficiaries. To be eligible for the ongoing maintenance sessions phase, a beneficiary must meet the minimum weight-loss requirement (5 percent weight loss from baseline), as defined in § 410.79(b), and maintain the minimum weight-loss requirement on a quarterly basis to continue to receive MDPP services in subsequent quarters. The ongoing maintenance sessions delivered in year 2 are a unique feature of MDPP. Both the CMS-funded Health Care Innovation Award (HCIA) to the Young Men's Christians Association (YMCA) of the USA (Y–USA), referred to as the DPP model test hereafter, and the CDC's National Diabetes Prevention Program (National DPP) was/are 12 months in length.

We included the ongoing maintenance sessions phase in the MDPP set of services to support participants in solidifying the behavioral changes that resulted in weight loss during the first 12 months. In the CY 2017 PFS proposed rule, we proposed adding the ongoing maintenance sessions phase to follow the completion of the 12-month core sessions phase if the beneficiary achieved and maintained the required minimum weight loss of 5 percent from the baseline weight. That proposed rule did not place a limit on the number of ongoing maintenance session phases an eligible beneficiary could attend. In response to stakeholder comments, we modified the proposed policy to limit access to up to 2 years of ongoing maintenance sessions after the 12-month core sessions phase. In the CY 2018 PFS, we again modified the policy to limit access to ongoing maintenance sessions to 1 year after the 12-month core sessions phase as long as MDPP beneficiaries maintained the 5 percent weight loss.

Despite limiting the ongoing maintenance sessions phase to 1 year, we have heard that the MDPP suppliers find the implementation, operation, and costs of the ongoing maintenance sessions phase burdensome. We anticipate that the changes we proposed will improve the uptake of organizations enrolling in Medicare to become MDPP suppliers, thus enabling more beneficiaries to access the MDPP set of services. Collectively, this will improve CMS ability to evaluate the MDPP expanded model as more suppliers and beneficiaries participate in the expanded model test. Currently, more than 1,000 organizations nationally are eligible to become MDPP suppliers based on their preliminary or full CDC DPRP status. However, only 27 percent of eligible organizations are participating in MDPP. Based on an analysis of National Health and Nutrition Examination Survey (NHANES) data, an estimated 16.4 million people are eligible for MDPP;[141] to date, over 3,600 beneficiaries are participating in the MDPP set of services. We anticipate that the removal of the second year of the MDPP set of services on a prospective basis will make MDPP attractive to more MDPP eligible organizations and beneficiaries.

The requirement to offer a second year of the MDPP set of services has also caused confusion among MDPP suppliers because it is inconsistent with the CDC National DPP requirements and curriculum. Because there is no defined curriculum for the ongoing maintenance sessions phase, MDPP suppliers repeat parts of the curriculum they previously used during the core sessions phase per CDC guidance and their updated 2021 DPRP Standards[142]. We have heard anecdotally, through written inquiries and questions asked by MDPP suppliers during MDPP educational events, that MDPP suppliers struggle with discerning the appropriate timing of determining whether a beneficiary has met and/or maintained the 5 percent minimum weight-loss requirement necessary for continued eligibility for and during the ongoing maintenance sessions phase. To be eligible to

[141] Lee AK, Warren B, Liu C, Foti K Selvin E (2019) Number and Characteristics of US Adults Meeting Prediabetes Criteria for Diabetes Prevention Programs: NHANES 2007–2016, J Gen Intern Med 34(8):1400–2. *https://link.springer.com/content/pdf/10.1007/s11606-019-04915-w.pdf.*

[142] CDC DPRP Standards (March 1, 2021) *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

continue to the ongoing maintenance phase of MDPP, beneficiaries must lose and/or maintain a 5 percent weight loss from baseline. MDPP suppliers are responsible for determining if a MDPP beneficiary has met and/or maintained the 5 percent weight loss from baseline during the applicable session and phase. A supplier must submit a claim to the Medicare Administrative Contractor (MAC) for the 5 percent weight loss achievement for each beneficiary, otherwise, all subsequent ongoing maintenance session claims may be rejected by the MAC. Suppliers have 12 months from the date of service to submit claims, if they delay the claim submission for the 5 percent weight loss performance goal, this may impact a supplier's ability to get paid for the ongoing maintenance sessions. For example, if a beneficiary achieves the 5 percent weight loss goal during the first 6 months of MDPP, or during the core services period, and they do not submit the claim for the 5 percent weight loss goal until after the ongoing maintenance interval has started, the supplier risks having their claim for the ongoing maintenance interval rejected. Furthermore, in this scenario, the supplier will need to submit a claim for the second core maintenance session interval with a 5 percent weight loss for the beneficiary to continue with ongoing maintenance sessions. MDPP monitoring data suggest that 82 percent of MDPP beneficiaries for whom we have claims for the 5 percent weight loss goal achievement reach that goal in the first 6 months of the expanded model. However, our monitoring data show claims for MDPP ongoing maintenance sessions for only 10 percent of MDPP beneficiaries and that beneficiary attendance sharply drops after the first quarter of the initial core session. Collectively, these data suggest that suppliers may not be incentivized to retain MDPP beneficiaries after they attend the 9th core session in the set of MDPP services, which MDPP beneficiaries likely reach during the first quarter of the expanded model, or after the MDPP beneficiary has achieved the 5 percent weight loss milestone.

Existing MDPP suppliers report frustration with the requirements associated with the ongoing maintenance phase and we believe that the additional burden and cost of providing the ongoing maintenance sessions is a deterrent to prospective MDPP suppliers. Organizations have communicated to CMS their difficulties in keeping MDPP beneficiaries engaged in the expanded model. For an example, suppliers are reimbursed after they successfully submit claims for beneficiary attendance, after the 1st, 4th, and 9th core sessions during the first 6 months of the MDPP set of services, and then if beneficiaries attend 2 monthly sessions per quarter thereafter. MDPP eligible organizations have cited beneficiary acquisition and retention as a leading barrier to their MDPP supplier enrollment. Stakeholders and suppliers have commented that the payment levels for a second year are inadequate to cover supplier costs given the low volume of beneficiaries who participate in the ongoing maintenance phase and drive up the per-beneficiary costs for the supplier. Stakeholders comment that sessions have the same fixed costs, yet there are a diminishing number of MDPP beneficiaries eligible to participate. As previously noted, our FFS claims-based monitoring data show that only approximately 10 percent of MDPP beneficiaries continue with the ongoing maintenance sessions phase and the majority of MDPP beneficiaries achieve the 5 percent weight loss milestone within the first 6 months of the MDPP set of services. Given our data, stakeholder comments, the lack of the ongoing maintenance year alignment with the CDC's National DPP and the DPP model test, the ongoing maintenance phase is not sufficiently beneficial to continue requiring and may be causing harm to the expanded model's overall goals.

As such, we proposed to amend our regulations to preclude coverage of ongoing maintenance sessions unless the MDPP beneficiary has started his or her first core session on or before December 31, 2021. Specifically, we proposed to amend § 410.79(c)(1)(ii) to provide that an MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary started his or her first core session on or before December 31, 2021. As finalized, this change will effectively make the MDPP timeframe consistent with the National DPP for MDPP service periods that begin on or after January 1, 2022. In addition, as finalized, we believe that this policy will reduce the administrative burden and costs associated with the ongoing maintenance sessions phase to MDPP suppliers with minimal impact to beneficiaries given their historically low participation rate in the second year of MDPP. This proposed change is consistent with the authority in section 1115A(c) of the Act, and we anticipate this change will improve our ability to evaluate the expanded model test due to an anticipated increase in supplier enrollment, which will increase beneficiary access to the expanded model.

In conjunction with the proposed change to remove the ongoing maintenance sessions phase from the MDPP services period, we proposed to redistribute a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments to address stakeholder concerns that the current MDPP payment structure does not cover reasonable costs of MDPP suppliers to deliver the MDPP set of services. For example, the proposed attendance-based performance payments are based on a standardized per-session rate, paid after the 1st, 4th, and 9th sessions attended during the core sessions intervals, and after attending the two (2) sessions during each of the core maintenance intervals. Based on the comments we received, we are modifying this proposal to redistribute all the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments in the final rule consistent with Table 39. We proposed to increase performance payments for MDPP beneficiary achievement of the 5 percent weight loss goal, as well as continued attendance during each core maintenance interval. Based on comments we received, we will maintain the current 2021 performance payment amount for achievement of the 5 percent weight loss goal, increase the payment amounts to the attendance only goals to incentivize attendance, and increase the total maximum payment to $705.

Our Office of the Actuary estimated that the average payment for an MDPP supplier will increase by $100 with the elimination of the second year of MDPP. While the maximum payment available to an MDPP supplier will decrease when compared to the maximum payment under the original 2-year payment structure, the second year of the MDPP set of services have historically been far less utilized than first year set of services. Therefore, it is anticipated that eliminating the second year of payments will have minimal negative impact on the expanded model's costs. Table 39 shows the current 2021 non-cumulative performance payments, the proposed performance payments, and the finalized performance payment amounts for those MDPP beneficiaries who will start their first core service on or after January 1, 2022. We did not propose to change the payment rates for ongoing maintenance sessions in cases where a beneficiary remains eligible for them

(that is, because they started receiving the MDPP set of services on or before December 31, 2021 and achieved the minimum required weight loss); rather, we proposed to maintain those payment rates until such time as ongoing maintenance sessions are phased out.

TABLE 39: MDPP Payment Structure

Payment Description	Current	Proposed	Final
Core Sessions (Months 1-6)			
Attend 1 Core Session or Bridge Payment	$26	$26	$35
Attend 4 Core Sessions	$52	$78	$105
Attend 9 Core Sessions	$95	$130	$175
Core Maintenance (CM) Sessions (Months 7-12)			
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	$15	$52	$75
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 1 (Months 7-9)	$63	$106	$93
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 2 (Months 10-12)	$15	$52	$75
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 2 (Months 10-12)	$63	$106	$93
5% WL Achieved from baseline weight	$169	$189	$169
9% WL Achieved from baseline weight	$26	$26	$35
Ongoing Maintenance Sessions (Months 13-24)			
Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)	$52		
Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)	$52		
Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)	$53		
Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months (22-24)	$53		
Subtotal Maximum Payment – Attendance Only	**$203**	**$338**	**$455**
Total Maximum Payment*	**$704**	**$661**	**$705**

Our data from the DPP model test showed beneficiaries who finished at least nine (9) sessions of the model were considered ''completers'' and had better weight loss and lower Medicare spending than non-completers (those who attended fewer than 9 sessions). The DPP model test showed that beneficiaries who attend nine or more sessions will, on average, experience a 6.24 percentage point increase in weight loss compared to beneficiaries attending fewer than nine sessions. Currently, our payment structure does not pay for per session attendance, and stakeholders have commented that the expanded model, in its current state, is creating inequities in access to MDPP among eligible beneficiaries because suppliers cannot invest in the costs to retain beneficiaries who may have access barriers related to transportation or distance of the MDPP location from their home. We anticipate the changes to the payment structure, which will pay a total of $81 more per beneficiary who attends at least 9 sessions and $55 more per core maintenance interval than what is currently paid, will encourage existing suppliers to retain MDPP beneficiaries given the one-year commitment versus two for the MDPP set of services. Continuous beneficiary attendance is critical to reaching key outcomes such as 5 percent weight loss and reduced Medicare spending. Additionally, we expect more eligible organizations will enroll as MDPP suppliers due to our eliminating the ongoing maintenance period, thereby increasing the number of locations beneficiaries may access the MDPP set of services. We expect the changes to the MDPP payment structure will not affect MDPP's qualification for expansion. We will use the CDC DPRP and MDPP claims data as planned to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending. We anticipate that these programmatic adjustments are likely to result in more MDPP suppliers, increased beneficiary access to MDPP services and an ongoing reduction of the incidence of diabetes in eligible Medicare beneficiaries, in both urban and rural communities.

In our regulatory impact analysis, the CMS Office of the Actuary updated its estimates that these changes will reduce Medicare spending over 10 years, with potential savings starting in 2027. There is no evidence that eliminating the second-year maintenance sessions, shortening the MDPP services period to 1 year, will have any negative effects on performance of the MDPP expanded model.

Increasing the first-year payment amounts to suppliers and waiving the Medicare enrollment fee (as discussed below) should increase access to MDPP, resulting in more utilization of the MDPP set of services.

We proposed a change to our emergency policy at § 410.79(e)(3)(v)(C) to account for the elimination of ongoing maintenance sessions for MDPP beneficiaries who start the set of MDPP services on or after January 1, 2022. Under this proposal, only beneficiaries who start the MDPP set of services between January 1, 2021, and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event may either resume or restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event if they elect not to continue with MDPP services virtually during the applicable 1135 waiver event. MDPP beneficiaries who are eligible to participate in MDPP ongoing maintenance phase sessions between January 1, 2021 and December 31, 2021 and who elected not to participate virtually during the COVID–19 PHE, will have the option to resume or restart the ongoing maintenance

session interval in accordance with § 410.79(c)(3).

As noted above, we proposed to remove the ongoing maintenance sessions phase for all MDPP beneficiaries who start MDPP set of services on or after January 1, 2022. MDPP beneficiaries who start the MDPP set of services on or before December 31, 2021 will be able to continue with the ongoing maintenance phase if they meet the eligibility requirements described in § 410.79(c)(3). Table 40 summarizes our proposal for the MDPP services period based on beneficiary start date.

TABLE 40: Summary of the MDPP Services Period Based on Beneficiary Start Date

Beneficiary MDPP Status	MDPP Services Period
Beneficiary starts MDPP set of services on or before December 31, 2021	Core Services Period, which is the first 12 months of the MDPP services period, and consists of: (A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and (B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period. Ongoing Maintenance Services Period, consists of up to four 3-month ongoing maintenance session intervals offered during months 13 through 24 of the MDPP services period.
Beneficiary starts MDPP set of services on or after January 1, 2022	Core Services Period, which is the first 12 months of the MDPP services period, and consists of: (A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and (B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

Additionally, we proposed to remove the second duplicate paragraph (c)(3)(ii) given that the electronic CFR contains two paragraphs (c)(3)(ii), both containing the exact same language.

We proposed to amend our regulation at § 410.79(b), (c), and (e). We solicited comments on these proposals and ways to simplify the policies.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters were very supportive of the proposed changes, including the removal of the second year. Most commenters agreed that this change aligns with the CDC 2021 Standards and Operating Procedures for the National DPP and increases the ability of eligible organizations to offer the MDPP set of services to and retain participants. Commenters generally supported the removal of the second year as it allows eligible organizations to phase out Ongoing Maintenance sessions and align with the current CDC Recognition Program Standards and Operating Procedures. Other commenters indicated that participants are more likely to complete the MDPP set of services if it is only 1 year vs 2 years.

We received several comments requesting that we keep the option of a second year given that some Medicaid and commercial plans offer a second year and may not require a 5 percent weight loss.

Response: We appreciate the interest in keeping the second year as optional; however, we believe that it would be overly burdensome and confusing to suppliers, beneficiaries, and the Medicare Administrative Contractors (MACs) to have some beneficiaries enrolled in MDPP on or after January 1, 2022 continue with a second year. Permitting beneficiaries to participate in a second year would create additional confusion regarding beneficiary eligibility and the claims process. Although Medicaid and some commercial plans might offer a second year, the current utilization rate of the second year of MDPP set of services reveals that it is no longer necessary to the efficacy of the expanded model. We are finalizing this policy as proposed.

Comment: Commenters stated that their understanding of this proposed change is that participants who are eligible to participate in MDPP ongoing maintenance (Months 13–24) between January 1, 2021 and December 31, 2021, but who elect not to participate virtually during the PHE, will have the option to resume or restart the ongoing maintenance session interval, even with the removal of this phase for beneficiaries beginning on or after January 1, 2022. The commenters requested clarifying language be added to the final rule if this understanding is correct, including whether there is a timeframe for these beneficiaries to re-start MDPP following the PHE.

Response: We appreciated comments and support of the proposed rule provisions. Yes, beneficiaries who are eligible to participate in MDPP ongoing maintenance phase sessions between January 1, 2021 and December 31, 2021 but who elect not to participate virtually during the PHE, will have the option to resume or restart the ongoing maintenance session interval in accordance with § 410.79(e)(3)(v)(C). We added clarifying language to this final rule. We are not imposing a requirement for MDPP beneficiaries to restart the MDPP set of services following the end of the current PHE, nor are we establishing a deadline for when such beneficiaries must restart at this time because we do not believe that it is necessary due to the uncertainty of the PHE end date.

Comment: Commenters encouraged CMS to go further and allow all current MDPP suppliers to stop offering ongoing maintenance sessions on January 1, 2022. For a period, MDPP suppliers may be delivering three interventions simultaneously: MDPP based on the 2022 changes, MDPP based on the prior iteration of the expanded model, and the National DPP, which would impose a substantial operational burden to program teams. As further rationale for this request, several MDPP suppliers

have shared that participants indicate they do not believe they need the second year.

Response: We recognize that offering ongoing maintenance sessions to certain MDPP beneficiaries after January 1, 2022 may be temporarily burdensome. However, we believe that it is important to permit all eligible beneficiaries who have attended their first core session prior to January 1, 2022 the opportunity to participate in the full MDPP set of services as they existed at the time in which the beneficiary initiated the service. Otherwise, the scope of the set of services would change, perhaps abruptly, while the MDPP beneficiary is already receiving the set of services. Keep in mind that while MDPP suppliers are required to offer ongoing maintenance sessions after January 1, 2022 to eligible MDPP beneficiaries who elect to continue with those services in accordance with the provisions of this final rule, MDPP beneficiaries are not required to participate in ongoing maintenance sessions. We are finalizing this policy as proposed.

Comment: Many commenters requested that flexibilities to provide a virtual option continue after the current PHE. Commenters noted that permitting a virtual option outside the PHE may address harder to reach populations, thereby increasing access to the expanded model (especially for rural and lower income beneficiaries with transportation needs) and ensuring a more equitable approach to accessing the expanded model. One commenter suggested that CMS change the payment structure to adopt new technologies for one-on-one virtual fitness coaching.

Several commenters suggested CMS make additional adjustments to align with CDC's DPRP standards. In particular, commenters recommended that CMS update the MDPP beneficiary eligibility requirements related to gestational diabetes and A1c levels. Commenters noted that the narrower eligibility criteria for MDPP may limit participation in the expanded model and cause confusion. In addition, we received many comments recommending that CMS consider removing or modifying the once per lifetime limitation. The commenters requested that CMS waive the once per lifetime requirement to allow for multiple attempts at weight loss. Also, several commenters expressed concern over the high-risk designation requirements for organizations enrolling in Medicare as MDPP suppliers. Commenters suggested that the designation is overly burdensome on businesses that do not have the capacity, profit, or bandwidth to address the extra requirements. One commenter requested that certified health providers such as Registered Dieticians and Registered Nutrition and Dietetics Technicians be the sole providers or provide the service with lay coaches to ensure correct nutrition information is relayed to beneficiaries. One commenter requested that CMS streamline the requirements for information collection for MDPP coaches. Several commenters expressed concern regarding the burden to become a supplier, particularly for those entities that serve historically underserved populations such as American Indians/Alaskan Natives (AI/AN). Commenters noted that the time it takes to become a CDC-recognized supplier can take 3 years, and then it can take another year to become an MDPP supplier after that. Finally, one commenter requested that CMS waive the requirement for tribes to become recognized by CDC before they can become MDPP suppliers.

Response: We appreciate the commenters' support and interest in MDPP. These suggested changes are outside the scope of this final rule. The provisions we are finalizing in this rule are only to waive the Medicare enrollment fee for MDPP suppliers as of January 1, 2021, prospectively remove the ongoing maintenance phase of the MDPP set of services, and update the MDPP payment amounts.

After consideration of public comments, we are finalizing § 410.79 (c) and (e) as proposed.

2. Changes to § 414.84(b) and (c)

We proposed to amend § 414.84(b) and (c) to update the amount of the performance payments for the core sessions, core maintenance sessions and ongoing maintenance sessions (where applicable) to be consistent with our proposal. We proposed that this change apply to all MDPP beneficiaries starting the MDPP set of services on or after January 1, 2022.

For those MDPP beneficiaries who started the first core session on or before December 31, 2021, we proposed that MDPP suppliers continue to submit claims for the ongoing maintenance sessions attended using the existing ongoing maintenance HCPCS G-codes, G9891, G9892, G9893, G9894, and G9895 when submitting claims for those MDPP beneficiaries who attended ongoing maintenance sessions.

We proposed to amend our regulation at § 414.84(b) and (c). We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters were supportive of our proposal to redistribute some of the ongoing maintenance performance payment to the core and core maintenance session performance payments. However, many commenters recommended CMS to make further changes to the proposed payment structure and amounts. Many commenters recommended that CMS redistribute all, not just a portion, of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments. The commenters noted that redistributing all the ongoing maintenance sessions phase performance payments would address ongoing concerns of MDPP suppliers of underpayment due to the current payment structure and help support long term sustainability of MDPP services. Several commenters stated that the proposed payment structure remains insufficient to cover the costs of MDPP and there is a large gap between costs and payment, especially when serving beneficiaries from diverse and low-income populations. These commenters suggested CMS to consider increasing the proposed payment rates to fully cover costs, including for serving diverse and low-income participants. One commenter expressed concern that the proposed total maximum payment amount in the restructured 1-year set of services is less than that available under the 2-year set of services. This commenter suggested that CMS ensure the finalized maximum payment is equal to the current 2021 payment amounts.

Response: We agree with the commenters that redistributing all the ongoing maintenance session phase performance payments to certain core and core maintenance sessions will address some concerns of MDPP supplier underpayment and help support long term sustainability of MDPP services. After reviewing all of the comments received regarding the redistribution of the ongoing maintenance session phase performance payment amounts and the concerns about the inadequacy of the proposed payment amounts, we have determined that distributing the current total maximum payment amount will make MDPP more attractive to suppliers and increase beneficiary participation. We acknowledge that the final payment structure may remain insufficient to cover the costs of MDPP for some suppliers, but hope that increasing the maximum per beneficiary attendance-based payments by $253 may help address some of costs associated with

serving diverse and low-income participants. Stakeholders have told CMS that diverse and low-income beneficiaries have more barriers to weight loss, are less likely to achieve the 5 percent weight loss achieved performance goal, and require more effort from the MDPP suppliers. As such, by establishing payments with a heavy reliance on weight loss achieved, CMS is disincentivizing MDPP suppliers who serve diverse and low-income populations because the MDPP suppliers are receiving lower overall average per-beneficiary payments. We believe that shifting some of the payment amounts to the attendance only performance goals will increase the overall average per-beneficiary payment, thereby addressing some of the costs associated with serving diverse and low-income populations.

We are modifying the proposed § 414.84(b) and (c) to redistribute all the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments in the final rule. Based on this modification, the total maximum payment will increase from the proposed $661 to $705. The $705 payment amount is $1 more than the current maximum payment of $704 under the original 2-year payment structure. Table 39 illustrates the updates to the payment amount redistribution and total maximum payment. We believe that this modification, along with the removal of Year 2 from the MDPP set of services and the removal of the Medicare enrollment fee we are finalizing will help address some of the payment inadequacy comments we have received since MDPP was originally implemented.

Comment: In addition to recommending that CMS redistribute all the ongoing maintenance performance payments, many commenters suggested that CMS make further changes to the proposed payment structure. Specifically, commenters recommended that we increase the amount of the performance payments available at the beginning of the MDPP set of services. Commenters stressed that staff time and programming expenses are highest during recruitment and enrollment (before core session 1) and during the first few weeks of the services (between core sessions 1 and 4). One commenter, commented that the reimbursement structure needs to recognize the upfront costs to delivering the MDPP set of services. The commenter stated that payment levels should adequately cover the costs of core and maintenance sessions. The commenter stated that most organizations still see average cost of MDPP delivery in the $450—$600 range per participant. The commenter calculated that, while the commenter received $462.78 per beneficiary during the Y–USA model test, MDPP suppliers receive currently receive an average of $262.40 per MDPP participant based on 2020 fee schedule and would receive $342.56 per participant based on proposed 2022 fee schedule. Several commenters requested that CMS align the total payment amount with the original model.

The commenter encouraged CMS to further adjust the performance payment structure to pay more in the first 6 months of service delivery to ensure suppliers' up-front costs of serving a Medicare population (especially for organizations unused to health care administration costs) are covered sufficiently. This commenter stated that the current fee schedule does not account for any opportunity loss from recruitment efforts that do not convert to participation. Lastly, the commenter noted that the model's success relied on the power of community-based organizations delivering a low-cost program effectively, but these organizations are not in a position with capital on hand to wait for their first outcomes-based payments. Other commenters suggested that the payment structure should also reflect the services required by MDPP suppliers and their coaches to engage and build relationships with MDPP participants. Commenters stated that CMS should redistribute a portion of the payments, at least $100.00, to core session 1 to compensate organizations for successful recruitment and enrollment efforts and redistribute a portion of the payments, at least $100.00 each, to core sessions 4 and 9 to compensate organizations for successful retention efforts.

Response: We agree that the current MDPP payment structure may not match the upfront costs to MDPP suppliers to deliver the MDPP set of services. In response to these comments, we are modifying proposed § 414.84(b) and (c) to adjust the MDPP payment structure to increase the performance payments available at the beginning of the MDPP set of services. These changes to the payment structure will pay a total of $81 more per MDPP beneficiary who attends at least 9 sessions during the core sessions phase than proposed ($315 as finalized versus $234 as proposed) and $142 more per beneficiary who attends at least 9 sessions during the core sessions phase than the current 2021 payment rates ($315 as finalized versus $173 current 2021 payment rates).

As finalized, MDPP suppliers will receive a subtotal maximum payment for attendance only of $455. The proposed subtotal maximum payment for attendance only was $338 as proposed and $203 currently, the final payment structure will result in an increase of the subtotal maximum payment for attendance only of $117 and $252 respectively. As finalized, MDPP suppliers will receive a total maximum payment of $705. The proposed total maximum payment was $661 as proposed and $704 currently, the final payment structure will result in an increase of the total maximum payment of $41 and $1 respectively. We believe these adjustments will increase the average payment to MDPP suppliers within the estimated average cost of MDPP delivery in the $450—$600 range per beneficiary provided by a commenter and will align the average per beneficiary payment with the estimated per beneficiary payment amount associated with the original model.

As finalized, both core sessions 4 and 9 are over $100 ($105 and $175 respectively). While we increased the payment amount for the first core session from $26 to $35, we do not agree that CMS should increase the payment amount for the first core session further. First, continuous beneficiary attendance is critical to reaching key outcomes such as 5 percent weight loss and reduced Medicare spending. Our data from the DPP model test showed beneficiaries who finished at least nine (9) sessions of the model were considered ''completers'' and had better weight loss and lower Medicare spending than non-completers (those who attended fewer than 9 sessions). The DPP model test showed that beneficiaries who attend nine or more sessions will, on average, experience a 6.24 percentage point increase in weight loss compared to beneficiaries attending fewer than nine sessions. Second, increasing the payment amount for the first core session substantially may place the agency at a higher risk of fraud and abuse. A higher first core session payment may entice bad actors to enroll beneficiaries for the sole purpose of collecting the payment for the first core session with no intention of providing the remaining MDPP set of services. Not only does this create a risk to the agency, but it may create a risk for beneficiaries who may not be able to access the full MDPP set of services once they have attended the first session and no other services are offered. As such, we are finalizing the rule with the payment amounts listed in Table 39.

Comment: Commenters encouraged CMS to reduce the emphasis on performance payments for weight-loss achievement and increase the performance payments for attendance-only achievements so that the payment methodology provides a stronger financial incentive for attendance. One commenter recommended that CMS refrain from increasing the payment for the 5 percent weight loss achievement to $179.00; rather, CMS should maintain the current (2021) payment for the achievement of 5 percent weight loss ($169.00) and increase the payments for attendance of the core maintenance sessions from $52.00 to $62.00. Several commenters stated that the proposed increase of the payment to $179.00 for 5 percent weight loss could have the unintended consequence of encouraging organizations to pursue ongoing participation by those who have already achieved 5 percent weight loss over those that have not yet achieved the 5 percent weight loss during the 9 core maintenance sessions. Commenters stressed that there should be an adequate financial incentive for suppliers to promote attendance amongst individuals who do not achieve 5 percent weight loss in the first 6 months. One commenter opined that session attendance payments at a level that covers operating costs only when a participant achieves 5 percent weight loss, even for early sessions, establishes incentives for unrealistic, quick, weight loss that is not aligned with the design of DPP, or evidence-based diabetes prevention. The commenter suggested that reimbursement for session attendance should be increased, and set to encourage organizations to achieve consistent session attendance from participants.

Response: We agree with the commenters recommendations that we should reduce the emphasis on performance payments for weight-loss achievement and increase the performance payments for attendance-only achievements so that the payment methodology provides a stronger financial incentive for attendance. As several commenters pointed out, placing too much emphasis on the weight-loss achieved goal could incentivize MDPP suppliers to seek out beneficiaries who are more likely to lose weight instead of focusing on the attendance of all eligible participants. While MDPP is a performance-based expanded model, we want to emphasize the importance of attending MDPP sessions along with the 5 percent weight loss goal. We are modifying the proposed § 414.84(b) and (c) to adjust the MDPP payment structure to place more emphasis on beneficiary attendance consistent with Table 39. We agree that we should not increase the payment for the 5 percent weight loss achievement from $169 to $179.00. As we stated before, MDPP is a performance-based expanded model. The goal of the expanded model is for beneficiaries to lose 5 percent of their weight from baseline during their participation. As such, achievement of this goal will still result in a higher reimbursement amount. However, we want to also emphasize the importance of attending MDPP sessions, therefore, we are shifting a larger portion of the Year 2 reimbursement amount to the attendance-goals to place additional emphasis on the importance of session attendance during the MDPP set of services. As finalized, we will maintain the current 2021 payment for the achievement of 5 percent weight loss of $169.00 and increase the payments for attendance of the core maintenance sessions to from $52.00 to $75.00. As finalized, MDPP suppliers will receive a subtotal maximum payment for attendance Only of $455. The proposed subtotal maximum payment for attendance only was $338 as proposed and $203 currently, the final payment structure will result in an increase of the subtotal maximum payment for attendance only of $117 and $252 respectively. We believe that these changes will provide more financial incentive for suppliers to promote consistent attendance from participants regardless of weight loss achievement. We are finalizing the rule with the payment amounts listed in Table 39.

Comment: Other commenters suggested that CMS remove performance-based payments entirely and simply pay MDPP suppliers for delivering MDPP services. One commenter stated that continuing payments to MDPP suppliers contingent on the beneficiary achieving a weight loss goal, attending a specific number of sessions, or any other performance goal is not consistent with the DPP model test or other preventive health programs, such as smoking cessation and obesity interventions, which do not base payments on the beneficiary achieving an outcome. One commenter opined that they would like to see MDPP suppliers receive payments for their efforts put into the long journey to preventing diabetes, not just for the attainment of the goal. One commenter encouraged CMS to provide organizations with an adequate revenue stream for MDPP delivery when beneficiaries attend sessions, even if beneficiaries do not achieve 5 percent weight loss during the first nine sessions. This commenter noted that the complex payment methodology runs counter to CMS' goal of Burden Reduction, Patients Over Paperwork, and increases the operating costs of both Medicare suppliers and the MACs.

Response: While we agree with commenters that the MDPP payment structure does not align with preventive service benefits that are paid on a fee-for-for service basis, we disagree with the recommendations to align MDPP payments with that of other FFS prevention programs such as smoking cessation and obesity counseling. During the DPP model test, the Y–USA included attendance and weight loss as performance-based milestones. For an example, they tracked the number of participants who attended the 1st, 4th, and 9th core sessions and the number of participants who achieved the 5 percent and 9 percent weight loss goals. When OACT certified the DPP Model test in 2016, they based their payment structure assumptions on that of the DPP model test, and included performance-based payments for beneficiary achievement of attendance and weight loss milestones. MDPP is an expanded model, and it is different from the DPP model test in that it established a performance-based payment structure that is designed to incentivize MDPP suppliers to deliver a service that will result in weight loss and ultimately savings to CMS.

In addition, while we do not agree that the payment structure runs counter to the CMS goals of Burden Reduction and Patients Over Paperwork, or that it increases the operating costs of both Medicare suppliers and the MACs, we recognize that the current level of complexity may cause barriers in enrollment and payments. We believe that the changes we are finalizing in this rule will simplify the payment structure and increase the overall payments received by MDPP suppliers. We are finalizing the rule with the payment amounts listed in Table 39.

Comment: One commenter noted that the total proposed performance payment per beneficiary without the 5 percent weight loss is $338 compared to $661 for those that achieve and maintain weight loss. This commenter stated that the reduced reimbursement for beneficiaries who do not meet the 5 percent weight loss is unacceptable and is not cost beneficial for Tribal Health Programs to participate. This commenter stated that American Indians/Alaskan Natives (AI/AN) have the highest risk of Type II diabetes and face challenges on lack of quality medical care, lack of access to healthy

food, and lack of access to safe or adequate places for physical activity. They included data by the University of Kansas Medical Center on the success rate of AI/AN in diabetes weight loss programs that found that only 36 percent of AI/AN lost weight and among those who lost weight, 76 percent lost an average of 2.98 percent body weight and only 6 participants, out of 72, lost 7 percent or more of their body weight. If this sample study reflects AI/AN communities, the success rate for a Tribal member to achieve and maintain 5 percent weight loss is less than 10 percent. The commenter recommended that CMS use other health outcome measures such as reductions in blood sugar levels and hypertension risk, lower BMI levels, increased intake of healthy foods, increased rate of physical activity, or risk reduction factors for performance payments instead of weight loss.

Response: We acknowledge the evidence presented by the commenter that certain populations show improvements in health outcomes with participation in weight loss programs even though they do not achieve the 5 percent weight loss milestone. However, we did not propose to use other health outcome measures such as reductions in blood sugar levels, hypertension risk, or lower BMI levels instead of the 5 percent weight loss performance-based milestone, and we decline to adopt such changes at this time. As finalized, MDPP suppliers will receive a subtotal maximum payment for attendance only of $455, compared to the subtotal maximum payment for attendance only of $338 as proposed and $203 currently. The final payment structure will result in an increase of the subtotal maximum payment for attendance only of $117 and $252 respectively. We believe that these changes will provide more financial incentive for suppliers to promote consistent attendance from participants regardless of weight loss achievement.

The changes we proposed to the rule and the modifications we are finalizing in this rule are in direct response to those concerns. By reducing the emphasis on the weight-loss achievement goals and increasing the attendance-payment amounts, we believe that we will adequately incentivize MDPP suppliers to deliver MDPP services even when weight-loss has not occurred.

Comment: One commenter suggested that MDPP's lack of flexibility, such as risk-adjusted payments to serve patient populations that may face transportation and other barriers to attendance and/or who the evidence has shown may be less likely to achieve the 5 percent weight loss threshold contributes to increased health inequities and lack of opportunities for Medicare beneficiaries to participate.

Response: We agree that many eligible beneficiaries face challenges that impact their ability to lose weight and achieve the 5 percent weight-loss goal. However, we believe that risk-adjusted payments would be too complicated to add to the expanded model at this time. In addition, we do not currently have a sufficiently large cohort nor enough data to accurately risk adjust the payments.

Finally, we believe that reducing the MDPP set of services to 1 year, shifting all of the Year 2 reimbursement amounts, and placing more emphasis on the attendance only goal payments will provide more financial incentive for suppliers to promote consistent attendance from participants regardless of weight loss achievement and increase access to beneficiaries who are less likely to achieve the 5 percent weight loss threshold and with the potential to increase health equity for Medicare beneficiaries.

We will consider this recommendation for future rulemaking.

Comment: One commenter recommended that CMS increase payment for session attendance regardless of weight loss outcomes with a bonus when an attendee attends 4 sessions within 6 weeks and 9 sessions within 12 weeks.

Response: We are modifying the proposed regulation text at § 414.84(b) and (c) to adjust the MDPP payment structure to place more emphasis on beneficiary attendance consistent with Table 39. We are not considering adding any bonus payments at this time because we believe that these changes will provide more financial incentive for suppliers to promote consistent attendance from participants regardless of weight loss achievement. We are finalizing the rule with the payment amounts listed in Table 39.

Comment: One commenter recommended that CMS establish incremental weight loss outcome payments, paying for achievement of 4 percent weight loss and 5 percent weight loss. The commenter noted that adding the 4 percent weight loss outcome payment would align MDPP with the current National DPP standards which include a 4 percent outcome, based on evidence of diabetes prevention.

Response: We appreciate the commenters' support and interest in MDPP. We did not propose to adjust the 5 percent weight loss achievement goal and we decline to do so now because incremental weight loss measurements would overly complicate the payment structure and make it more difficult to evaluate for the MDPP expanded model. We will continue to evaluate MDPP's alignment with the CDC's DPRP and make updates as necessary and feasible.

Comment: One commenter recommended that CMS eliminate the 9 percent weight loss outcome payment.

Response: We appreciate the commenters' interest in MDPP. We did not propose to eliminate the 9 percent weight loss achievement goal and we decline to do so now. The 9 percent weight loss goal was an outcome measure in the original DPP model test, and we believe it is important to retain the 9 percent weight loss goal as an outcome of the MDPP expanded model test.

Comment: One commenter recommended that CMS establish an additional performance payment for each beneficiary who achieved the 5 percent weight-loss goal and then maintained the 5 percent weight-loss at the twelfth month of attendance.

Response: We did not propose to add any new performance payments to the performance structure and we decline to do so now because adding additional payments would create more confusion for MDPP suppliers regarding claims submission. In addition, we believe that the finalized payment amounts already provides a higher payment amount for MDPP beneficiaries who maintain weight loss throughout the end of the twelfth month. The payment amount for the final performance goal ''Attend 2 Core Maintenance Sessions'' during months 10–12 provides a higher payment amount $70 versus $93 for beneficiaries who have maintained the 5 percent weight-loss.

Comment: One commenter recommended that CMS consider prospective bundled payments for a certain number of initial core sessions.

Response: We will consider this recommendation for future rulemaking.

After consideration of the comments received, we are finalizing our proposals with the following modifications:

- Redistribute all the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments consistent with Table 39, and
- Maintain the current 2021 performance payment amount for achievement of the 5 percent weight loss goal, increase the payment amounts to the attendance only goals to incentivize attendance, and increase the total maximum payment to $705.

3. Changes to § 424.205(b)

Medicare requires all organizations that deliver MDPP services to enroll separately in Medicare as a MDPP supplier and pay an enrollment application fee. This places a unique burden on MDPP suppliers. Approximately 39 percent of these entities are non-traditional suppliers that serve their local communities to increase diversity, equity, and inclusion of their services, including but not limited to YMCAs, county health departments, community health centers, and non-profit organizations that focus on health education that otherwise would neither enroll nor be able to enroll as a Medicare supplier. Indeed, they are often very different from most other Medicare providers and suppliers in terms of business model and financial wherewithal, and they frequently furnish non-health care services to the community. In this vein, they cannot be considered in the same light as, for example, hospitals, SNFs, ambulance suppliers, or other organizations specifically and exclusively designed for the provision of health care services.

The provider/supplier enrollment fee for CY 2021 is $599. Although MDPP suppliers may submit a written request to CMS for a hardship exception to the application fee in accordance with § 424.514, many will not qualify. We have heard from stakeholders that the enrollment application fee factors into an organization's decision to participate in MDPP. Organizations must submit the provider enrollment fee during the initial start-up phase of their expanded model implementation. This is when costs are likely the highest for organizations and the timing of the first CMS reimbursement is farthest away. MDPP suppliers would need to provide a first core session to at least 24 beneficiaries to simply recoup the Medicare provider enrollment fee. For many potential MDPP suppliers, the provider enrollment application fee, when combined with the additional MDPP requirements, such as the claims processing requirements, result in an organization declining to invest in enrolling as an MDPP supplier.

On April 9, 2020, CMS, through the COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers, waived all provider enrollment application fees. We saw an immediate increase in MDPP supplier enrollment in Q2 2020, the quarter the blanket waivers were announced, but MDPP supplier enrollment slowed thereafter, likely due to the impact of the pandemic and many CDC National DPP organizations pausing their delivery of DPP. We believe that granting a waiver of the fee for MDPP suppliers to extend beyond the COVID–19 Emergency Declaration Blanket Waiver may increase MDPP supplier enrollment, which will ultimately improve beneficiary access to the expanded model and our ability to evaluate the outcome of the MDPP because increasing the number of MDPP suppliers may provide for a more robust evaluation of the expanded model. Given our prior discussion of the unique character of MDPP suppliers in comparison to more traditional provider and supplier types, we believe this policy change is warranted.

In an effort to minimize the impact of this potential barrier and allow for a more robust expanded model evaluation, we proposed to utilize CMS' waiver authority under section 1115A(d)(1) of the Act to waive the provider enrollment Medicare application fee (described in sections 1866(j)(2)(C)(i) and (ii) of the Act) for all organizations that submit an application to enroll in Medicare as an MDPP supplier on or after January 1, 2022. We proposed to amend our regulation at § 424.205 (b) to reflect this waiver.

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were unanimous in their support of CMS' proposal to waive the Medicare enrollment fee for MDPP suppliers as of January 1, 2021 indicating the fee is cost prohibitive for many potential suppliers. Several commenters suggested that this change will advance CMS' health equity agenda and increase access to MDPP services for beneficiaries. Several commenters pointed to the idea that this change may be helpful to local community-based suppliers and will encourage more organizations to apply as MDPP suppliers. Other commenters highlighted that this change will increase access to tribal health programs, improve the program's ability to reach diverse and underserved communities, and entice community-based organizations (CBOs) and FQHCs to enroll as MDPP suppliers. One commenter indicated that removing the fee, along with the proposal to also modify the performance payment structure CMS, could demonstrate significant strides to making the delivery of the MDPP set of services financially viable for organizations.

One commenter expressed concern that there are other hurdles a MDPP supplier faces when enrolling to be a supplier but did not provide details on these concerns. Another commenter indicated that additional changes to supplier enrollment, qualifying criteria, performance outcomes, and payment structure are necessary to incentivize more eligible organizations to enroll.

Response: We appreciate the comments and support of the proposed rule provisions. We agree that this change has the potential to improve access to MDPP and increase MDPP supplier enrollment. We acknowledged that there are additional hurdles faced by organizations enrolling as MDPP suppliers. Within this final rule, we have addressed changes to other areas of concern. In addition to waiving the provider enrollment Medicare application fee, we modified the proposed policy to preclude the provision of ongoing maintenance sessions unless the MDPP beneficiary has started his or her first core session on or before December 31, 2021. We will continue to explore ways to reduce other hurdles in the future.

Comment: One commenter expressed concern related to requirements and timeline for MDPP suppliers to submit data in order to obtain recognition by the CDC. The commenter indicated the collection of data is not applicable to their communities when there is no support for funding for their already under-served health care community.

Response: The CDC DPRP recognition requirements are outside of the scope of this rule. The provisions we are finalizing in this rule are only to waive the Medicare enrollment fee for MDPP suppliers as of January 1, 2021 and update the MDPP payment structure and payment amounts.

After consideration of public comments, we are finalizing as proposed.

4. Changes to § 424.502

We proposed to make a conforming amendment to § 424.502 to remove the reference to the CMS–20134 from the definition of ''institutional provider.'' The CY 2018 PFS final rule, which established the application fee for MDPP suppliers, amended the definition of ''institutional provider'' in section § 424.502 to state that MDPP suppliers that complete the CMS–20134 enrollment application are ''institutional provider[s]''. Thus, the application fee described in section § 424.514 applies to organizations enrolling in Medicare as MDPP suppliers. We proposed to reverse this policy by amending § 424.502 to remove the reference to the CMS–20134 thereby removing MDPP suppliers from the list

of institutional providers required to pay the Medicare enrollment fee under § 424.514. As proposed, § 424.514 will no longer be applicable to organizations enrolling in Medicare as an MDPP supplier.

We solicited comments on this proposal.

We did not receive public comments on this provision, and we are finalizing as proposed.

M. Clinical Laboratory Fee Schedule: Laboratory Specimen Collection Fee and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs

1. Background on Laboratory Specimen Collection Fees for COVID–19

In the CY 2022 PFS proposed rule (86 FR 39309), we stated that we continue to believe that the laboratory specimen collection fees for COVID–19 CDLTs established in the context of and for the duration of the PHE for the COVID–19 pandemic should conclude at the termination of the PHE, as originally announced in the March 2020 COVID–19 IFC (85 FR 19258). Specifically, we stated that we believe that these increased payments for specimen collection specifically for COVID–19 tests would no longer be warranted beyond the end of the PHE. The two new level II HCPCS codes established to identify specimen collection for COVID–19 testing specifically are: Code G2023 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) (Coronavirus disease [COVID–19]), any specimen source*); and code G2024 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–Cov–2) (Coronavirus disease [COVID19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source*), for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the PHE for COVID–19.

As discussed in the CY 2022 PFS proposed rule, the increased fees were intended to address additional resources needed specifically during the PHE for the COVID–19 pandemic, particularly for the collecting of specimens using nasopharyngeal and oropharyngeal swabs or collection of sputum, which required a trained laboratory professional and additional precautions to minimize exposure risks in handling specimens that are suspected or confirmed for COVID–19. We stated that we expect that the termination of the PHE will occur when there is a reduced risk of COVID–19, which will mean the increase of supplies, personal protective equipment (PPE), and heightened sterilization and safety protocols for laboratory specimen collection and handling will be at a more manageable level. Likewise, we stated that we expect the potential ongoing spread of COVID–19 likely will diminish after the PHE ends, which will mean that advanced safety precautions, extensive PPE, and specialized training for laboratory specimen collection likely will no longer be required to the same extent as during the PHE. Because we anticipated that the PHE will end when there is a reduced risk of COVID–19 and not before such circumstances exist, we maintained that the laboratory specimen collection fees for COVID–19 CDLTs established in the context of and for the duration of the PHE for the COVID–19 pandemic should conclude at the termination of the PHE (86 FR 39310).

2. Specimen Collection Fee and Travel Allowance for Clinical Diagnostic Laboratory Tests

In the CY 2022 PFS proposed rule (86 FR 39310), we requested broad comments on our policies for specimen collection fees and the travel allowance for consideration for possible updates to policies in the future through notice and comment rulemaking. We requested comments regarding the nominal specimen collection fees for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), how specimen collection practices may have changed as a result of, or from insight gained during, the PHE for COVID–19, what additional resources might be needed for specimen collection for COVID–19 CDLTs and other tests after the PHE ends, as well as comments related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from such patients.

The following is a summary of the public comments we received related to the specimen collection fee and changes in practice associated with the PHE for COVID–19 and our responses.

Comment: Several commenters expressed appreciation that CMS recognized the need for additional resources required for specimen collection during the PHE and also for the expansion of access to laboratory testing in the home for Medicare beneficiaries. One commenter expressed support for CMS' decision to end the increased payment amounts for specimen collection at the termination of the PHE, stating that many laboratories realized financial profits during the PHE and suggested that those profits will continue to provide incentive to perform COVID–19 testing even after the termination of the PHE.

Conversely, several commenters stated that instead of ending increased payments for specimen collection, CMS should instead expand and permanently authorize the specimen collection payment under HCPCS codes G2023 and G2024 and allow the usage of these codes for all CDLTs in order to compensate for the supplies, equipment, and sterilization protocols required for safe and uncontaminated specimen collection and handling in the suspected presence of SARS–CoV–2. Commenters stated that an increased payment for the specimen collection of all CDLTs is necessary to compensate for the supplies, equipment, and sterilization protocols required for safe specimen collection and handling, not just in cases with suspected presence of SARS–CoV–2. Several commenters requested that CMS permanently allow the usage of G2023 to report specimen collection for all sites of service where specimens are collected by clinical laboratories and not exclusively for homebound patients, suggesting that extending the payment of specimen to additional settings would improve patient access to laboratory testing. One commenter suggested that any site where clinical laboratory personnel collect specimens should be permitted to bill Medicare for G2023, including on-site collection at clinical laboratories, pharmacies billing as clinical laboratories, drive through testing locations, and urgent care clinics.

Several commenters stated that the COVID–19 pandemic has permanently altered the public health paradigm, which the commenters stated necessitates permanent and resource-intensive infection control measures that merit higher specimen collection fees to account for such costs as heightened safety precautions, the need for PPE, and special training for specimen collection beyond the immediate PHE. The commenters stated that the novel coronavirus is transmitted through the air, widely circulating variants (for example, beta, delta) will continue to spread, more variants are likely to continue to emerge, and the duration of the vaccine protective immunity is unknown. For these reasons, the commenters stated that additional PPE and safety procedures and training necessary for safe specimen collection will be necessary indefinitely. Several commenters also stated that herd immunity has not yet been achieved and may still be years away; therefore, ongoing special training and protective measures, including PPE,

which require additional costs and supplies, will remain necessary. One commenter also stated that even if the overall testing volume for the novel coronavirus decreases, additional resources on a per test basis will remain the same. One commenter stated that laboratory tests that provide self-collection kits still require professionals for processing of the specimens, who in turn need appropriate infection control resources for that activity.

Several commenters described the types of costs incurred and supplies needed for specimen collection, specifically:

- PPE including N–95 or higher respiratory or masks; face shields; goggles; gloves; isolation gowns;
- Specimen collection supplies including swabs; collection kits;
- Disinfecting and sterilization equipment including cleaning supplies; sanitizers; sterile gauze and bandages; biohazardous material disposal receptacles and bags;
- Laboratory training and expertise for staff, including employee time used for existing and new clinical laboratory technicians or health care professionals to train on proper specimen collection and handling techniques; and
- Additional staffing costs, including employee time for existing and additional new clinical laboratory technicians or health care professionals required to follow safe and accurate specimen collection procedures, enforce safe distancing requirements and fulfill administrative requirements such as logging information into infection control tracking databases at the institutional, local, State and/or Federal level.

Several commenters stated that other Federal agencies have both recommended and mandated enhanced protective measures, including the Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA), respectively, in suspected COVID–19 cases. Commenters also suggested that the laboratory specimen collection fee should be updated annually to reflect inflation and the growth in costs.

Response: We appreciate the comments regarding the nominal specimen collection fees for the collection of specimens for COVID–19 clinical diagnostic laboratory testing. We acknowledge that the types of resources utilized and supplies needed for specimen collection have been influenced by the PHE for COVID–19. We plan to take this feedback into consideration for possible future rulemaking or guidance.

The following is a summary of the public comments we received related to the methodology for calculating the travel allowance for laboratory specimen collection and our responses.

Comment: Several commenters described their concerns with the current travel allowance policy, stating that the current system requires the individual tracking of miles and paperwork documenting those miles, and the calculation of billable charges. Commenters stated that this system creates inconsistencies across facilities providing specimen collection services and creates confusion and burden for health care providers and Medicare Administrative Contractors (MACs).

Several commenters requested that CMS simplify the travel allowance by creating a single per-encounter flat-rate payment for travel to be updated annually by the Consumer Price Index for All Urban Consumers (CPI–U), which the commenters stated would eliminate the need for the current system which they describe as cumbersome and inefficient since it requires tracking individual miles traveled in paper or electronic logs. Commenters suggested that the single per-encounter flat-rate payment rate be calculated using total aggregate payments made for the travel allowance in 2018, divided by the number of patient encounters, and then reduced by a percentage in support of a separate rural add-on payment and updated annually to reflect inflation and the growth in costs.

Commenters also stated that a single per-encounter flat-rate payment to reimburse the travel allowance would simplify personnel and transportation expenses, eliminating the individual tracking of miles and paper documenting those miles, as well as the calculation of billable charges. The commenters stated that the flat-rate approach would also provide greater consistency across facilities served and reduce the burden on health care providers and MACs, and therefore, further support continued patient access to these laboratory services. Several commenters also stated that the travel allowance is prone to billing inconsistencies, so simplifying the calculation of the travel allowance would increase the overall understanding of the policy among stakeholders, decrease the instances of health care providers inadvertently overbilling for mileage, and reduce program integrity concerns, creating clarity for all parties involved.

Several commenters also requested that CMS create a rural add-on payment to supplement the single per-encounter flat-rate payment for travel, which the commenters stated would account for additional resources required to provide specimen collection in distant and remote areas and ensure that beneficiaries residing in rural areas can continue receiving specimen collection services.

Several commenters also suggested that if CMS does not adopt a flat rate approach, CMS should consider modifying the existing travel allowance payment structure. Commenters recommended that salary and travel costs used to determine the travel allowance be updated to account for increased labor and fuel costs and adequately cover the costs associated with transportation and personnel expenses for trained personnel to travel to the location to collect the sample. Commenters also suggested that mileage calculations begin at an eligible laboratory or patient locations and end when the trained personnel no longer have the specimen in their possession. Several commenters also recommended that business requirements outlined in the annual Medicare travel allowance change request be updated to require the contractor to search their files to adjust claims already paid at the prior year travel allowance rather than require action by health care providers, instructing contractors to review claims and reprocess at the updated rates.

Response: We appreciate the comments regarding the travel allowance for CDLTs. We plan to take this feedback into consideration for possible future rulemaking or guidance.

3. Medicare Clinical Laboratory Fee Schedule: Electronic Travel Logs

In the CY 2022 PFS proposed rule (86 FR 39310 through 39311), we stated that we are making permanent the option for laboratories to maintain electronic logs of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample. This option for laboratories to maintain electronic logs is not limited to COVID–19 specimen collection and applies to specimen collection for any CDLT. We will provide guidance in future instructions via forthcoming Change Requests and other materials such as MLN Matters® Articles. Laboratories will need to be able to produce electronic logs in a form and manner that can be shared with MACs, and should continue to consult with their local MACs regarding the format and process for ongoing submission of this information.

N. Medicare Provider and Supplier Enrollment

1. Enrollment Process

a. General Discussion

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Since 2006, we have taken steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements.

We believe the Medicare provider enrollment screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse. As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) Engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as discussed further in this section III.N. of this final rule, we proposed several changes to our existing provider enrollment regulations.

b. Legal Authorities

There are two principal categories of legal authorities for our provider enrollment provisions. First, section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers. Second, sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

2. Provisions

a. Expansion of Authority To Deny or Revoke Based on Office of Inspector General (OIG) Exclusion

Under §§ 424.530(a)(2) and 424.535(a)(2), respectively, CMS denies or revokes a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is excluded by the OIG. We proposed several changes related to these authorities.

First, we proposed to expand the categories of parties within the purview of these denial and revocation provisions to include excluded administrative or management services personnel who furnish services payable by a Federal health care program, such as a billing specialist, accountant, or human resources specialist. This change would align with existing OIG guidance stating that providers and suppliers may not employ excluded persons to provide management or administrative services that are payable by a Federal health care program.[143]

Second, existing § 424.530(a)(2) references ''other health care personnel furnishing Medicare reimbursable services who is required to be reported on the enrollment application.'' To conform to our change described in the previous paragraph, we proposed to replace this language with ''other health care or administrative or management services personnel furnishing services payable by a Federal health care program.'' We also proposed to include this language within § 424.535(a)(2) so that the latter aligns with § 424.530(a)(2).

Third, § 424.535(e) states that if the revocation was due to adverse activity (sanction, exclusion, or felony) against an owner, managing employee, authorized or delegated official, medical director, supervising physician, or other personnel of the provider or supplier furnishing Medicare reimbursable services, the revocation may be reversed if the provider or supplier terminates (and submits proof that it has terminated) its business relationship with that individual within 30 days of the revocation notification. For the reasons already outlined, we proposed to replace the language in § 424.535(e) concerning other personnel furnishing Medicare reimbursable services with ''other health care or administrative or management services personnel furnishing services payable by a Federal health care program.''

We received several public comments on these proposals. The following is a summary of them and our responses.

Comment: Several commenters expressed concern that providers and suppliers (in their efforts to follow OIG compliance guidelines) may miss instances where a person they are reviewing against the OIG exclusion list has a name that does not exactly match that indicated on the OIG list as an excluded party, yet the two parties are in fact the same; this could mean that such person might avoid detection. The commenters suggested an exception to the application of expanded §§ 424.530(a)(2) and 424.535(a)(2) if the provider or supplier demonstrated a good-faith effort to identify potentially excluded parties among their employees or other personnel.

Response: We respectfully disagree with the commenters' recommended good-faith exception. It is ultimately the provider's or supplier's responsibility to ensure that the parties addressed in §§ 424.530(a)(2) and 424.535(a)(2) are not excluded by the OIG. While we recognize that this task may take more time with respect to a particular party if, for instance, the name-match issue to which the commenter refers arises, this does not and should not negate the provider's or supplier's responsibilities in this regard. The central principle associated with §§ 424.530(a)(2) and 424.535(a)(2) involves the provider's or supplier's need to avoid relationships with OIG-excluded parties, not the level of effort the provider or supplier undertook to confirm that no such relationships exist.

[143] *https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.*

Comment: One commenter maintained that our proposal could increase provider burden, particularly for smaller practices. The commenter stated that some providers and suppliers hire third-party organizations to submit claims and perform other functions on their behalf; as part of these contracts, the third-party performs OIG exclusion searches on the persons who will be undertaking these activities. The commenter stated that our proposal would require providers and suppliers to update such contracts to ensure that the provider or supplier is held harmless should the third-party fail to adequately conduct these searches. The commenter recommended that CMS mitigate the administrative burden and other impacts of this proposal.

Response: Consistent with our response to the previous commenters, we believe that the provider or supplier bears primary responsibility for ensuring adherence to Federal regulations irrespective of whether it delegates any compliance verification activities to a third-party. As for impact reduction, we emphasize that the only parties to which our expansion of §§ 424.530(a)(2) and 424.535(a)(2) would apply are those engaged in administrative or managerial services that are payable by a Federal health care program; if the service does not fall within this latter category concerning Federal reimbursement, the expansion is inapplicable. Moreover, we believe that: (i) Many providers and suppliers already review such parties against the OIG exclusion list; and (ii) many of these parties also fall within one of the other categories addressed in §§ 424.530(a)(2) and 424.535(a)(2) (for example, managing employees), meaning that they are already covered under these two regulatory provisions. Given the foregoing, we do not foresee an increase in the overall administrative effect of §§ 424.530(a)(2) and 424.535(a)(2) on the provider community.

After consideration of these public comments, we are finalizing our revisions to §§ 424.530(a)(2) and 424.535(a)(2) as proposed.

b. Deny or Revoke Enrollment for Surrender of Drug Enforcement Administration (DEA) Certificate of Registration in Response to Show Cause Order

We have existing authority under § 424.530(a)(11)(i) to deny a physician's or other eligible professional's enrollment if his or her DEA certificate of registration to dispense a controlled substance is currently suspended or revoked; a concomitant authority to revoke enrollment in this circumstance is outlined in § 424.535(a)(13)(i). We proposed to expand these authorities to include situations where the physician or other eligible professional surrenders his or her DEA certificate in response to an order to show cause.

We have encountered situations where a physician or other eligible professional who has engaged in improper prescribing or other DEA-monitored activities relinquishes his or her DEA certificate pending a DEA show cause order so as to avoid a likely suspension or revocation of his or her DEA certificate or other similar circumstance. We believe these scenarios are no less serious from the standpoints of program integrity and beneficiary safety than a DEA certificate suspension or revocation. Hence, we believe this change is warranted.

We received several public comments on these proposals. The following is a summary of them and our responses.

Comment: Several commenters supported our proposal to expand §§ 424.530(a)(11)(i) and 424.535(a)(13)(i). However, they urged that: (1) CMS carefully consider the facts of each situation before taking action; and (2) appeals processes be available for individuals denied or revoked under these provisions. One commenter stated that there could be reasons a physician surrendered his or her DEA certificate prior to a show cause order that may not merit denial or revocation. The commenter wanted CMS to ensure that innocent physicians are not revoked, since this could affect patient care.

Response: We appreciate the commenters' support. We would closely examine the facts of cases involving expanded §§ 424.530(a)(11)(i) and 424.535(a)(13)(i) to determine whether a denial or revocation is warranted; should either of these latter actions ensue, the provider or supplier could appeal the matter under 42 CFR part 498.

After consideration of these public comments, we are finalizing our revisions to §§ 424.530(a)(11)(i) and 424.535(a)(13)(i) as proposed.

c. Creation of Specific Rebuttal Rights for Deactivations

As outlined in § 424.540, deactivation means that the provider's or supplier's billing privileges are stopped (but not revoked or terminated). Deactivation is intended to protect the provider or supplier from the misuse of its billing number and to safeguard the Trust Funds from unnecessary overpayments. Under existing regulations, a provider's or supplier's billing privileges may be deactivated if the provider or supplier: (1) Does not submit any Medicare claims for 12 consecutive calendar months; (2) fails to report certain changes in its enrollment information within required timeframes; or (3) fails to fully and accurately comply with a CMS revalidation request within 90 days.[144]

Since a deactivated provider's or supplier's billing privileges are stopped, § 424.545(b) permits the affected provider or supplier to file a rebuttal in accordance with 42 CFR 405.374 (which allows rebuttals for Medicare payment suspensions). While we have outlined deactivation rebuttal procedures in subregulatory guidance, these procedures are not reflected in regulation. Consequently, we proposed to revise 42 CFR part 424, subpart P to describe the deactivation rebuttal process in detail, a process that would generally mirror our existing subregulatory procedures on the topic.

The specific changes we proposed were as follows:

- At § 424.545(b), we proposed to change the language that reads ''in accordance with § 405.374 of this chapter'' to ''in accordance with § 424.546.'' Instead of continuing to reference § 405.374, we proposed to create a new § 424.546 to address the deactivation rebuttal process.
- At new § 424.546(a)(1), we proposed that if a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated under § 424.540, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS.
- At new § 424.546(a)(2), we proposed that CMS may, at its discretion, extend the 15-day time-period referenced in § 424.546(a)(1).
- At new § 424.546(b)(1) through (4), we proposed that any rebuttal must: (1) Be in writing; (2) specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or effective date, as well as the reasons for disagreement; (3) submit all

[144] We proposed additional grounds for deactivation in the CMS proposed rule titled, ''Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-term Care Hospital Quality Reporting Program Requirements'' (CMS–1747–P).

documentation the provider or supplier wants CMS to consider in its review of the deactivation; and (4) be submitted in the form of a letter that is signed and dated by the individual supplier (if the latter is enrolled as an individual physician or NPP), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in 42 CFR 498.10). Concerning paragraph (b)(4), if the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement will be sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

- At new § 424.546(c), we proposed that the provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (a) and fully compliant with all of the requirements of paragraph (b) constitutes a waiver of all rebuttal rights under this section and § 424.545(b).
- At new § 424.546(d), we proposed that upon receipt of a timely and compliant deactivation rebuttal, CMS reviews the latter to determine whether the imposition of the deactivation and/or the designated effective date are correct.
- At new § 424.546(e), we proposed that nothing in § 424.546 or § 424.545(b) will require CMS to delay the imposition of a deactivation pending the completion of the CMS review described in paragraph (d).
- At new § 424.546(f), and consistent with both current subregulatory policy concerning deactivation rebuttals, as well as payment suspension rebuttal regulations at § 405.375(c), a determination made under § 424.546 will not be an initial determination under § 498.3(b) and, therefore, will not be appealable.

We received several public comments on these proposals. The following is a summary of them and our responses.

Comment: Although supporting our proposal to address deactivation rebuttal rights in regulation, several commenters suggested modifications. First, some commenters recommended that a deactivated provider or supplier have 30 days from its receipt of the deactivation notice to submit its rebuttal. One commenter stated that this would account for situations where mail is delayed or the deactivation notice was sent to the wrong location. Second, a good cause exception should exist for untimely or less-than-fully compliant rebuttals; an example would be when the provider or supplier could not access all the documentation it needed to support its rebuttal. Third, CMS should have to make its determination regarding the rebuttal submission within 15 days of receiving it. Disagreeing that CMS' decision is not an initial determination (as proposed § 424.546(f) states), the commenter believed that a 15-day response time for CMS was warranted or, in lieu of this, CMS should afford formal appeal rights; otherwise, CMS would have no incentive to quickly review a rebuttal submission.

Response: We respectfully disagree with these recommendations and assertions for several reasons. First, we believe our proposed 15-day timeframe is sufficient for the provider or supplier to prepare and submit a detailed rebuttal. Indeed, this has been our experience with payment suspensions under § 405.372, for which the affected provider or supplier has 15 days from the date of the payment suspension notice to submit a rebuttal under § 405.374. Second, it is the deactivated provider's or supplier's responsibility to ensure that its rebuttal is timely and complete. Requiring CMS to grant good cause exceptions (above and beyond the discretionary timeliness extension that CMS may provide under proposed § 424.546(a)(2)) could lead providers and suppliers to conclude that a fully compliant rebuttal is unnecessary because an exemption will typically be furnished. Third, we believe that deactivated providers and suppliers would want CMS to give the most thorough and detailed consideration of their rebuttal submission; this is our desire as well. To afford us this ability, therefore, we do not believe our timeframe for review should be so restricted. Fourth, we maintain our long-held position that a deactivation should neither constitute an initial determination nor entail appeal rights under 42 CFR part 498. This is because, unlike with a revocation, a deactivated provider or supplier remains enrolled in Medicare and does not lose their billing privileges. Therefore, we believe that a rebuttal (as opposed to 42 CFR part 489 appeal rights) is a proper and proportionate mechanism for the deactivated provider or supplier to contest the action.

Comment: A commenter suggested that CMS give a deactivated provider or supplier 20 days (rather than 15) from the date it received the deactivation notice to submit its rebuttal. In a similar context, another commenter suggested that the timeframe be 15 days from the date of receipt of the deactivation notice instead of 15 days from the date of the notice itself; this presumes a 5-day timeframe for the notice to reach the provider or supplier via mail.

Response: For reasons already stated, we believe that 15 days from the date of the notice is an adequate rebuttal timeframe.

Comment: A commenter encouraged CMS to implement a system for correspondence (such as deactivation notices) to be sent and received electronically. The commenter stated that they believe this would lead to cost savings and more efficient communication.

Response: We appreciate and will consider this suggestion with respect to provider enrollment correspondence, for we constantly seek to improve the enrollment process and alleviate burden for all stakeholders.

After consideration of these public comments, we are finalizing our aforementioned deactivation rebuttal provisions as proposed.

d. Modernizing Enrollment Policies for Emerging Technologies in Independent Diagnostic Testing Facilities

Section 410.33(a) states that CMS pays for diagnostic procedures under the PFS only when performed by the suppliers listed in that section. Among these supplier types are independent diagnostic testing facilities (IDTFs). An IDTF may be a fixed location, a mobile entity, or an individual NPP. It is independent of a physician's office or hospital, although the IDTF regulations outlined in § 410.33(a) also apply when an IDTF furnishes diagnostic procedures in a physician's office.

Section 410.33 as a whole contains provisions with which IDTFs must comply in order to enroll in (and maintain enrollment in) Medicare, such as requirements for nonphysician personnel (§ 410.33(c)). In addition, § 410.33(g) contains various compliance standards that IDTFs must meet. We established these standards to help ensure the quality and safety of IDTF diagnostic testing and to strengthen our ability to verify the IDTF's adherence to enrollment requirements.

IDTFs generally perform diagnostic tests on beneficiaries in, for instance, a health care facility, physician's office, or mobile setting. The IDTF standards at § 410.33(g) (as well as other provisions at § 410.33) were, in fact, designed for traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing.

Yet some health care entities have developed or utilize diagnostic tests that do not require such interaction. That is, certain IDTFs perform diagnostic services via computer modeling and analytics, or other forms of testing not involving direct beneficiary interaction. The service is often conducted by a technician who undertakes a computer analysis offsite or at another location at which the patient is not present. The physician then reviews the image to determine the appropriate course of action. In short, these entities generally, though not exclusively, have two overriding characteristics. First, the tests they perform do not involve direct patient interaction, meaning that the test is conducted away from the patient's physical presence and is non-invasive. Second, the test involves off-site computer modeling and analytics.

Despite the comparatively new and innovative forms of testing these entities undertake, they can still qualify as IDTFs (notwithstanding the offsite and indirect nature of the test) so long as they meet the applicable requirements of § 410.33. The dilemma is that these entities often cannot meet certain IDTF requirements, and thus cannot enroll in Medicare, strictly because of the test's indirect nature. In other words, the types of tests at issue do not fall within the category of those to which several of our standards in § 410.33 were intended to apply (specifically, to in-person procedures). To account for such technological advances in diagnostic testing, we believe that revisions to § 410.33 are necessary. To this end, we proposed that IDTFs that have no beneficiary interaction, treatment, or testing whatsoever at their practice location will be either partially or wholly exempt from the following requirements in § 410.33 (hereafter occasionally referenced as ''exempted'' IDTFs).

Section 410.33(c) requires all nonphysician personnel the IDTF uses to perform diagnostic tests to demonstrate the basic qualifications to perform these tests as evidenced by State licensure or State certification; the IDTF must maintain documentation available for review that these requirements are met. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. However, the aforementioned indirect tests and the performing personnel frequently do not require State licensure or State/national credentialing, meaning that § 410.33(c) becomes a difficult requirement for such IDTFs to meet. Indeed, § 410.33(c) has typically been applied to the qualifications needed to perform in-person tests in traditional IDTF settings; that is, the staff at exempted IDTFs often will instead be primarily trained in the test's particular software and computer analytics (or other non-beneficiary-based services)). Extending § 410.33(c)'s purview to indirect tests reduces the number of personnel who can perform them, thus hindering beneficiary access to such services and potentially preventing the enrollment of otherwise qualified IDTFs.

Accordingly, we proposed to divide current § 410.33(c) into two paragraphs. New paragraph (c)(1) would contain the existing requirements of § 410.33(c), with an exception for exempted IDTF personnel in new paragraph (c)(2). We proposed in the latter paragraph that, for services that do not require direct or in-person beneficiary interaction, treatment, or testing, any nonphysician personnel performing the test must meet all applicable State licensure requirements for doing so; if such State licensure requirements exist, the IDTF must maintain documentation available for review that these requirements have been met.

While we believed that personnel performing the tests described in paragraph (c)(2) should meet whatever State requirements exist for those services, paragraph (c)(2) did not include any reference to national credentialing bodies. Further, we recognized that, in some instances, States may have no requirements for technicians involved in the particular type of computer analytics involved in the Medicare-covered service.

We also proposed that the following IDTF certification standards in § 410.33(g) would not apply to exempted IDTFs:

- The IDTF must have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF (§ 410.33(g)(6)).
- The IDTF must answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (§ 410.33(g)(8)).
- The IDTF must openly post the standards outlined in § 410.33(g) for review by patients and the public (§ 410.33(g)(9)).

Concerning § 410.33(g)(8), exempted IDTFs would not be furnishing direct services to beneficiaries that could result in a beneficiary's written clinical complaint. Thus, we believe this standard should be inapplicable to exempted IDTFs, and we proposed to revise paragraph (g)(8) in this vein. We proposed a similar approach with § 410.33(g)(9); neither beneficiaries whose tests are sent to the exempted IDTF nor the public in general would visit its physical location, therefore negating the need for a posting of standards. As for § 410.33(g)(6), the liability policy addressed therein was designed for IDTFs that provide services to beneficiaries in a facility or mobile unit and, thus, could have issues concerning medical negligence and/or malpractice. We recognized, however, that the performance of a particular test by an exempted IDTF could raise questions of possible liability. Therefore, we solicited public comment on the types of situations where this could arise, as well as on the following issues: (1) Whether exempted IDTFs should indeed be required to maintain a $300,000 liability policy; (2) whether a liability amount of less than $300,000 is warranted for these IDTFs and, if so, what that amount should be (for example, $50,000 or $100,000 or $200,000); and (3) whether no liability policy should be required for exempted IDTFs. (We also solicited comment on whether we should still apply the IDTF standards in § 410.33(g)(6) and (8) to exempted IDTFs.)

We received several public comments on these proposals. The following is a summary of them and our responses thereto:

Comment: Several commenters supported our proposed IDTF supplier standard exemptions.

Response: We appreciate the commenters' support.

Comment: Several commenters asked CMS to clarify that the proposed exemptions apply when there is no direct or in-person beneficiary interaction, treatment, or testing at the place of the delivery of the service—that is, at the IDTF. One commenter explained that when an IDTF performs or administers an entire diagnostic test at, for example, the beneficiary's location, the beneficiary's location is the place of service; however, when one or more aspects of the test are performed at the IDTF, the IDTF is the place of service. To avoid any confusion as to the exemptions' applicability, the commenter suggested regulatory text stating that our exemptions would apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing at the place of service as defined in § 410.33(e)(2).

Response: We do not believe the recommended change is necessary. The current standards in § 410.33(g) have always applied to the IDTF itself irrespective of the place of service under

§ 410.33(e)(2). Indeed, § 410.33(e)(2) deals mostly with claim submission requirements and is largely immaterial to the question of whether the IDTF meets the § 410.33(g) standards. We believe that the regulatory wording of our exemptions is clear as to the scope of the latter's applicability and that no need exists for a reference therein to § 410.33(e)(2).

Comment: Several commenters suggested that CMS retain the liability insurance requirement for exempted IDTFs. One commenter stated that malpractice liability could occur with these IDTFs as it does with IDTFs that perform in-person testing; if the exempted IDTF's malpractice risk is low, the insurance should not be expensive.

Response: We maintain our position that liability insurance would be largely inapplicable to IDTFs performing indirect, non-in-person testing. Nevertheless, we intend to closely monitor the implementation of our § 410.33 exemptions, including that pertaining to § 410.33(g)(6). Should we determine that modifications to our exemptions are necessary based on, for instance, program integrity or quality assurance concerns, future rulemaking will be considered.

Comment: Several commenters recommended that CMS not finalize its proposed IDTF nonphysician personnel exemption regarding national credentialing and instead outline credentialing requirements (State and/or Federal) for these individuals. The commenters stated that they do not believe that, in the absence of applicable State licensure requirements, such personnel should be permitted to operate without meeting any qualifications; they maintained that staff performing any test (with or without direct beneficiary interaction) should be qualified to do so. The commenters also stated that they believe these persons should have national certification from a national accrediting body if no State licensure requirements exist. Some commenters suggested that if CMS does not establish formal national credentialing requirements for such personnel, the exempted IDTFs could at least be required to submit evidence that their nonphysician staff have some type of national certification.

Response: We believe that our proposed exemption language in § 410.33(c)(2) is appropriate. Our understanding is that there are very few, if any, national health care certifications applicable to the technicians who will be performing indirect tests with no beneficiary interaction; many of these individuals are instead trained in non-health care related computer analytical fields. To require them to be nationally credentialed by a national health care accrediting body would, in many cases, prohibit them from performing IDTF tests. This result would be inconsistent with the general aim of our exemptions, which is to prevent unnecessary and insurmountable barriers to the enrollment of these types of IDTFs. As with the aforementioned liability insurance exemption, however, we will maintain oversight of the enforcement of § 410.33(g)(2) and, if necessary, consider modifications in future rulemaking.

Comment: Though supportive of our IDTF proposals, a commenter urged CMS to continually examine how Medicare enrollment and other applicable regulations can be modified to allow for greater use of innovative technologies.

Response: We agree with this comment and will consistently review our enrollment regulations and policies to, as warranted, account for emerging health care innovations.

Comment: Several commenters recommended that CMS not finalize its exemption regarding the posting of IDTF standards at the IDTF's place of business; at a minimum, exempted IDTFs should have to post the standards online for review by IDTF personnel and beneficiaries. One commenter explained that even if patients are not on-site at the IDTF, they should have access to, and understand, the standards required of exempted IDTFs and their technicians.

Response: We respectfully disagree that the above-referenced exemption should not be finalized. As previously indicated, the IDTF standards in § 410.33(g) were originally intended for traditional IDTFs engaging in direct or in-person beneficiary interaction, treatment, and/or testing at the IDTF site. This was especially true concerning § 410.33(g)(9), the core aim of which is to ensure that beneficiaries visiting the facility can actually view the standards while on site. Given that exempted IDTFs neither test nor treat patients at its location, such entities simply do not fall within the scope of facilities to which § 410.33(g)(9) was always meant to apply. However, should we later determine that modifications to this exemption are warranted, we will consider future rulemaking.

Comment: Several commenters stated that CMS should, for several reasons, create an additional exemption concerning § 410.33(g)(15)(i), which prohibits a fixed-based IDTF (excluding hospital-based IDTFs) from sharing its practice location with another Medicare provider or supplier. First, the commenters stated that the space-sharing prohibition (like other IDTF standards) is primarily directed towards IDTFs that treat patients on-site and is largely immaterial to indirect testing situations. Commenters also maintained that the prohibition is designed to prevent improper referral arrangements and kickbacks but that IDTFs with no on-site beneficiary interaction often simply seek to share administrative resources, which does not fall within the scope of the aforementioned inappropriate activities; the risk these IDTFs therefore pose in a space-sharing situation is comparatively small. In addition, the space-sharing prohibition currently does not apply to IDTFs that are mobile, a scenario the commenters believed is somewhat akin to off-site, indirect testing. Finally, the commenters stated that enforcing the space-sharing prohibition against exempted IDTFs could limit beneficiary access to care.

If a complete exception from this standard is unfeasible, the commenters requested that CMS at least elucidate the scope of the standard's application to exempted IDTFs that seek to share administrative and non-clinical operations with another remote provider or supplier, where neither entity provides on-site patient services.

Response: We believe the space-sharing prohibition should still apply to exempted IDTFs. The overall concept behind this prohibition is that each IDTF must independently meet all IDTF requirements on its own merits, rather than in unison with another IDTF or Medicare provider or supplier. Even with the beneficiary off-site, having two exempted IDTFs at the same location could lead to confusion as to which IDTF performed the test, which personnel were used, etc. Given the program integrity concerns (which remain) that led to the establishment of our IDTF standards many years ago, we believe that the potential intermingling of IDTF resources via space-sharing should be avoided, regardless of whether beneficiaries are actually seen at the IDTF site. Moreover, and at least for purposes of the space-sharing exemption, mobile IDTFs are not analogous to exempted IDTFs. This is because it is, by and large, physically impossible for two mobile IDTF units to share the same space.

Any clarification regarding the scope of the space-sharing exemption's applicability to the sharing of exempted IDTF resources would, as needed, be addressed in future rulemaking or guidance.

Comment: Several commenters recommended that CMS limit and modify its proposed exemption from

§ 410.33(g)(8). First, they maintained that complaints could be maintained at a single location (which need not be on-site), though they must be made available to CMS upon request. In addition, the exempted IDTF should be able to require beneficiaries to submit clinical complaints in writing via a specified submission form or process (such as a comment ''box''), provided the IDTF informs beneficiaries of this requirement. The commenters stated that these two revisions would reduce the administrative burden on exempted IDTFs while ensuring that they can still properly address beneficiary complaints.

Response: For reasons similar to those stated previously in this section not to finalize our proposed exemption to § 410.33(g)(9), we do not believe modifications to our proposed § 410.33(g)(8) exemption are needed. The original and continued purpose of § 410.33(g)(8) is to make certain that beneficiaries receiving direct, in-person tests can register clinical complaints. It was never intended to apply to situations where testing is distant and indirect, and we believe our § 410.33(g)(8) exemption falls within the original intent of § 410.33(g)(8). However, should we determine in the future that revisions to this exemption might be required, rulemaking will be contemplated.

Comment: One commenter requested that CMS clarify the use of the language ''licensure or certification by the appropriate State health or education department'' currently in § 410.33(c), a paragraph we proposed to redesignate as § 410.33(c)(1) though without any change in its content or meaning. Specifically, the commenter stated this provision should clarify that a technician who receives certification (related to services furnished in the IDTF) from an educational program at a school overseen by the State's education department satisfies the requirements of existing § 410.33(c), irrespective of any national certifications. The commenter maintained that such an interpretation is consistent with CMS' general policy concerning IDTF technician requirements and would better explain the types of State requirements that must be met. The commenter also urged CMS to confirm that an IDTF can use the aforementioned State certification in lieu of national credentialing to demonstrate § 410.33(c) compliance.

Response: We believe that the commenter is seeking clarification of the policies in existing § 410.33(c) rather than our proposed exemption in § 410.33(c)(2). Since, aside from the aforementioned redesignation, we did not propose any change to current § 410.33(c) or the policy therein, we believe this comment is outside the scope of this final rule.

Comment: A commenter stated that proposed § 410.33(c)(2) does not include the language in current § 410.33(c) concerning certifications from an educational program at a school overseen by the State's education department. The commenter asked CMS to explain this omission and/or more thoroughly identify the types of State qualifications (for example, certifications) by which exempted IDTF nonphysician personnel can demonstrate compliance with Federal and State requirements.

Response: Existing § 410.33(c)'s reference to State education program certifications was not included in proposed § 410.33(c)(2) because we do not believe such certifications, which frequently focus on direct patient testing, would generally apply to the off-site, computer analytics-oriented testing that exempted IDTFs perform. As stated in proposed § 410.33(c)(2), IDTF personnel must meet State licensure requirements for the tests being performed, assuming such requirements exist; nothing in proposed § 410.33(c)(2) permits education to be used in lieu of licensure.

Comment: One commenter requested that CMS clarify the applicable State licensure laws for nonphysician personnel at exempted IDTFs; specifically, the commenter asked whether the laws of the State in which the beneficiary is located or the State of the IDTF's practice location are governing.

Response: The applicable State law in the commenter's scenario is the State in which the IDTF's practice location (as reported on the Form CMS–855) is located.

After consideration of these public comments, we are finalizing our aforementioned IDTF provisions as proposed.

e. Revisions at § 424.535(a)(8)

Under § 424.535(a)(8)(ii), CMS may revoke a provider's or supplier's enrollment if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In determining whether a revocation is appropriate under § 424.535(a)(8)(ii), CMS considers, as appropriate and applicable, the factors outlined in § 424.535(a)(8)(ii)(A) through (F); respectively, these are:

(A) The percentage of submitted claims that were denied.

(B) The reason(s) for the claim denials.

(C) Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

(D) The length of time over which the pattern has continued.

(E) How long the provider or supplier has been enrolled in Medicare.

(F) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

We have recently encountered situations where providers and suppliers have engaged in periods of non-compliant billing that, though comparatively brief, have or could have harmed the Medicare program. While we have attempted revocation action per § 424.535(a)(8)(ii) against such providers and suppliers, the current wording of some of the factors in paragraphs (a)(8)(ii)(A) through (F) have hampered our ability to do so. To increase our flexibility to address periods of abusive billing irrespective of their duration, we proposed to revise § 424.535(a)(8)(ii)(A) through (F) as follows:

- In paragraph (a)(8)(ii)(A), we proposed revisions to focus on the percentage of denials within subsets of the provider's or supplier's claim submissions rather than across the entire universe of their claim submissions. Specifically, we would consider the percentage of submitted claims that were denied during the timeframe under consideration. We believe existing paragraph (a)(8)(ii)(A) inhibits our capacity to target brief periods involving a significant percentage of denied claims; this is because this factor has been interpreted to require said percentage to be weighed against claim denials over the entire period of the provider's or supplier's enrollment. Proposed revised paragraph (a)(8)(ii)(A) would better enable CMS to address these non-compliant periods by restricting the scope of denial percentages to a shorter duration.
- For reasons similar to our revision of § 424.535(a)(8)(ii)(A), we proposed to remove § 424.535(a)(8)(ii)(D) altogether. As already indicated, short but very intense periods of improper billing can endanger the Medicare program no less than a longer pattern of non-compliant yet merely moderate-volume billing. Yet the ''length of time'' standard in paragraph (a)(8)(ii)(D) often deters us from taking action under paragraph (a)(8)(ii) to address these shorter timeframes. Given this, we believed that eliminating paragraph (a)(8)(ii)(D) would strengthen our program integrity efforts.

• We also proposed to remove § 424.535(a)(8)(ii)(E), which addresses the length of the provider's or supplier's enrollment. We believed the enrollment length should have no bearing on whether paragraph (a)(8)(ii) can be applied, for the main issue is the behavior itself and not the period of enrollment.

• We proposed to remove § 424.535(a)(8)(ii)(B) as well. Notwithstanding our original inclusion of this factor in paragraph (a)(8)(ii), the overall purpose of paragraph (a)(8)(ii) has always been to deter non-compliant billing, regardless of the reason for it. Even if a period of erroneous claim submissions reflected no nefarious intent by the provider, the latter still failed to comply with Medicare billing requirements and thus presented a risk to the Medicare program. For this reason, we do not view the claim denial reason as particularly germane to the question of whether paragraph (a)(8)(ii) should apply in a particular case.

• In addition, we proposed to add new paragraph (a)(8)(ii)(C) by which we would consider the type of billing non-compliance and the precise facts surrounding said non-compliance (to the extent this can be determined). We believed this paragraph would provide slightly more specificity than the broader, catch-all factor at § 424.535(a)(8)(ii)(F) (which we will nonetheless retain). It would also allow us to more narrowly tailor our review to the unique facts of the case, thus also strengthening our ability to consider any aggravating or mitigating circumstances.

In summary, we proposed that paragraph (a)(8)(ii) would include the following factors, respectively designated as paragraphs (A) through (D):

• The percentage of submitted claims that were denied during the period under consideration.

• Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

• The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

• Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

We received several public comments on this proposal. The following is a summary of them and our responses thereto:

Comment: Several commenters expressed concern about our proposal. They stated that the proposed revision and/or removal of factors in § 424.535(a)(8)(ii) gives CMS unfettered discretion to target any short period of non-compliant billing without having to consider the provider's/supplier's behavior during its period of enrollment. The commenters stressed that brief periods of erroneous claims can occur for many reasons (for example, technological, system, or inadvertent mistakes, or changes in CMS or MAC procedures) without any ill intent by the provider or supplier; in some cases, the provider or supplier may be unaware that such errors even occurred. Revocation in such situations, the commenters stated, is far too severe a penalty, and our proposal in general could impose significant burdens on providers and suppliers.

Response: While we appreciate the commenters' concerns, we must emphasize several things. First, our revocation authority under § 424.535(a)(8)(ii) is strictly discretionary and not mandatory. In every potential § 424.535(a)(8)(ii) revocation case, we carefully weigh the facts and circumstances of the situation, conscientiously consider the regulatory factors (as appropriate and applicable), and only take revocation action when it is genuinely warranted. We have never applied § 424.535(a)(8)(ii) as a matter of course, and this will not change under our revisions thereto. Second, and on the other hand, providers and suppliers have a responsibility to always submit correct claims. Simply because a period of repeated non-compliant billing was comparatively short does not remove this responsibility; even such brief periods involve the provider or supplier having failed to comply with Medicare billing requirements. Third, we have an obligation to protect the Medicare program and the Trust Funds. As we explained in section III.N of the proposed rule, we have encountered instances where short timeframes of non-compliant billing have led to significant Trust Fund dollars being improperly paid. We must have the authority to address such situations, and we believe our proposal helps facilitate this.

Comment: One commenter stated that in potential § 424.535(a)(8)(ii) revocation cases, CMS should consider the provider's or supplier's overall history of billing compliance during its entire period of enrollment, rather than its billing compliance over a very short period.

Response: We respectfully disagree. Requiring an analysis of the provider's or supplier's complete Medicare billing history (which could extend for many years) could hamper our attempts to address shorter but significant periods of non-compliant billing within that larger period. In several potential § 424.535(a)(8)(ii) situations, we could not undertake action because, in effect, the provider's or supplier's length of enrollment (a criterion not altogether different from the entire period of billing during enrollment) overrode any shorter billing aberrations. We believe this problem must be remedied via revised § 424.535(a)(8)(ii).

Comment: One commenter supported our new factor under which CMS would consider the type of billing non-compliance and the specific facts of non-compliance. However, the commenter stated that this factor appears inconsistent with our proposed removal of § 424.535(a)(8)(ii)(B), which addresses the reason(s) for the claim denials. The commenter recommended that both the current version of § 424.535(a)(8)(ii)(B) and the aforementioned new factor be included in § 424.535(a)(8)(ii), stating that the claim denial reason is extremely relevant to whether any abusive conduct was involved. Several other commenters also urged the retention of § 424.535(a)(8)(ii)(B) for this same reason.

Response: We do not believe this new factor contradicts our removal of § 424.535(a)(8)(ii)(B). The former is merely intended to give CMS additional ability to consider all of the surrounding circumstances of the case, which may, but only at CMS' discretion, include the bases for the claim denials. By the same token, the core consideration is the incorrect claim submission itself rather than the reason it occurred. Even if a series of non-compliant claims did not involve any deceit by the provider or supplier, the fact remains that the latter did not adhere to Medicare claim submission requirements. To require us to consider the reason(s) for the claim denial would, in our view, at least partially alleviate the provider or supplier of its responsibility to always remain compliant with our billing policies. We believe such a result is inconsistent with the need to protect the Trust Funds.

Comment: One commenter noted that the billing pattern's length should remain a factor in § 424.535(a)(8)(ii) determinations.

Response: We respectfully disagree. Similar to our aforementioned position concerning the provider's or supplier's overall billing history, we believe that retaining § 424.535(a)(8)(ii)(D) would continue to hinder us from effectively dealing with the very periods of brief but significant billing non-compliance to which our proposal was aimed. Again, even brief timeframes of aberrant billing can result in sizable improper

payments. We note further that our removal of some of § 424.535(a)(8)(ii)'s more specific factors (such as claim denial reasons and the period of enrollment) is designed to give us greater flexibility to address the wide variety of factual scenarios that can arise (and have arisen) in § 424.535(a)(8)(ii) cases. We have found in some instances that the greater the specificity of a particular factor, the more can it constrain our ability to act. It was with this in mind that we proposed the more wide-ranging factor in revised § 424.535(a)(8)(ii)(C).

Comment: Consistent with other comments concerning this proposal, several commenters urged CMS not to finalize our changes to § 424.535(a)(8)(ii). At a minimum, some commenters recommended that before revoking a provider or supplier under revised § 424.535(a)(8)(ii), CMS should: (1) Give the provider or supplier an opportunity to correct such errors; or (2) otherwise provide advanced notice of CMS' concerns. Failure to do so, they stated, could negatively affect patient care if a revocation is prematurely issued.

Response: We appreciate all of the concerns the commenters have expressed regarding our proposed revisions to § 424.535(a)(8)(ii). Nonetheless, and for the reasons already identified, we intend to finalize them as proposed and without the commenters' suggested corrective or waiting period. If the provider or supplier is submitting non-compliant claims, it is the provider's or supplier's responsibility to remedy the matter on its own initiative; respectfully, it is not CMS' obligation to delay a crucial program integrity measure, such as a revocation, to enable the provider or supplier to execute steps that should have been taken previously.

Should the provider or supplier disagree with its § 424.535(a)(8)(ii) revocation, it may exercise its appeal rights under 42 CFR part 498.

After consideration of these public comments, we are finalizing our revisions to § 424.535(a)(8)(ii) as proposed.

f. Miscellaneous Comments

We also received the following comments that did not directly pertain to our proposed regulatory revisions.

Comment: We received several comments regarding the Medicare Diabetes Prevention Program (MDPP) enrollment process. Some commenters recommended that MDPP suppliers be subject to limited-risk level screening under § 424.518 instead of the high-risk level screening currently applicable to MDPP suppliers. Another commenter urged CMS to make the provider enrollment application process less lengthy and arduous for MDPP suppliers. One commenter recommended that CMS either eliminate or modify the requirement that MDPP suppliers report the social security numbers of their board members in section 6 of the Form CMS–20134 enrollment application. Still another commenter suggested that CMS streamline the collection of MDPP enrollment information so that it need only be reported once. These commenters noted that the foregoing initiatives could reduce MDPP supplier cost and burden while spurring MDPP enrollment.

Response: We appreciate these suggestions but believe they are outside the scope of this rule.

Comment: One commenter stated that they supported the policy in § 424.535(e) that permits reversal of a provider's or supplier's revocation if the provider or supplier terminates within 30 days its business relationship with the party that engaged in the adverse activity that led to the revocation. However, the commenter asked CMS to clarify how this impacts the provider's or supplier's claims during the 30-day period.

Response: We appreciate this comment but stress that we did not propose to alter § 424.535(e) other than to expand the parties to which it could apply (that is, to the additional parties addressed in proposed §§ 424.530(a)(2) and 424.535(a)(2)). That is, the general ''30-day revocation reversal'' policy, which has existed for many years, is not changing with this rule. Accordingly, we believe that the stakeholder's comment concerning the claim aspects of said policy is outside the scope of this rule.

Comment: A commenter stated that opioid treatment programs (OTPs) should not have to undergo high-risk level screening under § 424.518(a). The commenter maintained that such intense screening (1) is unwarranted given that OTPs are already subject to strict Federal and State oversight requirements and (2) has proven overly burdensome for OTPs.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: Concerning the reference to the PECOS system of records notice (SORN) in section III.N of the proposed rule, a commenter stated that this SORN includes identifiers/systems that CMS no longer uses (such as the Unique Provider Identification Number). The commenter stated that CMS should accordingly update the PECOS SORN.

Response: This comment is outside the scope of this rule.

Comment: A commenter stated that the OMB Control Number reference for the Form CMS–855 in section III.N of the proposed rule (specifically, OMB No. 0938–0635) should have included every control number associated with the form.

Response: The reference to the Form CMS–855 in the proposed rule was a brief and generic one. We elected to simply include the OMB Control Number associated with most of the Form CMS–855 variations rather than exhaustively list them all.

2. Provider/Supplier Medical Review Requirements

a. Background

CMS identifies improper payments in the Medicare FFS program through a variety of program integrity-related activities, and we use a network of contractors to carry out program integrity initiatives, including Recovery Audit contractors (RACs), the Supplemental Medical Review Contractor (SMRC), Unified Program Integrity Contractors (UPICs), Medicare Administrative Contractors (MACs), and the Comprehensive Error Rate Testing (CERT) contractor. We are purposely excluding Quality Improvement Organizations (QIOs) from this discussion and the following proposals since QIOs are governed by separate and distinct statutory and regulatory requirements. For information about the QIOs, see sections 1151–1163 of the Act and 42 CFR parts 475–480.

Both UPICs and MACs perform prepayment medical review, while the RACs, SMRC, UPICs, MACs, and CERT all perform post-payment medical reviews. Both prepayment medical reviews and post-payment medical reviews are used by our contractors to determine, among other things, whether items or services are reasonable and necessary under section 1862(a)(1) of the Act. In carrying out these reviews, each contractor requests additional documentation from providers and suppliers, which the contractors then assess to either support the payment of claims or conversely, deny (in full or in part) claims thereby protecting the Medicare Trust Funds against improper payments. Our contractors may also carry out follow-up prepayment or post-payment reviews on the same providers or suppliers to ensure improper payments are not continuing.

Our contractors are authorized to request additional documentation through multiple statutory authorities, including sections 1815(a), 1833(e) and

1862(a)(1)(A) of the Act. Sections 1815(a) and 1833(e) of the Act provide that no payments shall be made to any provider or supplier unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider for the period with respect to which the amounts are being paid or any prior period. Under section 1862(a)(1)(A) of the Act, payment must generally be limited to those items and services that are reasonable and necessary.

b. Regulations Governing Prepayment and Post-Payment Medical Review

Despite the statutory authority authorizing our contractors' activities, we do not have regulatory provisions governing certain medical review activities, specifically prepayment and post-payment medical reviews. In this final rule, we are codifying key terms and definitions associated with these two review types; finalizing contractors' authority to request additional documentation within established timeframes; and finalizing provisions detailing a provider's or supplier's responsibility to comply with requests for additional documentation, including the impact should a provider or supplier fail to comply with a request. These provisions are based on existing operational practices used by our contractors. Adding these provisions in regulation will enhance provider and supplier understanding of our review processes, as well as, improve consistency among our contractors.

c. Key Terms and Definitions

To ensure consistency across prepayment and post-payment reviews and establish clear requirements, we proposed the following key terms and their definitions to § 405.902: ''Additional documentation'' means any information requested by a contractor when conducting a prepayment review or post-payment review; ''Additional Documentation Request (ADR)'' means a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review; ''Post-payment medical review (or post-payment review)'' means a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate; and ''Prepayment medical review (or prepayment review)'' means a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made. These definitions are consistent with longstanding manual language and common use of these terms by our contractors.

We did not receive any public comments on this specific section and have decided to finalize as proposed.

d. Prepayment and Post-Payment Medical Review

We proposed to add new § 405.903 that outlines the prepayment medical review provisions.

- At paragraph (a), we proposed to codify our contractors' authority to conduct prepayment medical review on selected claims in order to determine whether and how much payment should be made.
- At paragraph (b), we proposed language detailing our contractors' authority to request additional documentation while conducting a prepayment review.
- At paragraph (b)(1), we proposed language stating that a provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request except as stated in paragraphs (b)(2) and (c).
- At paragraph (b)(2), we proposed language stating that a contractor may accept documentation received after 45 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.
- At paragraph (c), we proposed language detailing a UPIC's authority to provide 30 calendar days to a provider or supplier submitting additional documentation and that a UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

These provisions reflect longstanding requirements MACs and UPICs have used in conducting prepayment reviews. The different time-periods within which additional documentation must be received is based on unique processing requirements for each contractor. Although both conduct prepayment reviews, the UPICs work directly with law enforcement and focus on potentially fraudulent providers or suppliers. Thus, the different timeframes for receiving additional documentation is necessary to account for the distinction and enables each type of contractor to appropriately balance their need for documentation in completing reviews with the potential burden on providers and suppliers should reviews take longer than is warranted. Efforts to limit the burden placed on providers and suppliers as much as possible is also warranted so that patient care is not unnecessarily impacted.

Additionally, both MACs and UPICs historically have had the authority to accept documentation received after the initial timeframe has expired based on good cause, such as natural disasters, interruptions in business practices, or other extenuating circumstances. These circumstances are best determined on a case-by-case basis by the MAC or UPIC, and the language at paragraphs (b)(2) and (c), respectively, convey the MAC and UPIC authority to determine that good cause exists to warrant accepting documentation received after the initial timeframe given.

- At paragraph (d), we proposed that a contractor's prepayment review will result in an initial determination under § 405.920. Again, this has been the longstanding approach to the results of prepayment reviews.

We also proposed similar provisions at new § 405.929 regarding post-payment medical reviews.

- At paragraph (a), we proposed language outlining our contractors' authority to select claims and conduct post-payment medical reviews.
- At paragraph (b), we proposed language that specifies our contractors' authority to request additional documentation.
- At paragraph (b)(1), we proposed that a contractor will give a provider or supplier 45 calendar days to submit additional documentation in response to a request, except as stated in paragraphs (b)(2) and (c).
- At paragraphs (b)(2) and (c), we proposed that a contractor may accept documentation received after 30 days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.
- At paragraph (c), we proposed language that specifies the UPIC's authority to provide 30 calendar days when requesting additional documentation and that a UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

• At paragraph (d), we proposed that when conducting a post-payment review, a contractor's review will result in either no change or a revised determination under § 405.984.

As with prepayment reviews, these provisions reflect longstanding requirements UPICs and MACs, RACs, the CERT contractor, and SMRC have used in conducting post-payment reviews. While the MACs, RACs, CERT contractor, and SMRC have relatively comparable medical review processes, the UPICs are somewhat different given their close working relationship with law enforcement and focus on potentially fraudulent providers or suppliers. Thus, the different timeframes for receiving additional documentation is necessary to account for the distinction and enables each contractor to appropriately balance their need for documentation in completing reviews with the potential burden on providers and suppliers should reviews take longer than may be expected. Efforts to limit the burden placed on providers and suppliers as much as possible is also warranted so that patient care is not unnecessarily impacted.

Given that for post-payment reviews the claims have already been paid, all the contractors have historically had the authority to accept documentation received after the initial timeframe has expired based on good cause. As with prepayment reviews, this may include situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the specific contractor deems good cause in accepting the document after 30 or 45 calendar days. These circumstances are best determined on a case-by-case basis, and the language at paragraphs (b)(2) and (c) convey the authority to determine that good cause exists to warrant accepting documentation received after 30 or 45 calendar days.

We also proposed to add new § 405.930 to clearly outline our contractors' authority to deny a claim should a provider or supplier fail to convey the additional documentation in response to a request. The language clarifies that the contractor must give the provider or supplier notice and time to respond to the additional documentation request. Contractors have authority to require additional documentation through multiple statutory provisions, including sections 1815(a), 1833(e) and 1862(a)(1)(A) of the Act. While our contractors maintain discretion to provide additional time to a provider or supplier in responding to an additional documentation request, our contractors also have the authority to deny additional time and the associated claim(s) when the additional documentation is not received within the requested timeframe.

We also proposed to revise the section heading of § 405.986(a) to read, ''Establishing good cause for reopening.'' This revision clarifies the distinction made between the process for establishing good cause to reopen an initial determination made on a claim, and the good cause factors that may be applied in accepting documentation submitted after the applicable timeframes in §§ 405.903 and 405.929. In establishing criteria to determine whether to accept late documentation in response to an ADR, we adopted the criteria set forth in §§ 405.903 and 405.929, and we did not utilize the good cause criteria for reopening an initial determination on a claim in § 405.986. We believe this change will add further clarification to the substantive text to reflect that the section only applies to reopenings of initial determinations on a claim.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported our proposals, acknowledging our need to conduct oversight activities to protect the Medicare program.

Response: We thank the commenters for their support.

Comment: One commenter suggested that CMS provide additional flexibility to providers who cannot meet ADR deadlines due to the challenges of collecting the necessary information from other providers.

Response: We appreciate the commenter's suggestion; however, the timeframes reflect longstanding practices, providing what we believe to be adequate time for providers and suppliers to respond. Further, we have provided exceptions where there is good cause to accept documentation after applicable timeframes.

Comment: Several commenters suggested that CMS attempt to minimize the burden of these reviews, including contractors coordinating with referring and treating clinicians to gather orders, images, and other documentation.

Response: We thank the commenters for their suggestion and seek to reduce burden on providers when we can. However, these comments are outside the scope of this rule and we may consider these suggestions in future rulemaking.

After consideration of the public comments, we are finalizing our proposal without modification.

O. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. In the CY 2021 PFS final rule (85 FR 84683 through 84688), we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone. We are continuing to monitor Medicare enrollment by OTPs and utilization of the new benefit to ensure that Medicare beneficiaries have appropriate access to care, as well as monitoring for fraud, waste, and abuse. For CY 2022, we proposed several refinements to the regulations governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Annual Updates

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy under which the payment for the drug component of episodes of care will be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. The payment for the non-drug component of the bundled payment for OUD treatment services will be updated annually based upon the Medicare Economic Index (MEI) (84 FR 62668 and 62669). The CY 2022 MEI update is 2.1 percent based on data through the 2nd quarter of 2021 and reflects published historical Bureau of Labor Statistics estimates of multifactor productivity (MFP) data through 2020. The current

payment rates, as finalized in the CY 2021 PFS final rule, both with and without locality adjustments, can be found on the CMS OTP website under Billing and Payment at *https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.* The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2022, will be made available at the time of publication of this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program.* Additionally, please see the ''Opioid Treatment Programs: CY 2022 Methadone Payment Exception'' interim final rule with comment period published elsewhere in this **Federal Register** related to the CY 2022 payment rate for methadone under the Medicare OTP benefit.

3. Refinements to Regulations Governing Medicare Payment to OTPs

In the CY 2021 PFS final rule (85 FR 84684 through 84685), we extended the definition of OUD treatment services to include short acting opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, such as naloxone, and overdose education furnished in conjunction with opioid antagonist medication. We also established an adjustment to the weekly bundled payments when the OTP furnishes take-home supplies of these medications at § 410.67(d)(4)(i)(E). This adjustment includes both a drug component and a non-drug component for overdose education. The payment for the drug component of the adjustment will be determined using the methodology in § 410.67(d)(2)(i), and will be updated annually using the most recent data available at the time of ratesetting. The amount of the non-drug component of the adjustment, which includes overdose education, will be determined based on the CY 2020 Medicare payment rate for CPT code 96161; however, we did not explicitly address either geographic adjustments or annual updates to this payment rate.

In the CY 2020 PFS final rule (84 FR 62666 through 62667), we finalized the application of a geographic adjustment to the non-drug component of the OTP bundled payments, as well as the add-on payment adjustments for non-drug services, using the Geographic Adjustment Factor (GAF). We explained that unlike the national pricing of drugs, the costs for the services included in the non-drug component of the OTP bundled payments for OUD treatment services are not constant across all geographic localities. For example, OTPs' costs for rent or employee wages could vary significantly across different localities and could potentially result in disparate costs for the services included in the non-drug component of OUD treatment services; therefore, we stated we believed it would be appropriate to apply a geographic locality adjustment to the non-drug component of the bundled payments. We also specifically stated our belief that the same logic regarding the differential costs for the non-drug services included in the bundled payments would apply and should be recognized for add-on payment adjustments for non-drug services. This geographic adjustment is codified in the regulations at § 410.67(d)(4)(ii).

Additionally, in the CY 2020 PFS final rule we finalized an annual update to the non-drug component of the bundled payment for an episode of care based upon the MEI (84 FR 62668 through 62669). We noted that we believed the same logic regarding the potential for changes in the costs of the services included in the non-drug component of the bundled payment rates also applied to the add-on payment adjustments for non-drug services. This annual update is codified in the regulations at § 410.67(d)(4)(iii).

In the CY 2022 PFS proposed rule (86 FR 39317 through 39318), we explained that when we adopted the adjustment to the weekly bundled payments for take-home supplies of opioid antagonist medications in the CY 2021 PFS final rule, we did not specifically address either geographic adjustments or annual updates to the non-drug component of this adjustment and did not update the provisions governing the geographic adjustment and annual update in order to reference the new adjustment. Because the adjustment for take-home supplies of opioid antagonist medications includes a non-drug component, we stated that we believe the same considerations regarding varying costs based on geographic locality and the need for annual updates apply. Accordingly, we proposed to revise the regulation at § 410.67(d)(4)(ii) to include the adjustment for take-home supplies of opioid antagonist medications in the list of items for which the non-drug component will be geographically adjusted using the GAF. We also proposed to revise the regulation at § 410.67(d)(4)(iii) to include the adjustment for take-home supplies of opioid antagonist medications in the list of items that will be updated annually using the MEI.

In addition, we stated that in the CY 2021 PFS final rule (85 FR 84688) we had explained that, consistent with § 410.67(d)(5), any payment to an OTP for naloxone would be duplicative if a claim for the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service, and that we would recoup any duplicative payment made to an OTP for naloxone. However, the regulation on duplicative payments at § 410.67(d)(5) does not specifically reference payments for medications that are furnished as part of an adjustment to the bundled payment. Accordingly, we also proposed to revise § 410.67(d)(5) to state explicitly that payments for medications that are delivered, administered or dispensed to a beneficiary as part of an adjustment to the bundled payment are considered a duplicative payment if a claim for delivery, administration or dispensing of the same medication(s) for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. We stated that consistent with the policies finalized in the CY 2020 PFS final rule (84 FR 62663 through 62664) regarding duplicative payments for medications dispensed as part of the weekly bundle, we believe that it is appropriate to also ensure that Medicare payments for drugs provided as an add-on to the bundled payment rate are not duplicative. We noted that this proposed revision would apply not only to duplicative payments for take-home supplies of naloxone, but also to duplicative payments for additional take-home supplies of other medications that are made under § 410.67(d)(4)(i)(D).

We solicited public comments on these proposed changes.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported making these proposed changes to the OTP regulations. A few commenters noted that applying the geographic adjustment to the non-drug component of the add-on payments for take-home supplies of opioid antagonist medications will help OTPs to maintain financial viability, and therefore, ensure continued access to OUD treatment services for beneficiaries.

Response: We appreciate commenters' support for these changes.

After consideration of the public comments, we are finalizing our proposal to revise the regulation text at § 410.67(d)(4)(ii) and (iii) as proposed to codify the application of the annual updates and locality adjustments to the non-drug component of the codes describing add-on payments for opioid antagonist medications (naloxone) that

were new for CY 2021. In addition, we are finalizing our proposal to revise the regulation text at § 410.67(d)(5) as proposed to make clear that the prohibition on duplicative payments applies to drugs provided as part of an add-on payment, as well as the bundled payment.

4. OTP Coding and Payment for New Nasal Naloxone Product

In the CY 2022 PFS proposed rule (86 FR 39318), we discussed that FDA had recently announced the approval of a new, higher dose naloxone hydrochloride nasal spray product used to treat opioid overdose and that the newly approved product delivers 8mg of naloxone.[145] We stated that in the CY 2021 PFS final rule (85 FR 84683 through 84685), we finalized payment for HCPCS code G2215 (*Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*). HCPCS code G2215 was priced based on an assumption of a typical case in which the beneficiary would be provided with a box of two 4mg nasal spray products. We explained that at the time of drafting the proposed rule, we did not yet have any available pricing information for this newly approved product. However, in order to be able to make payment to OTPs under Medicare for this product, we proposed to create a new G-code describing a take-home supply of this higher dose naloxone hydrochloride nasal spray product.

We stated that under this proposal, we would price this new add-on code based on the established methodology under the OTP benefit for determining the adjustment for take-home supplies of opioid antagonist medications at § 410.67(d)(4)(i)(E). This adjustment includes both a drug component and a non-drug component. The amount of the drug component of the adjustment would be determined using the methodology for pricing the drug component of an episode of care at § 410.67(d)(2)(i). Accordingly, consistent with the approach used to price the drug component of HCPCS code G2215, we would apply the payment methodology set forth in section 1847A of the Act to determine the payment for the new naloxone hydrochloride nasal spray product, except that payment amounts that are determined based on ASP or wholesale acquisition cost (WAC) would not include any add-on percentages (85 FR 84685). As stated in the CY 2021 PFS final rule (85 FR 84685), we believe using ASP provides a transparent and public benchmark for manufacturers' actual pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions as noted in section 1847A(c)(2) of the Act) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Therefore, we believe ASP to be the most market-based approach to set drug prices. Additionally, we proposed to price the drug component of the code based on an assumption of a typical dosage for a take-home supply of this new product to be a box of two 8mg nasal sprays. Consistent with the methodology established in § 410.67(d)(4)(i)(E), the amount of the non-drug component of the code would be determined based on the CY 2020 Medicare payment rate for CPT code 96161. In addition, payment for the add-on code would be limited to once every 30 days except when a further take-home supply of the medication is medically reasonable and necessary.

We solicited public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to create a new G-code describing a take-home supply of the new higher dose naloxone hydrochloride nasal spray product and recommended we finalize this proposal. One commenter noted that while they believe there is a potential for up-coding or overutilization of the higher strength naloxone, they believe that the benefits of adopting the proposed new add-on code for this new product outweigh the risks since the widespread availability of naloxone and other medications that can rapidly reverse an opioid overdose, along with education on its proper use, will save lives. Some commenters noted that drug overdose death rates reached an all-time high in 2020. These commenters stated that because many patients are experiencing overdoses from illicitly manufactured fentanyl, it is important that patients with OUD have access to the new, more potent overdose reversal drug. A few commenters expressed concern about the proposal to price the higher dose naloxone product using the ASP without the 6 percent add-on, noting that the payment for Part B drugs outside of the OTP benefit includes a 6 percent add-on to account for overhead costs, administrative expenses, or additional mark-ups accrued in traditional drug distribution channels and recommended CMS include a factor for overhead/administrative costs in its drug pricing methodology for take-home supplies of naloxone furnished by OTPs.

Response: After considering the comments received, we are finalizing our proposal to establish a new code for a higher dose of naloxone hydrochloride nasal spray. We acknowledge the commenter's concern about potential for upcoding, but we agree that the benefits of adopting the new add-on code outweigh the risks because naloxone is a life-saving drug. In light of the comments regarding the increase in overdoses from illicitly manufactured fentanyl, which can require a more potent overdose reversal drug, we believe it is especially important to ensure that this new, higher-dose naloxone nasal spray is available to beneficiaries receiving OUD treatment services from OTPs. The new code is G1028 (*Take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program)); List separately in addition to code for primary procedure.*) Additionally, we are updating the code descriptor for existing HCPCS code G2215 to reflect the dosage included in that code in order to distinguish it from the higher dosage in this new nasal naloxone code. The new code descriptor for HCPCS code G2215 will be *Take-home supply of nasal naloxone; 2-pack of 4mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program)); List separately in addition to code for primary procedure.)*

With regard to the commenters' concerns about the proposal to price the higher dose naloxone product using the ASP or WAC without any add-on percentages, as we discussed in the CY 2021 PFS final rule (85 FR 84685), we believe this approach is most consistent with the approach we adopted in the CY 2020 PFS final rule for pricing the drug component of an episode of care that includes implantable or injectable medications. In addition, for the reasons discussed in the CY 2020 PFS final rule (84 FR 62652 and 62653), we continue to believe that limiting the payment amount to 100 percent of the volume-weighted ASP for a HCPCS code, when ASP is available, instead of 106 percent of the volume-weighted ASP for a HCPCS code will incentivize the use of the most clinically appropriate drug for a given patient. Similarly, as discussed in in the CY 2021 PFS final rule (85 FR 84685), we continue to believe that 100 percent of WAC is a closer estimate of

[145] *https://www.fda.gov/news-events/press-announcements/fda-approves-higher-dosage-naloxone-nasal-spray-treat-opioid-overdose.*

the actual acquisition cost for OTPs compared to WAC with an add-on percentage because, as defined in section 1847A(c)(6)(B) of the Act, WAC does not include prompt pay discounts, rebates or reductions in price.

Accordingly, we will price HCPCS code G1028 as proposed; the payment rate for the drug component of the code will be based on the methodology at § 410.67(d)(2)(i) and the amount of the non-drug component of the code will be determined based on the CY 2020 Medicare payment rate for CPT code 96161 as provided in § 410.67(d)(4)(i)(E). We note that we have WAC pricing information available for this higher-dose naloxone nasal spray. For CY 2022, consistent with § 410.67(d)(2)(i)(A), the drug component of the new code will be priced at $125 for a 2-pack of the 8mg spray, which is 100 percent of the WAC.

Comment: One commenter expressed support for our proposal to geographically adjust the payment for the non-drug component of the codes for take-home supplies of naloxone, but stated that this payment should be updated by the hospital market basket update, not the MEI.

Response: We thank the commenter for this feedback. We believe we should be consistent in applying the same geographic adjustment to the codes describing take-home supplies of naloxone that is applied to adjust the non-drug component of other codes under the OTP benefit. Therefore, we are finalizing our proposal that the non-drug component of the new naloxone code will be updated annually based on the MEI.

5. Out of Scope Comments

Comment: We received one comment that stated that as of July 28, 2021, the Drug Enforcement Administration (DEA) had published a final rule allowing OTPs to add mobile methadone units to their existing registration. The commenter requested that CMS specify that Medicare coverage for opioid use disorder by OTPs extend to services that are provided through mobile units.

Response: We thank the commenter for this comment and note that this comment is outside of the scope of this final rule, as we did not make any proposals involving mobile vans for CY 2022. We may consider addressing this issue in the future rulemaking.

Comment: One commenter stated that CMS should create a 17 percent rural add-on payment to be applied to the non-drug component of the codes for OTP services when services are furnished in low-population density areas where it is difficult to find doctors, nurses, and counselors to treat patients with OUD. The commenter noted that CMS could encourage expansion of access to OUD treatment services by providing add-on payments in areas that do not currently have an OTP provider.

Response: We note that this comment is outside of the scope of this final rule, as we did not make any proposals related to a rural add-on code. We may consider addressing this issue in future rulemaking.

4. Counseling and Therapy Furnished Via Audio-Only Telephone

In the CY 2020 PFS final rule (84 FR 62645 and 62646), we finalized allowing the use of two-way interactive audio/video communication technology, as clinically appropriate, to furnish the counseling and therapy portions of the weekly bundle of services and additional counseling or therapy services furnished by OTPs. Due to the PHE for COVID–19, in the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we revised § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, and any additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio/video communication technology for the duration of the PHE for COVID–19. Under the policy adopted in the March 31, 2020 COVID–19 IFC, counseling and therapy can be furnished using audio-only telephone calls only where two-way audio/video communications technology is not available to the beneficiary, and provided all other applicable requirements are met. In the March 31, 2020 COVID–19 IFC, we stated that we believed this change was necessary to ensure that beneficiaries with opioid use disorders would be able to continue to receive these important services during the PHE during which the public has been instructed to practice self-isolation or social distancing, and because interactive audio/video communication technology may not be available to all beneficiaries.

As we discussed in the CY 2022 PFS proposed rule (86 FR 39318 through 39319), we have continued to evaluate whether this flexibility will be needed after the end of the PHE. According to MedPAC's March 2021 Report to the Congress, allowing audio-only interaction for certain telehealth services can improve beneficiary choice and equity in access to care for beneficiaries who do not have access to the technology for a video telehealth visit.[146] Additionally, OTPs and organizations representing OTPs have encouraged us to reconsider our position on coverage of audio-only services following the conclusion of the PHE for COVID–19 and have suggested that CMS consider permanently allowing OTPs to furnish certain OUD treatment services using audio-only telephone calls. Stakeholders have commented that allowing OTPs to furnish services via audio-only interactions facilitates broader access to services, particularly for vulnerable populations, and ensures providers have flexibility to deliver care to beneficiaries as efficiently and seamlessly as possible. Given the sensitivity of OUD treatment services, they noted that this is an area in which more flexibility will promote not only access but also effective and sustained treatment for beneficiaries in need of care. Some stakeholders have noted that the use of communication technology has reduced stress and stigma for those who require OUD treatment services and the allowance of audio-only services has greatly expanded access for beneficiaries who may not be able to use interactive video. One stakeholder stated that allowing use of audio-only communication to continue after the PHE for COVID–19 would be essential in addressing disparities in healthcare, especially for dually eligible beneficiaries who do not have access to audio-visual communication technology.

In the CY 2022 PFS proposed rule (86 FR 39319) we stated that after further consideration of the public comments and other stakeholder feedback, we were persuaded that using audio-only telephone calls to furnish therapy and counseling in cases where two-way audio/video communication technology is not available to the beneficiary after the end of the PHE for the COVID–19 pandemic would facilitate broader access to services. Therefore, we proposed to allow OTPs to continue to furnish the therapy and counseling portions of the weekly bundles, as well as any additional counseling or therapy that is billed under the add-on code, using audio-only telephone calls rather than via two-way interactive audio/video communication technology following the end of the PHE for COVID–19 in cases where audio/video

[146] *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0.*

communication technology is not available to the beneficiary, provided all other applicable requirements are met. Accordingly, we proposed to revise the regulations at § 410.67(b)(3) and (4) to allow OTPs to furnish therapy and counseling using audio-only telephone calls rather than via two-way interactive audio/video communication technology after the conclusion of the PHE for COVID–19 in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met. We noted that we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: We received many public comments that expressed support for our proposal to allow OTPs to furnish therapy and counseling using audio-only telephone calls rather than via two-way interactive audio/video communication technology after the conclusion of the PHE for COVID–19, noting that this change would ensure continued access to care for beneficiaries receiving treatment at OTPs. Some commenters stated that audio-only services have helped to advance health equity and have been a vital linkage to care for many patients during the PHE and that these services have been especially beneficial for patients in rural areas who may not have access to reliable internet service, which limits their ability to access two-way, audio-video communications technology. One commenter agreed that CMS should permanently extend the ability to provide counseling via audio-only telehealth, but only for patients who are compliant with their treatment plan.

Response: After consideration of the public comments, we are finalizing our proposal to revise the regulations at § 410.67(b)(3) and (4) to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the PHE for COVID–19 in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met. As we explained in the proposed rule, we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary.

Regarding the suggestion that CMS should only permanently extend the ability to provide counseling via audio-only telehealth for patients who are compliant with their treatment plan, we defer to the judgment of treating clinicians to determine when audio-only or audio/video counseling or therapy are appropriate and whether there are certain circumstances, such as when patients are considered to be high risk, when in-person services are needed.

Additionally, in the CY 2022 PFS proposed rule (86 FR 39319), we proposed that after the conclusion of the PHE for COVID–19, when two-way interactive audio/video communication technology is used to furnish additional counseling and therapy services billed under the add-on code, OTPs would be required to append modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) to the claim. We did not propose to require the use of this modifier when counseling and therapy services included in the weekly bundle are furnished using two-way interactive audio/video communication technology. We recognized that it may be difficult to determine which modifier to use in cases where multiple services within the bundle are furnished using different modalities; therefore, we limited our proposal regarding the use of modifier 95 to claim lines for the counseling and therapy add-on code (HCPCS code G2080).

We also proposed that, following the conclusion of the PHE for COVID–19, when counseling or therapy services are furnished using audio-only telephone calls, either as part of a weekly bundle or billed using the counseling and therapy add-on code (HCPCS code G2080), OTPs would be required to document in the beneficiary's medical record that the counseling or therapy was furnished via audio-only telephone call and the rationale for doing so. In addition, we proposed the use of a new service-level modifier to be appended to claims submitted for the counseling and therapy add-on code (HCPCS code G2080) when services are furnished via an audio-only interaction, which would serve to certify that the practitioner had the capacity to furnish the services using two-way, audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary. We explained that the use of this modifier would allow CMS to track utilization of this flexibility in the claims data and evaluate that data as we consider ongoing refinements to the OTP benefit in the future. To avoid placing additional burden on OTPs during the PHE for COVID–19, we proposed that these new requirements would take effect on January 1, 2022, but would apply only for services furnished after the conclusion of the PHE for COVID–19. Accordingly, if the PHE for COVID–19 extends into 2022, OTPs that furnish counseling and therapy services using either two-way audio/video technology or audio-only telephone calls would not be required to use the applicable modifier or to comply with the new documentation requirements until after the end of the PHE.

Accordingly, we proposed to revise § 410.67(d) to add a new paragraph (6) to state that when substance use counseling under paragraph (b)(3) of this section or therapy services under paragraph (b)(4) of this section are furnished using audio-only telephone calls after the end of the PHE, as defined in 42 CFR 400.200, the practitioner must document in the beneficiary's medical record that the services were furnished using audio-only technology and the rationale for doing so. For purposes of the add-on code for additional counseling and therapy services, the practitioner would also be required to certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because the beneficiary did not have access to two-way audio/video communication technology. We explained that under these proposals we would defer to clinician judgment in determining whether in-person counseling or therapy, rather than the use of audio-only telephone calls, would be most appropriate in certain circumstances, such as for patients who are considered to be high risk. Additionally, we solicited comment on whether we should put any additional or alternative conditions in place to promote program integrity, minimize patient safety concerns, and ensure that beneficiaries

have access to the most appropriate form of care.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that the agency not require additional documentation in the medical record to support the use of audio-only services, especially if this is the only way the patient can receive care, stating that additional documentation is duplicative and unnecessary. A few commenters supported the use of an audio-only claims coding modifier that could be used to track utilization and conduct effectiveness research for audio-visual vs. audio-only services, noting that evaluation of audio-only services would also be beneficial to demonstrate quality and efficacy for SUD treatment programs.

Response: After consideration of the public comments, we are finalizing our proposal that a new service-level modifier be appended to claims submitted for the counseling and therapy add-on code (HCPCS code G2080) when services are furnished via an audio-only interaction. Consistent with policies finalized for other audio-only services furnished by physicians and certain NPPs in section II.D of this final rule, the use of this modifier will serve to certify that the practitioner had the capacity to furnish the services using two-way, audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary. Additionally, we are finalizing our proposal that after the conclusion of the PHE for COVID–19, when two-way interactive audio/video communication technology is used to furnish additional counseling and therapy services billed under the counseling and therapy add-on code (HCPCS code G2080), OTPs will be required to append modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) to the claim. The use of these modifiers will allow us to track utilization of these flexibilities in the claims data and to evaluate that data as we consider future refinements to the OTP benefit.

However, we are persuaded by the comments stating that the proposed requirement that OTPs document the use of audio-only services in the beneficiary's medical record would be duplicative because the new service-level modifier for services furnished via an audio-only interaction will also identify when a service was furnished via audio-only communication. Therefore, we are not finalizing the proposal to require additional documentation in the medical record to support the use of audio-only services.

Accordingly, we are finalizing our proposal to revise § 410.67 to add a new paragraph (d)(6) with modifications. As revised, the new paragraph (d)(6) will require that for purposes of the adjustment to the bundled payment for additional counseling or therapy services under § 410.67(d)(4)(i)(A), after the end of the PHE for COVID–19, as defined in § 400.200, when services are furnished using audio-only technology the practitioner must certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology but used audio-only technology because audio/video communication technology was not available to the beneficiary.

P. Physician Self-Referral Updates

1. The Physician Self-Referral Statute and Regulations

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act; see 66 FR 857 through 858.

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was a final rule with comment period published in the January 4, 2001 **Federal Register** (66 FR 856). The second final rulemaking (Phase II) was an interim final rule with comment period (69 FR 16054) published in the March 26, 2004 **Federal Register**. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published in the April 6, 2004 **Federal Register** (69 FR 17933). The third final rulemaking (Phase III) was a final rule published in the September 5, 2007 **Federal Register** (72 FR 51012).

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the Fiscal Year (FY) 2009 Inpatient Prospective Payment System final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) Revisions to the ''stand in the shoes'' provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; (3) prohibitions on per unit of service (often referred to as ''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of ''entity.''

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. The new exception at § 411.357(y) for timeshare arrangements included a limitation on certain per unit of service and percentage-based compensation formulas. On November 15, 2016, in the CY 2017 PFS final rule, we again finalized requirements that the rental charges for the lease of office space or equipment are not determined using a formula based on per unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (81 FR 80534). The requirements are identical to those in effect since October 1, 2009, and are included in the exceptions for the rental of office space at § 411.357(a)(5)(ii)(B), the rental of equipment at § 411.357(b)(4)(ii)(B), fair market value compensation at § 411.357(l)(3)(ii), and indirect compensation arrangements at § 411.357(p)(1)(ii)(B). The terms ''rental'' and ''lease'' both refer to an arrangement under which dominion and control of the rented or leases property is transferred from the lessor to the lessee. In this final rule, we generally use the term ''lease'' for consistency.

In the December 2, 2020 **Federal Register**, we published a final rule entitled ''Modernizing and Clarifying the Physician Self-Referral Regulations'' (the ''MCR final rule'') (85 FR 77492) that established three new exceptions to the physician self-referral law applicable to compensation arrangements that qualify as ''value-based arrangements,'' established exceptions for limited remuneration to a physician and the donation of cybersecurity technology and services, and revised or clarified several existing exceptions. The MCR final rule also provided guidance and updated or established regulations related to the fundamental terminology used in many provisions of the physician self-referral law. Most notably, we defined the term ''commercially reasonable'' in regulation, established an objective test for evaluating whether compensation varies with the volume or value of referrals or other business generated between the parties, and revised the definitions of ''fair market value'' and ''general market value.'' The MCR final rule also revised the definition of ''indirect compensation arrangement.''

2. Indirect Compensation Arrangements (§ 411.354(c)(2))

a. Summary of Proposals

We proposed to revise and renumber the regulation at § 411.354(c)(2) that sets forth the conditions for the existence of an indirect compensation arrangement. First, we proposed to revise and renumber § 411.354(c)(2)(ii), which identifies when aggregate compensation to a physician results in an indirect compensation arrangement (if the other conditions of § 411.354(c)(2) are met), to more precisely address the concerns and effectuate the policies that we articulated in the MCR final rule. Specifically, we proposed to revise the regulation to include as a potential indirect compensation arrangement any unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member of the physician) involves compensation for anything other than services that he or she personally performs. This would have included arrangements for the lease of office space or equipment that meet the other conditions of the regulation at § 411.354(c)(2), which would be subject to, among other requirements, the prohibition on percentage-based and unit-based (often referred to as ''per-click'') compensation formulas at § 411.357(p)(1)(ii) in the exception for indirect compensation arrangements (or subject to the requirements of another applicable exception). Second, after receiving inquiries from stakeholders requesting clarification on the term ''unit'' in § 411.354(c)(2)(ii)(A) following the publication of the MCR final rule, we proposed to define the term ''unit'' for purposes of applying the regulation. We also proposed to define ''services that are personally performed'' for purposes of applying proposed § 411.354(c)(2)(ii)(A)(4).

b. Definition of ''Indirect Compensation Arrangement''

Although section 1877(h)(1) of the Act defines the term ''compensation arrangement'' as including both direct and indirect compensation, the statute does not define the term ''indirect compensation arrangement.'' In Phase I, relying on the Secretary's authority under section 1877(b)(4) of the Act, we set forth in regulation the conditions under which an indirect compensation arrangement exists and a corresponding exception for such arrangements (66 FR 684 through 687). In Phase II, we revised the regulation at § 411.354(c)(2)(ii) to distinguish the language identifying when an indirect compensation arrangement exists from the language of the exception for indirect compensation arrangements at § 411.357(p) (69 FR 16069). Most recently, in the MCR final rule, we further revised the regulation at § 411.354(c)(2) that identifies when an indirect compensation arrangement exists (85 FR 77544 through 77546).

Prior to the MCR final rule, an unbroken chain of financial relationships between a referring physician (or a member of his or her immediate family) and the entity furnishing designated health services established an ''indirect compensation arrangement'' if all the elements of § 411.354(c)(2), as then in effect, existed. The indirect compensation arrangement must satisfy the requirements of an applicable exception in order to avoid the referral and billing prohibitions of the physician self-referral law. (In the alternative, the parties could use an exception at § 411.355 to except the physician's referrals on a service-by-service basis.) This two-step process, which first identified the universe of unbroken chains of financial relationships that might be of concern and then excepted from the physician self-referral law's prohibitions those unbroken chains of financial relationships that did not pose a risk of program or patient abuse, was developed to closely correspond to the statutory treatment of compensation arrangements directly between an entity and a referring physician (or an immediate family member of the referring physician) (69 FR 16059). When analyzing compliance with the requirement that compensation does not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity, which is included in the exception for indirect compensation arrangements at § 411.357(p) and certain exceptions for direct compensation arrangements, special rules on unit-based compensation at § 411.354(d)(2) and (3) that deemed certain compensation not to take into account the volume or value of the physician's referrals or the other business generated by the physician could be applied.

As noted above, in the MCR final rule, we established an objective test for evaluating whether compensation varies with the volume or value of referrals or other business generated between the parties and responded to commenters that questioned whether compensation to a physician would run afoul of the objective tests under specified circumstances (85 FR 77539 through 77547). Inquiring about proposed

modifications to § 411.354(c)(2)(ii) that we did not ultimately finalize, one commenter presented the example of a physician who performs surgeries at a hospital and receives a fixed amount per personally-performed RVU that is consistent with the fair market value of the physician's services (85 FR 77544). In developing our response to the commenter (and other commenters), we revisited the regulatory construct for determining which unbroken chains of financial relationships between entities and physicians (or immediate family members of physicians) establish indirect compensation arrangements and how to determine if they pose a risk of program or patient abuse (85 FR 77545).

With the underlying goal of reducing unnecessary burden on providers and suppliers, we stated that we do not see a need to treat compensation arrangements that may qualify as ''indirect compensation arrangements'' in the exact same way that the statute treats direct compensation arrangements when that construct creates unnecessary burden on the regulated industry (85 FR 77545 through 77546). We stated that it is possible to simplify the analysis of whether an unbroken chain of financial relationships presents a risk of patient or program abuse or poses program integrity concerns (85 FR 77546), and finalized revisions to § 411.354(c)(2) intended to achieve the same result as the two-step Phase I regulatory construct in protecting against program or patient abuse while reducing unnecessary burden on the regulated industry (85 FR 77546). The revised (now current) regulation at § 411.354(c)(2)(ii) effectively incorporates and applies the conditions of the special rules on unit-based compensation at § 411.354(d)(2) and (3) at the definitional level when determining whether there exists an indirect compensation arrangement that implicates the physician self-referral law.

Under the regulation finalized in the MCR final rule, an unbroken chain of financial relationships between an entity and a physician is considered an indirect compensation arrangement if the physician (or immediate family member of the physician) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing the designated health services, and any of the following are true: (1) The individual unit of compensation received by the physician (or immediate family member) is not fair market value for items or services actually provided; (2) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or (3) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity. In addition, the entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity. Under the regulation, unless all the elements of § 411.354(c)(2)(i), (ii), and (iii) exist, an unbroken chain of financial relationships between an entity furnishing designated health services and a physician (or immediate family member of a physician) is not considered an indirect compensation arrangement.

As explained previously, the changes to the regulations that identify indirect compensation arrangements of concern under the physician self-referral law occurred in response to comments and inquiries primarily in the context of compensation paid to physicians for their personally performed services (85 FR 77539 through 77547). The revisions to § 411.354(c)(2)(i) through (iii) were intended to more precisely identify arrangements that pose a risk of overutilization, patient steering, and other abusive conduct at an earlier stage of the analysis (85 FR 77546). However, in streamlining the former two-step process for analyzing unbroken chains of financial relationships, we inadvertently omitted a longstanding and important program integrity requirement that previously always applied when determining satisfaction of the requirements of the exception at § 411.357(p) for indirect compensation arrangements. Specifically, we inadvertently excluded from the definition of ''indirect compensation arrangement'' a subset of unbroken chains including compensation arrangements that we have long identified as presenting significant program integrity concerns: Certain arrangements involving unit of service-based payment for the rental or lease of office space or equipment. (See 73 FR 48713 through 48721; 81 FR 80524 through 80534; and 85 FR 77605 through 77608).)

We have repeatedly stated our view that unit of service-based compensation formulas in arrangements for the lease of space and equipment are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. Beginning with the 1998 proposed rule, we stated that unit of service-based payments for patients who are referred for the service by the lessor physician were not consistent with the requirement that compensation not reflect the volume or value of a physician's referrals or other business generated (63 FR 1714). In Phase I, we revisited the issue, reviewed the legislative history, and concluded that, as long as the per-unit payment reflected fair market value in arms' length bargaining and did not vary over the course of the arrangement, unit of service-based payments could qualify for the protection of an exception, provided that the other requirements of the applicable exception are met. (66 FR 876). We noted that such arrangements might run afoul of the anti-kickback statute and stated our intent to continue to monitor such arrangements for potential abuse (66 FR 878).

Subsequently, in the 2009 IPPS final rule, based on our observations of program integrity concerns and comments in support of prohibiting unit of service-based compensation formulas in office space and equipment leases, we finalized revisions to the exceptions for the rental of office space at § 411.357(a), the rental of equipment at § 411.357(b), fair market value compensation at § 411.357(l), and indirect compensation arrangements at § 411.357(p). The revised exceptions required that, to the extent that such arrangements related to the lease of office space or equipment, the rental charges may not be determined using a formula based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the service performed or business generated in the office space; or (2) unit of service-based rental charges, to the

extent that such charges reflect services provided to patients referred by the lessor to the lessee (73 FR 48713 through 48714). Commenters largely supported the change. A significant number of commenters reported their own experiences of situations in which unit of service-based compensation arrangements resulted in patients being referred for medically unnecessary treatment. Some hospitals reported being effectively compelled to lease equipment from physician groups (73 FR 48715). In the 2016 PFS final rule, we included similar restrictions on percentage-based and unit of service-based compensation formulas in the new exception at § 411.357(y) for timeshare arrangements. In support of that limitation, we again cited concerns that unit of service-based compensation formulas in arrangements involving the use of premises or equipment could lead to overutilization and patient steering (80 FR 71331 through 71332).

We most recently addressed the issue of unit of service-based compensation formulas in depth in the 2017 PFS proposed and final rules. In those rules, at the direction of the D.C. Circuit Court in Council for Urological Interests v. Burwell, 790 F.3d 212 (DC Cir. 2015), we explained our rationale for the restrictions as they apply to arrangements for the lease of office space or equipment or for the use of premises or equipment, again identifying overutilization and patient steering as the primary program integrity concerns supporting our conclusion that such compensation provisions present a significant program risk (81 FR 46452 through 46453 and 80528 through 80534). We reiterated that unit of service-based compensation formulas, in particular in arrangements for the lease of equipment:

- Create an incentive for overutilization of imaging services (as described by MedPAC in its comments to our proposal in the CY 2008 PFS proposed rule), as well as other services, including therapeutic services;
- Create an incentive for physicians to narrow their choice of treatment options to those for which they will realize a profit, even where the best course of action may be no treatment;
- Influence physicians to refer to the lessee instead of referring to another entity that utilizes the same or different (and perhaps more efficacious) technology to treat the patient's condition;
- Result in physicians steering patients to equipment they own, even if it means having the patient travel to a non-convenient site for services using the leased equipment; and
- Increase costs to the Medicare program when referring physicians pressure hospitals to use their leasing company despite not being the low cost provider.

We also identified two advisory opinions issued by OIG in which OIG voiced concerns about unit of service-based compensation arrangements and indicated that such arrangements are disfavored under the anti-kickback statute (81 FR 80528). Commenters again were largely supportive of the proposal, which merely re-proposed the then-existing prohibitions on such compensation formulas in arrangements for the lease or use of office space or equipment (81 FR 80528 through 80529).

As discussed in prior rulemakings, our policies regarding unit of service-based compensation formulas relate to both the lease of office space or equipment—where dominion and control over the office space (the subject of the statutory exception at section 1877(e)(1)(A) of the Act and the regulatory exception at § 411.357(a)) or equipment is transferred from the lessor to the lessee—and to arrangements for the use of premises (which may or may not be office space) or equipment—where the grantee is granted a right to use the premises or equipment but dominion and control over the premises or equipment is not transferred from the grantor to the grantee. Our position on the inherent risks presented by unit of service-based compensation formulas in the context of the lease of office space or equipment and the use of premises or equipment has not changed since the CY 2016 and 2017 PFS final rules. This fact is evident elsewhere in the MCR final rule. For example, the rule finalized changes to the exception for fair market value items and services at § 411.357(l), making it applicable to the lease of office space (85 FR 77606). With this change, we also revised the exception to state that the previously-established restrictions at § 411.357(l)(3)(i) and (ii) applicable to fair market value equipment leases also apply to leases of office space. We reiterated our longstanding concerns with unit of service-based compensation formulas for leases of office space and equipment, described the history of such concerns, and stated, in response to a comment supporting the inclusion of the restriction, that it was ''a necessary safeguard'' for the reasons articulated in our prior rulemakings (85 FR 77607). We included similar restrictions on compensation for the lease of office space or equipment and the use of premises or equipment in the newly-finalized exception for limited remuneration to a physician at § 411.357(z), citing the same concerns (85 FR 77624).

We continue to believe that arrangements involving unit of service-based compensation for the lease of office space or equipment or for the use of premises or equipment, whether direct or indirect, may pose a significant risk of program abuse, and proposed revisions to § 411.354(c)(2)(ii) to ensure that prohibitions on certain unit of service-based compensation formulas for the lease of office space or equipment or for the use of premises or equipment applies to all compensation arrangements that include them. Under proposed § 411.354(c)(2)(ii), an unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member) is an arrangement for the lease of office space or equipment or an arrangement for the use of premises or equipment would be an indirect compensation arrangement if all other conditions of § 411.354(c)(2)(i) through (iii) are met. If the parties to the compensation arrangement elect to use the exception at § 411.357(p) instead of another applicable exception, if any, the compensation for the lease of office space or equipment may not be determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessee to the lessor. Moreover, § 411.357(p)(1)(i) requires that compensation received by a physician (or immediate family member)—including compensation for the lease of office space or equipment or for the use of premises or equipment—is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician for the entity furnishing designated health services.

As we stated in the proposed rule and continue to believe, arrangements involving compensation to a physician for items or the services of others where the physician's referral of designated health services to an entity or other business generated by the physician for an entity may contribute to the compensation received by the physician are distinguishable from arrangements that solely involve compensation for a physician's personally performed services. Program integrity concerns arise when payment for items or services provided as the result of a physician's referrals or the other business the physician generates, rather than the physician's own labor, is included in the calculation of

compensation. As discussed previously, the MCR final rule policy that identifies indirect compensation arrangements of concern under the physician self-referral law in a single-step process was focused on reducing unnecessary burden related to the analysis of unbroken chains of financial relationships that do not pose a risk of program or patient abuse, and was developed in the context of compensation paid to physicians for their personally performed services. However, the current regulations, as finalized in the MCR final rule, are not limited to indirect compensation arrangements under which a physician (or immediate family member) is paid solely for services that he or she personally performs, which, as a general matter, do not raise significant program integrity concerns, provided that the compensation is consistent with fair market value for the personally performed services.

If finalized, proposed § 411.354(c)(2)(ii) would have required a two-step analysis of any unbroken chain of financial relationships in which the compensation paid under the arrangement closest to the physician (or immediate family member) is for anything other than services personally performed by the physician (or immediate family member), including arrangements for the lease of office space or equipment or for the use of premises or equipment. Specifically, we proposed to revise the condition at § 411.354(c)(2)(ii)(A) to consider an unbroken chain of financial relationships between a physician and an entity that meets the other conditions of § 411.354(c)(2)(i) through (iii) to be an indirect compensation arrangement for purposes of the physician self-referral law if the unit of compensation received by the physician (or immediate family member) is payment for anything other than services personally performed by the physician (or immediate family member). We stated that the application of the proposed revision to all unbroken chains of financial relationships in which the compensation paid under the arrangement closest to the physician (or immediate family member) is for anything other than services personally performed by the physician (or immediate family member) was intended to better align with our view regarding the reduced risk of program or patient abuse where compensation is for personally performed services.

We also proposed slight revisions to the language of § 411.354(c)(2)(ii)(A)(2) and (3) to clarify that these conditions relate to the formula for calculating the amount of compensation per unit. The condition at proposed § 411.354(c)(ii)(A) stated that the referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services and the individual unit of compensation received by the physician (or immediate family member): (1) Is not fair market value for items or services actually provided; (2) Is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation that positively correlates with the number or value of the physician's referrals to the entity; (3) Is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation per unit that positively correlates with the physician's generation of other business for the entity; or (4) Is payment for anything other than services personally performed by the physician (or immediate family member). For purposes of proposed § 411.354(c)(2)(ii)(A)(*4*), services that are performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member) would not be personally performed by the physician. We proposed to codify this policy at § 411.354(c)(2)(ii)(B)(*3*). We are finalizing our proposal to ensure that the prohibition on certain unit of service-based compensation formulas for the lease of office space or equipment or for the use of premises or equipment applies to all compensation arrangements that include them. We are not finalizing our proposal regarding payment for anything other than services personally performed by the physician (or immediate family member) or our proposal to codify our interpretation of services that are personally performed by a physician (or immediate family member).

c. Definition of ''unit'' for Purposes of Applying § 411.354(c)(ii)(A)

As explained above, under current § 411.354(c)(2)—which was finalized in the MCR final rule—the determination of whether an indirect compensation arrangement exists requires the evaluation of the individual unit of compensation that the physician (or immediate family member) receives. If the individual unit of compensation does not meet any of the conditions at current § 411.354(c)(2)(ii)(A)(*1*) through (*3*), the unbroken chain of financial relationships does not constitute an indirect compensation arrangement. Following the publication of the MCR final rule, we received inquiries from stakeholders regarding how the provisions of § 411.354(c)(2)(ii)(A) should be applied in situations where compensation does not appear to be unit-based or is calculated using two or more different units or types of units. We proposed revisions to § 411.354(c)(2)(ii)(B) to clarify how to identify the unit to analyze against the conditions of current § 411.354(c)(2)(ii)(A)(*1*) through (*3*), as well as proposed § 411.354(c)(2)(ii)(A)(4).

As a preliminary matter, it is our position that all compensation essentially is unit-based compensation. The underlying unit may be a discrete item, a unit of service, a unit of time, or a unit that results from combining different types of units into a single unit used to calculate the compensation. The identification of purely time-based or service-based units is straightforward. With respect to compensation that is entirely paid per hour, per day, per month, per year, or per similar period of time, the individual unit of compensation is the smallest unit of time for which the compensation is paid. For example, where a physician is paid $150 per hour for his or her medical director services, the unit is an hour. Similarly, where a physician is paid $350,000 per year for his or her full-time professional services, the unit is a year. With respect to compensation that is entirely paid per service, such as a work relative value unit (wRVU) or the provision of a training seminar, the unit is the individual service. For example, where a physician is paid $30 per wRVU that he or she personally performs, the unit is a wRVU. Similarly, where a physician is paid $1000 to provide a training session on infection control measures for an organization's employees, the unit is a training session. Compensation formulas that incorporate a percentage of a variable are also unit-based. For example, if a physician is

paid 50 percent of the amount collected for the professional services that he or she performs in a calendar year, the unit is a calendar year. If a physician is paid 95 percent of the Medicare PFS amount for a particular service that he or she personally performs, the unit is the service.

We are aware that compensation arrangements may include different units of compensation paid to a physician. According to stakeholders inquiring about the application of § 411.354(c)(2)(ii)(A), a physician employed by a physician organization may receive an annual salary for his or her full-time professional services furnished to patients of the physician organization plus a productivity bonus for each wRVU that he or she personally performs. The stakeholders inquired how to identify the unit that results from combining different types of units into a single unit used to calculate the physician's compensation. In such instances, we consider the unit of compensation to be time-based and reflect the aggregate compensation paid to the physician during the period of time applicable to the payment; that is, the period of time during which compensation is paid (for example, per month or per year) or over the entire term of the arrangement. It is our understanding that fair market valuations generally follow this construct, determining the fair market value of various types of compensation for a physician's personally performed services, such as fixed salary payments and productivity or bonus compensation, by assessing the physician's compensation in the aggregate over a period of time. Further, a service-based unit of compensation is easily converted to a time-based unit by incorporating the period of time applicable to the payment for the services (for example, $30 per wRVU per month), while the reverse is not true. It is for these reasons that we believe that ''hybrid'' compensation—that is, compensation that has both a time-based unit component and a service-based unit component—is appropriately analyzed by converting it to compensation for a unit of time for purposes of applying § 411.354(c)(2)(ii).

To illustrate, assume that an employment arrangement between a physician and a physician organization specifies compensation of $200,000 per calendar year for the physician's full-time professional services plus a productivity bonus of $10 for each wRVU that he or she personally performs, and that the physician is paid on a monthly basis. The unit of compensation is a month, and the formula for determining the compensation per month is ($200,000 ÷ 12 months) + ($10 x the number of wRVUs personally performed during the month). (In the alternative, the parties could analyze the arrangement under § 411.354(c)(2)(ii)(A) using a calendar year as the unit of compensation.) However, if the employment arrangement specified productivity bonus compensation of $10 per wRVU only for those personally performed wRVUs above a predetermined target, the unit is the period of time for which the target is applicable. To illustrate, instead of $10 for each wRVU that the physician personally performs, assume that the physician receives $10 for the wRVUs that he or she personally performs in excess of 4,000 wRVUs per calendar year. The unit of compensation is a calendar year, and the formula for determining the compensation per year is $200,000 + $10 x (actual number of wRVUs personally performed during the calendar year—4,000).

We note that a compensation arrangement may also involve multiple units of the same type. For example, a physician employed by a physician organization may receive a salary of $200,000 per year for his or her full-time professional services plus $150 per hour for his or her personally performed medical director services or $500 per month for each of the physician organization's NPPs that he or she supervises. Or, a physician may receive compensation for services based on a fee schedule; for example, $50 for service A, $75 for service B, and $100 for service C. In circumstances where more than one unit of the same type is used to calculate the physician's compensation, each unit must be analyzed under § 411.354(c)(2)(ii)(A)(*1*) through (*4*) to determine whether the conditions for an indirect compensation arrangement exist.

To facilitate compliance with the physician self-referral law as it applies to indirect compensation arrangements, we proposed a new regulation at § 411.354(c)(2)(ii)(B)(*2*) that expressly identifies the unit to consider for purposes of applying the regulation at § 411.354(c)(2)(ii)(A) and determining the existence of an indirect compensation arrangement that must satisfy the requirements of an applicable exception. Under proposed § 411.354(c)(2)(ii)(B)(*2*), for purposes of applying § 411.354(c)(2)(ii)(A), the individual unit was specified as: (1) Time, where the compensation paid to the physician (or immediate family member) is based solely on the period of time during which the services are provided; (2) service, where the compensation paid to the physician (or immediate family member) is based solely on the service provided; and (3) time, where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided. We are finalizing our proposal to clarify the unit for purposes of determining the existence of an indirect compensation arrangement with the modifications as described in our response to comments below.

We solicited comment on the proposals discussed above and whether additional guidance is needed with respect to the determination of whether an indirect compensation arrangement exists. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters acknowledged the longstanding CMS policy that compensation for the lease of office space or equipment or for the use of premises or equipment may not be determined using a formula based on per-unit of service (or ''per-click'') rental charges or ''use'' fees to the extent that such charges reflect services provided to patients referred by the lessor to the lessee or by the party granting permission to use the premises or equipment (often referred to as the ''licensor'') to the party to which the permission is granted (often referred to as the ''licensee''), respectively. These commenters supported finalizing our proposal to retain the policy with respect to indirect compensation arrangements, with several noting that our failure to revise the regulations at § 411.354(c)(2) in the MCR final rule to include the prohibition on per-click payments for the lease of office space or equipment must surely have been an oversight given that the agency: (1) Made no express statement that it was abandoning its policy with respect to unbroken chains of financial relationships where the compensation arrangement closest to a physician (or immediate family member of a physician) is for the lease of office space or equipment; and (2) retained the policy with respect to arrangements for the lease of office space or equipment that are directly (or are deemed to be directly) between an entity and a physician (or immediate family member of a physician). Several commenters asserted that the policy is necessary to protect against the program integrity concerns that underly the policy, but others asserted that per-click payments for the lease of equipment do not pose a risk to the Medicare program or its

beneficiaries and, therefore, the policy is unnecessary. A few commenters expressed concern with the burden of learning how to apply new regulations, some of whom supported a prohibition on per-click payments for the lease of office space and equipment, and some of whom opposed such a prohibition.

Response: As we stated in the proposed rule, in the MCR final rule, we inadvertently omitted the important program integrity requirement related to per-click payments for the lease of office space and equipment or for the use of premises or equipment when revising our regulations at § 411.354(c)(2) in order to identify arrangements that pose a risk of overutilization, patient steering, and other abusive conduct at an earlier state of the analysis (86 FR 29322). As the commenters correctly noted, this was in no way an abandonment of our longstanding policy with respect to unbroken chains of financial relationships where the compensation arrangement closest to a physician (or immediate family member of a physician) is for the lease of office space or equipment, nor was it an express indication that unbroken chains of financial relationships where the compensation arrangement closest to a physician (or immediate family member of a physician) is for the use of premises or equipment pose no risk of program or patient abuse. We are finalizing our proposal to address the inadvertent omission of arrangements involving unit of service-based payment for the lease of office space or equipment or for the use of premises or equipment from those unbroken chains of financial relationships that constitute indirect compensation arrangements under § 411.354(c)(2). However, as explained in the responses to comments below, we are finalizing revisions to address this omission in a more precise and targeted manner.

With respect to commenters' concerns about the potential burden of learning how to apply new regulations, we note that, for all unbroken chains of financial relationships where the compensation arrangement closest to a physician (or immediate family member of a physician) is for the lease of office space or equipment or for the use of premises or equipment, the analysis under the physician self-referral law will revert to the two-step analysis in place since our Phase I regulations were finalized in 2004. Once a determination is made that an indirect compensation arrangement exists, the requirements of an applicable exception must be satisfied. If the parties to the indirect compensation arrangement rely on the exception for indirect compensation arrangements at § 411.357(p), the compensation for each unit of office space, equipment, or premises may not be determined in any manner that takes into account the volume or value of the physician's referrals to or other business generated for the entity. The special rules at § 411.354(d)(5) and (6) regarding when compensation takes into account the volume or value of a physician's referrals to or other business generated for an entity were finalized in the MCR final rule (85 FR 77535 through 77547). A compensation formula under which a physician (or immediate family member) receives a lease payment or a ''use'' fee—either as the direct lessor or licensor or through an ownership interest in a lessor or licensor—each time the office space, equipment, or premises is used to provide a service to a patient referred by the physician to the lessee or licensee would not satisfy this requirement, because the formula used to determine the compensation would include the physician's referrals to and other business generated for the entity as a variable, resulting in an increase in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to and other business generated for the entity. In addition, the exception for indirect compensation arrangements expressly requires that the compensation for the lease of office space or equipment may not be determined using a formula based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or (2) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. This requirement has been in place since October 1, 2009, and therefore, it is not a ''new'' policy or analysis that will result in burden to parties designing or reviewing their indirect compensation arrangements for compliance with the physician self-referral law.

Comment: Although the vast majority of commenters that addressed our proposal to revise the conditions under which an indirect compensation arrangement exists supported a prohibition on per-click payments for the lease of office space or equipment and the use of premises or equipment, many of these commenters asserted that our proposed revisions to § 411.354(c)(2), if finalized, would be overbroad in application. Specifically, commenters objected to proposed § 411.354(c)(2)(ii)(A)(*4*), which would have treated any unbroken chain of financial relationships in which the physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the physician for the entity as an indirect compensation arrangement that must satisfy the requirements of an applicable exception if the individual unit of compensation is payment for anything other than services personally performed by the physician (or immediate family member). All of these commenters urged CMS to take a more targeted approach to its policy concerns in this final rule.

Some commenters noted that, if finalized, the regulations would prohibit all arrangements for services furnished ''under arrangement'' to a hospital or other entity—which are typically purchased on a per-service basis—where the entire service is not performed personally by the physician who receives the unit-based compensation, including service arrangements that historically did not constitute indirect compensation arrangements or, if they did, satisfied the requirements of the exception for indirect compensation arrangements at § 411.357(p). Commenters explained that, as generally structured, in an arrangement involving services furnished ''under arrangement'' to a hospital (or other entity), a physician (or immediate family member) receives per-unit compensation for a complete service when the physician generated the referral of designated health services or generated other business billed by the entity (and when he or she did not). One of the commenters further explained that, under the current regulations at § 411.354(c)(2), such arrangements would not constitute indirect compensation arrangements, provided that the amount of compensation that the physician (or immediate family member) receives per individual unit of service is fair market value and does not positively correlate with the number or value of the physician's referrals to or other business generated for the entity. Further, according to this commenter, under the regulations as they existed prior to the MCR final rule, although such unbroken chains of financial relationships constituted indirect compensation arrangements, the special rules at § 411.354(d)(2) and (3) could be applied, and properly structured per-service payments were not considered to take into account the volume or value of the physician's referrals or other

business generated by the physician in violation of § 411.357(p)(1)(i). The commenter asserted that, if CMS finalizes this proposal, because § 411.354(d)(2) and (3) are no longer applicable to an analysis of whether compensation takes into account the volume or value of referrals or other business generated (the ''volume or value standards''), compensation under the typical ''under arrangements'' service arrangement would violate the volume or value standards at § 411.357(p)(1)(i).

Other commenters highlighted that the application of the proposal to certain lithotripsy services would conflict with longstanding CMS policy related to unit-based compensation for such services when furnished as a full package of services (as opposed to a lease of equipment and a technician). One commenter posited that, given that CMS focused on ensuring the continuation of the prohibition on per-click payments for the lease of office space or equipment and the use of premises or equipment as support for the proposal, the broad application of the regulations, if finalized, must be an inadvertent oversight or mistake.

Response: Our proposal to revise § 411.354(c)(2) was intended to support policies finalized in the MCR final rule that were made in the context of assessing the risk of program and patient abuse associated with services personally performed by a physician. However, we agree that the regulation at proposed § 411.354(c)(2)(ii)(A)(*4*) would have resulted in unintended limitations on unbroken chains of financial relationships that historically constituted indirect compensation arrangements but satisfied all requirements of an applicable exception and, therefore, were not considered to pose a risk of program or patient abuse. The commenters are correct that, under the MCR final rule, certain unbroken chains of financial relationships no longer constitute indirect compensation arrangements and, thus, are outside the reach of the physician self-referral law. Our proposal to revise § 411.354(c)(2) was not based on a new review of these unbroken chains and a determination that they now pose a risk of program or patient abuse that had not historically existed. As noted in this section III.P., our proposal was intended to reinstate the prohibition on certain per-click compensation formulas in arrangements for the lease of office space or equipment that was inadvertently omitted in the MCR final rule changes and to ensure the application of this policy to arrangements for the use of premises and equipment. Accordingly, we are persuaded that a narrow, more targeted approach is appropriate. Under final § 411.354(c)(2)(ii)(A)(*2*)(*iv*), an indirect compensation arrangement exists if the amount of compensation that the physician (or immediate family member) receives per individual unit is payment for the lease of office space or equipment or for the use of premises or equipment, and all other conditions at § 411.354(c)(2) exist. As explained in the CY 2016 PFS final rule, an arrangement is for the lease of office space or equipment where dominion and control over the office space or equipment is transferred from the lessor to the lessee (80 FR 71325). In addition, an arrangement that grants a party permission to use the grantor's premises and equipment is a ''use'' or ''license'' arrangement. In contrast, an arrangement for the provision and purchase of a complete service (or a package of services) that includes all the personnel, supplies, office (or other) space, and equipment necessary to provide the service (or the package of services) but does not transfer dominion and control over the office space or equipment from the provider of the service—for example, a service provided ''under arrangements'' to a hospital that is performed entirely by a physician's practice or a joint venture in which the physician is a partner—is not an arrangement for the lease of office space or equipment, nor is it a ''use'' arrangement where the licensee uses the premises and equipment to perform services. This is true even though office space or equipment are necessary components of the complete service (or package of services) (see 81 FR 80534).

Comment: Several commenters requested clarification regarding when a service is considered to be personally performed by a physician (or immediate family member) as described at proposed § 411.354(c)(2)(ii)(B)(*3*), which states that services that are personally performed by a physician (or immediate family member) do not include services that are performed by any person other than the physician (or immediate family member), including, but not limited to, the physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member). One commenter expressed appreciation for the proposed codification of CMS' policy, noting that the guidance would be helpful in properly allocating productivity credit to physicians in certain settings. Some commenters, in virtually identical statements, suggested that we should consider services to be personally performed by a physician, regardless of who actually furnishes them, as long as they are billed using a billing number assigned to the physician, including services furnished by another individual but billed as services ''incident to'' the physician's service. Many of these commenters urged CMS not to confirm its interpretation of when services are personally performed by a physician (or immediate family member) for purposes of the physician self-referral law, arguing that proposed § 411.354(c)(2)(ii)(B)(*3*) is inconsistent with Medicare claim submission rules that allow a physician to bill for the services of employees or contractors that are furnished incident to the physician's professional services. Another commenter suggested that, if CMS finalizes a narrower approach to the analysis of unbroken chains of financial relationships involving the lease or use of office space, equipment, or premises, there would be no need to clarify what it means to personally perform a service for purposes of the physician self-referral law.

Response: As discussed in the response to other comments, we are not finalizing the policy at § 411.354(c)(2)(ii)(A)(*4*). Therefore, we need not and are not finalizing the regulation at proposed § 411.354(c)(2)(ii)(B)(*3*). However, it appears that commenters discussing incident to billing may be conflating Medicare billing conventions with physician self-referral policy, and we believe that clarification is warranted. For purposes of the physician self-referral law, as stated in the definition of ''referral'' at § 411.351, a designated health service is not personally performed by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members. This includes designated health services furnished incident to the referring physician's professional services. (*See* 66 FR 871 through 872 and 69 FR 16063.) To be clear, it is our longstanding policy that, for purposes of the physician self-referral law, an item or service is not personally performed by a physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

Comment: One commenter requested confirmation whether compensation under certain arrangements would impermissibly take into account the volume or value of referrals or other

business generated if the arrangements qualify as ''indirect compensation arrangements'' under our proposal to treat any unbroken chain of financial relationships in which the physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the physician for the entity as an indirect compensation arrangement that must satisfy the requirements of an applicable exception if the individual unit of compensation is payment for anything other than services personally performed by the physician (or immediate family member). The commenter presented three distinct, but similar, scenarios. In all three scenarios, a hospital has an arrangement with a physician organization for the provision of the personal services of the physicians in the physician organization. There are no employed or independent contractor physicians in the physician organization. The commenter stated that the compensation under the arrangement is a fair market value, fixed dollar amount per wRVU personally performed by the physicians or NPPs.

In the first scenario presented by the commenter, the arrangement with the physician organization also covers the provision of the personal services of the NPPs in the physician organization. The hospital pays the physician organization directly for each wRVU performed by the NPPs (as well as the physicians) in the physician organization. The commenter stated that the NPPs only perform services that they order in the exercise of their independent clinical judgment. Patients are not referred to the NPPs by the physicians in the physician organization. The commenter asserted that the services of the NPPs in this scenario do not result from ''referrals'' by the physicians in the physician organization and are not ''other business generated'' by such physicians.

In the second and third scenarios presented by the commenter, the hospital also enters into an arrangement directly with each of the NPPs for their personally performed services, some of which are provided to patients referred to the NPPs by the physicians in the physician organization. The commenter stated that the compensation under each of these arrangements is a fair market value, fixed dollar amount per wRVU personally performed by the NPP. The hospital accepts reassignment of each physician's and NPP's right to bill and receive payment from Medicare and other payors. In the first of these scenarios, the physicians in the physician organization refer to the NPPs all the services that the NPPs then personally perform. The physician organization enters into a payment-to-bank arrangement with each NPP under which the hospital's direct payment to the NPP is deposited into a bank account belonging to the NPP and then, under a revocable agreement between the NPP and the bank, is swept into a bank account belonging to the physician organization. In the second of these scenarios, the physicians in the physician organization refer to the NPPs all the services that the NPPs then personally perform. However, the hospital makes payment directly to the physician organization as ''agent'' for the NPPs. According to the commenter, the physician organization receives payment from the hospital on behalf of the NPPs, but not in its own right, for the services personally performed by the NPPs.

Response: In all the scenarios presented by the commenter, the physicians would stand in the shoes of the physician organization under the regulations at § 411.354(c)(1)(ii); therefore, the physicians would be deemed to have the same compensation arrangements with the hospital (and on the same terms) as the physician organization. In the scenarios presented by the commenter, each physician would be deemed to directly receive payment from the hospital for services that the physician personally performs, as well as for services that are performed by someone other than that physician (either another physician in the physician organization or an NPP in the physician organization). Such compensation arrangements would implicate the physician self-referral law; however, there would not be an unbroken chain of two or more financial relationships between the hospital and each physician, and the condition set forth at § 411.354(c)(2)(i) would not be met. As a result, there would not be an indirect compensation arrangement between the hospital and any of the physicians in the physician organization. Even if the physicians did not stand in the shoes of the physician organization, as described previously, we are not finalizing our proposal to treat all unbroken chains of financial relationships in which the physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the physician for the entity as an indirect compensation if the individual unit of compensation is payment for anything other than services personally performed by the physician (or immediate family member). We note that the commenter's inquiry relates to and is within the scope of our proposal to include as indirect compensation arrangements certain unbroken chains of financial relationships where the individual unit of compensation is payment for anything other than services personally performed by the physician (or immediate family member). However, because we are not finalizing that proposal, the commenter's inquiry, on its face, is moot. An analysis of the application of the regulations at § 411.354(d)(5) to the scenarios presented by the commenter is outside the scope of this rulemaking.

Comment: A few commenters stated that, following the MCR final rule, some stakeholders have been uncertain how to identify the individual unit of compensation to which the provisions of current § 411.354(c)(2)(ii)(A)(*1*) through (*3*) apply. These and other commenters generally supported finalizing the regulation at proposed § 411.354(c)(2)(ii)(B)(*2*), which specifies the individual units of compensation to which to apply the regulations that determine when an indirect compensation arrangement exists.

Response: As we explained in the proposed rule, it is our position that all compensation essentially is unit-based compensation. The underlying unit may be a discrete item, a unit of service, a unit of time, or a unit that results from combining different types of units into a single unit used to calculate the compensation. At final § 411.354(c)(2)(ii)(B), we are finalizing with revisions our proposal to specify the individual units of compensation to which to apply the regulations that determine when an indirect compensation arrangement exists. The revisions are intended to further clarify and simplify the application of the regulations at § 411.354(c)(2) that establish the conditions under which an indirect compensation arrangement exists. Specifically, under final § 411.354(c)(2)(ii)(B), the individual unit of compensation is the item, where the physician (or immediate family member) is compensated solely per item provided; the service, where the physician (or immediate family member) is compensated solely per service provided, including arrangements where the ''service'' provided by the physician (or immediate family member) includes both items and services, such as ''under arrangement'' service arrangements where both items and services are included in the complete service (or package of services) provided to the purchaser; and time, in all other

circumstances, including arrangements where the physician (or immediate family member) receives compensation for each item provided or unit of service performed (or both) in addition to compensation for each unit of time worked. The final regulations effectuate our policy, as stated in the proposed rule, that ''hybrid'' compensation—that is compensation that is comprised of payments for both time-based units and service-based or item-based units (or both)—is appropriately analyzed by converting it to compensation for a unit of time. In other words, the compensation paid to the physician (or immediate family member) must be totaled over a period of time, which period would be considered the individual ''unit'' of compensation for purposes of applying § 411.354(c)(2)(ii). (*See* 86 FR 39323 through 39324.)

Comment: One commenter claimed that there is confusion in the industry regarding the interpretation and application of the provisions at § 411.354(c)(2)(ii)(A)(*2*) and (*3*), as finalized in the MCR final rule and as proposed for modification in the CY 2022 PFS proposed rule. The commenter interpreted § 411.354(c)(2)(ii)(A)(*2*) and (*3*) to be a test of whether the amount of compensation *per individual* unit increases or decreases in a manner that positively correlates with referrals or other business generated by a physician. To illustrate, the commenter offered the example of a tiered compensation structure for physician compensation. In the commenter's example, the physician is paid a rate of $15 for the first 100 units of service provided and $20 per unit of service thereafter. The commenter concluded that this compensation structure would meet the conditions for the existence of an indirect compensation arrangement under § 411.354(c)(2)(ii)(A)(*2*) and (*3*), because the amount of compensation per individual unit of service could increase from $15 to $20 as the number of referrals or amount of other business generated increases. The commenter asserted that, in contrast, many stakeholders incorrectly believe that the conditions at § 411.354(c)(2)(ii)(A)(2) and (3) are met if the physician's (or immediate family member's) *aggregate compensation* increases or decreases in a manner that positively correlates with referrals or other business generated by the physician, even if the amount of compensation *per individual* unit remains constant. The commenter requested that CMS confirm that § 411.354(c)(2)(ii)(A)(*2*) and (*3*) address variations in the unit of compensation itself, not variation in the aggregate compensation received by the physician (or immediate family member).

Response: The commenter is correct that the focus of § 411.354(c)(2)(ii)(A)(*2*) and (*3*), as finalized in the MCR final rule and proposed for modification in the CY 2022 PFS proposed rule, is variation in the amount of compensation per individual unit itself, not the *aggregate compensation* received by the physician (or immediate family member). To avoid possible stakeholder confusion, in this final rule we are revising and renumbering the provisions in § 411.354(c)(2)(ii)(A) to explicitly distinguish between the conditions that must be met for aggregate compensation, on the one hand, and the conditions that must be met for the *individual unit* of compensation, on the other, in order for an indirect compensation arrangement to exist. We are making corresponding clarifying changes to § 411.354(c)(2)(*ii*)(C).

Under final § 411.354(c)(2)(ii)(A)(*1*), for an indirect compensation arrangement to exist, the referring physician (or immediate family member) must receive *aggregate compensation* from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services. When a physician is paid on a per unit of service or time basis, the physician's *aggregate compensation* will increase as the physician performs more services or completes more units of time. And, where the services performed by the physician correlate to designated health services referred or other business generated by the physician for the entity, the aggregate compensation received by the physician varies with the volume or value of referrals or other business generated by the physician for the entity. Under these circumstances, the condition at final § 411.354(c)(2)(ii)(A)(*1*) is met.

In addition to the test for aggregate compensation, one of the conditions in § 411.354(c)(2)(ii)(A)(*2*) for the *individual unit* of compensation received by the physician (or immediate family member) must also be met for an indirect compensation arrangement to exist. Final § 411.354(c)(2)(ii)(A)(2)(ii) and (*iii*) pertain to variability in the amount of compensation per individual unit relating to the volume or value of a physician's referrals or other business generated, respectively. In response to the comment requesting clarification of the application of these provisions, we are revising and renumbering the conditions that relate to the individual unit of compensation in § 411.354(c)(2)(ii)(A)(*2*) to clarify the application of these conditions generally and to illustrate how the regulations will apply in the case of tiered compensation as described by the commenter.

To illustrate, assume that the conditions for an indirect compensation arrangement between a physician and a hospital at §§ 411.354(c)(2)(i), 411.354(c)(2)(ii)(A)(*1*), and 411.354(c)(2)(iii) are met. In order for an indirect compensation arrangement to exist, one of the conditions for the *individual unit* of compensation in § 411.354(c)(2)(ii)(A)(*2*) must also be met. In the commenter's example of tiered compensation, the individual unit of compensation received by the physician could increase from $15 to $20 per unit if the physician provides over 100 units of service to the entity. We assume for purposes of this example that the physician's services are typically correlated with designated health services or other business generated for the hospital, and further that both $15 and $20 per unit of service are within the range of fair market value for the services actually provided. Because the amount of compensation per individual unit of service could increase from $15 to $20 as the number or value of the physician's referrals to the entity increase or the amount or value of the other business generated by the physician for the entity increases, the conditions for an indirect compensation arrangement at final § 411.354(c)(2)(ii)(A)(2)(*ii*) and (*iii*) are met. Therefore, the unbroken chain of financial relationships between the physician and the hospital would constitute an indirect compensation arrangement under § 411.354(c)(2). Importantly, at this step in the analysis, it does not matter if the physician is being paid for his or her personally performed services or if the tiered compensation formula does not include designated health services or other business generated as a variable. Although these are important factors in determining compliance with certain exceptions, including the exception for indirect compensation arrangements at § 411.357(p), the analysis under final § 411.354(c)(2)(ii)(A)(2)(*ii*) and (*iii*) focuses solely on whether the individual unit of compensation could increase as referrals or other business generated increase (or could decrease as referrals or other business generated decrease). Lastly, even if the physician

never performed the required number of services to trigger the increase from $15 to $20 per service, because the amount of compensation per individual unit of service *could* increase under the tiered compensation formula, the conditions for an indirect compensation arrangement at final § 411.354(c)(2)(ii)(A)(2)(*ii*) and (*iii*) are met in this illustration.

In general, we believe that tiered compensation models warrant additional scrutiny under the physician self-referral law when structured in a way that the amount of compensation per individual unit could increase as the number or value of the physician's referrals or the amount or value of other business generated by the physician increases. We are equally concerned with tiered compensation models where the amount of compensation per individual unit could decrease as the number or value of the physician's referrals decreases or the amount or value of other business generated by the physician decreases (for example, an arrangement under which a physician is paid $35 per wRVU if the physician furnishes 500 wRVUs during the month, but only $30 per wRVU if the physician does not reach the targeted 500 wRVUs). We have modified the conditions for the existence of an indirect compensation arrangement at § 411.354(c)(2) to ensure that an unbroken chain of financial relationships involving a tiered compensation structure under the compensation arrangement closest to the physician (or immediate family member) is considered an indirect compensation arrangement. When these conditions are met, the compensation arrangement or the individual referrals of designated health services must satisfy the requirements of an applicable exception to the physician self-referral law. If the compensation arrangement to which the physician is a direct (or deemed direct) party is not a value-based arrangement and the entity is not an MCO or IPO, the only available exception in § 411.357 is the exception for indirect compensation arrangements at § 411.357(p). Among other things, the exception at § 411.357(p) requires that the arrangement is set out in writing, thus ensuring greater transparency, and that the aggregate compensation received by the physician (or immediate family member) is fair market value for items and services actually provided. In addition, the exception requires that the compensation received by the physician (or immediate family member) is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician. The special rules at § 411.354(d)(5) and (6) are applied for purposes of determining satisfaction of this requirement. In applying the special rules at § 411.354(d)(5) and (6) to tiered compensation under an indirect compensation arrangement, the focus of the analysis is the formula used in determining the amount of compensation that the physician (or immediate family member) receives per individual unit—that is, per item, per service, or per unit of time. Provided that the formula used to calculate the amount of compensation to the physician (or immediate family member) per individual unit (that is, the amount of compensation per item, per service, or per unit of time) does not include as a variable the physician's referrals to or other business generated for the entity with which the physician (or immediate family member) has the indirect compensation arrangement, the compensation received by the physician (or immediately family member) would not be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the entity. We note that the application of § 411.354(d)(5) and (6) with respect tiered compensation arrangements is the same for both direct compensation arrangements and indirect compensation arrangements.

Comment: A few commenters urged CMS to delay the effective date of any revisions to the regulations addressing when an indirect compensation arrangement exists. These commenters asserted that affected parties would need time to identify and revise existing arrangements that would again implicate the physician self-referral law, but would not satisfy the requirements of an applicable exception to the law. Other commenters urged CMS not to delay the effective date of any final regulations that correct the inadvertent omission of the prohibition on per-click payments for the lease of office space or equipment and the use of premises or equipment in indirect compensation arrangements due to the important program integrity concerns at issue. These commenters also urged CMS not to ''grandfather'' any arrangements that were entered into after the effective date of the MCR final rule, noting that parties that entered into arrangements involving per-click payments for the lease of office space or equipment (or for the use of premises or equipment) after the effective date of the MCR final rule did so with full knowledge of CMS' longstanding concerns regarding such arrangements.

Response: We decline to delay the effective date of the regulations we are finalizing in this final rule, nor are we ''grandfathering'' arrangements involving per-click payments for the lease of office space or equipment or for the use of premises or equipment that were entered into after the effective date of the MCR final rule. We expect that the number of affected lease arrangements that will again implicate the physician self-referral law is limited, and parties to such arrangements have over a decade of experience in applying the requirement at § 411.357(p)(1)(ii) that prohibits compensation for the lease of office space or equipment that is determined using a formula based on per-unit of service rental charges, to the extent such charges reflect services provided to patients referred by the lessor to the lessee. We remind stakeholders that this requirement applies to all services, whether or not they are designated health services, that are provided to patients referred by the lessor to the lessee. The term ''referral'' has its general meaning and not the meaning set forth at § 411.351. For a more detailed explanation of this requirement, we refer readers to the FY 2009 IPPS final rule (73 FR 48713 through 48721) and the CY 2017 PFS final rule (81 FR 80524 through 80534). We also expect that the number of affected unbroken chains of financial relationships that involve arrangements for the use of premises or equipment that will again implicate the physician self-referral law is similarly limited.

3. Exception for Preventive Screening Tests, Immunizations, and Vaccines (§ 411.355(h))

As a general matter, vaccines fall within the definition of ''outpatient prescription drugs'' at § 411.351, and therefore, are considered designated health services for purposes of the physician self-referral law. Because the Federal Government purchased the initial supply of COVID–19 vaccines, Medicare does not make payment for COVID–19 vaccines at this time,[147] and COVID–19 vaccines do not fall within the definition of ''designated health services'' at § 411.351. However, should COVID–19 vaccines become payable by Medicare, unless the requirements of an applicable exception to the physician self-referral law are satisfied, the physician self-referral law's prohibitions under section 1877(a)(1) of the Act and § 411.353(a) and (b) will apply to the

[147] See *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

referral and billing of COVID–19 vaccines.

In Phase I, using the Secretary's authority at section 1877(b)(4) of the Act to create additional exceptions that do not pose a risk of program or patient abuse, we finalized an exception at § 411.355(h) that excludes from the physician self-referral law's referral and billing prohibitions certain preventive screening tests, immunizations, and vaccines covered under Medicare (66 FR 939). As finalized in Phase I, in addition to requirements related to compliance with the Federal anti-kickback statute and Federal and State laws and regulations related to billing and claims submission, the exception at § 411.355(h) required that the preventive screening test, immunization, or vaccine is subject to CMS-mandated frequency limits, reimbursed by Medicare based on a fee schedule, and listed on the CMS website and in annual PFS Updates. In Phase II, in recognition that some of the vaccines eligible for the exception may be paid by Medicare using different reimbursement methods, we removed the requirement that the preventive screening test, immunization, or vaccine is reimbursed based on a fee schedule (69 FR 16116). In the MCR final rule, as part of a broader effort to decouple the physician self-referral law from the Federal anti-kickback statute and Federal and State laws or regulations governing billing or claims submission, we removed the requirement at former § 411.355(h)(2) that the arrangement does not violate the Federal anti-kickback statute, as well as the requirement at former § 411.355(h)(3) that the arrangement does not violate any Federal or State law or regulation governing billing or claims submission (85 FR 77567).

Services to which the exception at § 411.355(h) is applicable remain designated health services for purposes of the physician self-referral law; however, referrals may be made and claims submitted for such services if all requirements of the exception are satisfied (69 FR 16100). In the CY 2021 PFS final rule, we added COVID–19 vaccines to the list of immunization and vaccine codes to which the exception at § 411.355(h) is applicable (85 FR 84954 through 85955). We did so to ensure that the physician self-referral law will not impede the availability of COVID–19 vaccines for Medicare and other patients if they become payable by Medicare (85 FR 84955).

Under current § 411.355(h)(1), a preventive screening test, immunization, or vaccine must be subject to CMS-mandated frequency limits, among other requirements. Frequency limits determine the maximum number of times that Medicare will pay for a service for a particular beneficiary during an established period, often a calendar year or 12-month period. CMS-mandated frequency limits also serve to minimize the risk of program or patient abuse due to a physician's financial self-interest, because Medicare will not pay for additional services referred and furnished in excess of the frequency limitation. In Phase I, we stated our belief that, under the terms of the exception at § 411.355(h) as finalized in Phase I—which included the requirement that the service is subject to CMS-mandated frequency limits—the risk of abuse is extremely low. We also stated that the exclusion of certain preventive screening tests, immunizations, and vaccines from the reach of the physician self-referral law is consistent with the statutory language and structure and the expressed Congressional intent to provide preventive care to Medicare beneficiaries (66 FR 939).

The United States continues to respond to the outbreak of COVID–19 caused by the severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2). At this time, we have not mandated frequency limits for the COVID–19 vaccines identified on the List of CPT/HCPCS Codes (Code List) to which the exception at § 411.355(h) is applicable and we are uncertain whether or, if so, when CMS may mandate frequency limits for COVID–19 vaccines. Thus, although COVID–19 vaccines are identified on the Code List as codes to which the exception at § 411.355(h) is applicable, they could not satisfy the requirement at current § 411.355(h)(1) that the preventive screening test, immunization, or vaccine is subject to CMS-mandated frequency limits. We are concerned that the current absence of CMS-mandated frequency limits on the available COVID–19 vaccines could impede the availability of critically important COVID–19 vaccines for Medicare and other patients, as physician referrals for COVID–19 vaccines would be prohibited unless another exception to the physician self-referral law is applicable and all its requirements are satisfied. Therefore, we proposed to permit the use of the exception at § 411.355(h) for COVID–19 vaccines even when they are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. Specifically, we proposed to revise and renumber the regulation at § 411.355(h). We are finalizing the regulation as proposed. Revised § 411.355(h)(1) includes the conditions that must be met to avoid the physician self-referral law's referral and billing prohibitions. The requirement at current § 411.355(h)(4) that the preventive screening test or vaccine is listed on the Code List as a code to which the exception at § 411.355(h) is available will be renumbered as § 411.355(h)(1)(i); the requirement at current § 411.355(h)(4) that the preventive screening test or vaccine is covered by Medicare will be renumbered as § 411.355(h)(1)(ii); and the requirement at current § 411.355(h)(1) that the preventive screening test or vaccine is subject to a CMS-mandated frequency limit will be renumbered as § 411.355(h)(1)(iii). As finalized, § 411.355(h)(2) states that the requirement at § 411.355(h)(1)(iii) does not apply to a COVID–19 vaccine code during such period that the vaccine is not subject to a CMS-mandated frequency limit. In light of the impact of the COVID–19 pandemic on the United States and the vital need to protect beneficiaries (and others) from the SARS-CoV–2 virus, we do not believe that making the exception at § 411.355(h) available for COVID–19 vaccines to which no CMS-mandated frequency limits apply poses a risk of program or patient abuse.

We solicited comment on our approach to this exception and its applicability to COVID–19 vaccines, including whether we should limit relief from the requirement at § 411.355(h)(1)(iii) to the period during which the current PHE is in effect, until such time as CMS-mandated frequency limits apply for COVID–19 vaccines, or some other period of time. Based on the comments, we are finalizing our proposal to permit the use of the exception at § 411.355(h) for COVID–19 vaccines during such period as the vaccines are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. As finalized, the availability of § 411.355(h)(1)(iii) for COVID–19 vaccines is not limited to the period during which the current PHE is in effect.

We note that, as explained in section II.J. of this final rule, monoclonal antibody products used to treat COVID–19 are currently covered and paid for under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act. Thus, under final § 411.355(h)(2), the requirement pertaining to CMS-mandated frequency limits at final § 411.355(h)(1)(iii) does not apply to monoclonal antibody products used to treat COVID–19 during such period as

the products are paid for under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act and are not subject to a CMS-mandated frequency limit.

We also alternatively proposed to remove the CMS-mandated frequency limit requirement for all vaccines. We solicited comment on whether it would then be necessary to include alternative program integrity requirements in the exception at § 411.355(h) if we were to do so. We stated that we were interested in comments regarding whether physicians are likely to order vaccines more frequently than recommended by the Department and any other organization the Department identifies as an authority on this matter. Based on our review of the comments related to this alternative proposal, we are not finalizing the alternative proposal.

Finally, for clarity and consistency, we proposed to revise the terminology used in the exception at § 411.355(h). Specifically, we proposed to remove the terms ''immunization'' and ''immunizations'' throughout § 411.355(h) and the headers used in the Code List. In the proposed rule, we noted that the Centers for Disease Control and Prevention (CDC) defines immunization as a process by which a person becomes protected against a disease through vaccination. The term ''immunization'' is often used interchangeably with vaccination or inoculation. The CDC defines the term ''vaccine'' as a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease.[148] All the codes currently on the Code List to which the exception at § 411.355(h) is applicable have a descriptor containing ''vaccine'' or a derivative of ''vaccine.''

Vaccines fall within the definition of ''outpatient prescription drugs'' at § 411.351, and therefore, are considered designated health services for purposes of the physician self-referral law. As defined by the CDC, an immunization is not an item or service that is a ''designated health service'' (as defined at § 411.351) to which the physician self-referral law applies. We believe that ''vaccine'' is the appropriate term to use in § 411.355(h) and in the headers in the Code List. Although we are not aware that including both terms in § 411.355(h) and the Code List has caused stakeholder confusion to date, we proposed to improve the accuracy of the terminology at this time to prevent any possible confusion in the future. We are finalizing our proposal to remove the terms ''immunization'' and ''immunizations'' throughout § 411.355(h) and the headers used in the Code List. The revisions to the title and text of § 411.355(h) that we are finalizing in this final rule do not affect whether a code is a designated health service for purposes of the physician self-referral law.

We received the following public comments regarding our proposals, and our responses follow.

Comment: Several commenters supported our proposal to permit the use of the exception at § 411.355(h) for COVID–19 vaccines during such period as the vaccines are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. No commenters opposed the proposal. Commenters noted that removing the CMS-mandated frequency requirement for COVID–19 vaccines would reduce barriers to vaccine delivery and ensure that the physician self-referral law will not impede vaccine availability for beneficiaries. According to one commenter, if finalized, the proposal would allow physicians to make referrals for vaccines without fear of violating the physician self-referral law and would likely increase access to vaccines. Another commenter highlighted the continuing impact of the COVID–19 PHE on practices, physicians, and patients. The commenter noted that ensuring life-saving vaccines are available to Medicare beneficiaries is critical, particularly as new virus variants emerge and booster vaccinations are potentially required for many patients. Several commenters opposed limiting the suspension of the requirement for a frequency mandate to the period of the PHE. Commenters generally agreed with CMS that the proposal, if finalized, would not pose a risk of program or patient abuse.

Response: In light of the impact of the COVID–19 pandemic on the United States and the vital need to protect Medicare beneficiaries (and others) from the SARS–CoV–2 virus, we remain concerned that the current absence of CMS-mandated frequency limits on COVID–19 vaccines could inadvertently impede the availability of the vaccines due to the application of the physician self-referral law's referral and billing prohibitions. Therefore, we are finalizing our proposal to permit the use of the exception at § 411.355(h) for COVID–19 vaccines during such period as the vaccines are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. We agree with the commenters that finalizing this proposal does not pose a risk of program or patient abuse. We also agree that we should permit the use of the exception at § 411.355(h) for COVID–19 vaccines until such time as CMS-mandated frequency limits apply for COVID–19 vaccines, without regard to the PHE timeframe, to ensure that we do not impede the continuing availability of COVID–19 vaccines.

Comment: Several commenters supported our alternative proposal to remove the CMS-mandated frequency limit requirement for all vaccines. One commenter maintained that this proposal, if finalized, would reduce barriers to vaccine delivery. Several commenters contended that finalizing this proposal would not necessitate including alternative program integrity requirements in the exception at § 411.355(h). Several commenters asserted that physicians are unlikely to order vaccines more frequently than recommended by the CDC's Advisory Committee on Immunization Practices (ACIP), especially given Medicare's current payment rates for non-COVID–19 vaccines and their administration. Another commenter explained that, because vaccines are generally administered at discrete intervals, based on age or medical indications, vaccines do not present the same program integrity concerns as other outpatient drugs and can even reduce health care costs by preventing more serious diseases.

Response: We are not persuaded to remove the CMS-mandated frequency limit requirement for all vaccines at this time. In particular, we are concerned about potential harm to patients from receiving unnecessary or duplicative vaccinations. There are only a limited number of requirements under the exception at § 411.355(h), and we are concerned that, in the absence of alternative requirements, an open-ended exception permitting the furnishing of all vaccines, even if the vaccines are not subject to CMS-mandated frequency limits, may pose a risk of program or patient abuse.

Comment: Several commenters supported our proposal to remove the terms ''immunization'' and ''immunizations'' throughout § 411.355(h) and the headers used in the Code List. No commenters opposed the proposal.

Response: After consideration of the comments, we continue to believe that ''vaccine'' is the appropriate term to use in § 411.355(h) and in the headers in the Code List. Therefore, we are finalizing our proposal to remove the terms

[148] *https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm.*

''immunization'' and ''immunizations'' throughout § 411.355(h) and the headers used in the Code List. We reiterate that the final revisions to § 411.355(h) do not affect whether a code is a designated health service for purposes of the physician self-referral law.

4. List of CPT/HCPCS Codes (§ 411.351)

As described in section III.P.1. of this final rule, unless an exception applies and all its requirements are satisfied, the physician self-referral law prohibits a physician from making a referral for the furnishing of certain designated health services if the physician has a financial relationship with the entity to which the referral is made. Recognizing that providing precise definitions of which designated health services implicate the physician self-referral law would facilitate compliance with the law, in the Phase I final rule, we determined to define certain designated health services by publishing specific lists of CPT and HCPCS codes that physicians and providers most commonly associate with a given designated health service (66 FR 922). This list of CPT and HCPCS codes defines the entire scope of the designated health services category for purposes of the physician self-referral law and is controlling vis-à-vis the definition of the category at § 411.351, which contains a general explanation of the principles used to select the codes.

In Phase I, we stated that, because HCPCS Level I and II codes change and can quickly become out-of-date, we would not include the list of CPT and HCPCS codes that are designated health services in the text of our regulations (66 FR 923). We also stated that the definitions of specific services in our regulations would cross-refer to a comprehensive table that would appear initially in the **Federal Register** along with Phase I and thereafter in an addendum to the annual final rule concerning payment policies under the PFS rule. We defined at § 411.351 the term ''List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act)'' to mean the list of certain designated health services under section 1877 of the Act initially posted on the CMS website and updated annually thereafter in an addendum to the PFS final rule and on the CMS website. In the Phase II interim final rule, we revised the term to ''List of CPT/HCPCS Codes'' and its definition to ''the list of CPT and HCPCS codes that identifies those items and services that are designated health services under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act.'' The Phase II definition also stated that the list is updated annually, as published in the **Federal Register**, and is posted on the CMS website at *http://www.cms.gov/medlearn/refphys.asp.* Other than including an updated URL for the location of the list on the CMS website, the current definition of ''List of CPT/HCPCS Codes'' is identical to the Phase II definition. The CMS website currently identifies this list as the Code List for Certain Designated Health Services (the Code List).[149]

As we discussed in the proposed rule, coding changes have become more frequent since we initially began publishing the Code List. In an effort to more closely align with the frequency of the coding changes, we proposed to update the Code List more frequently than annually. Specifically, we proposed to update the Code List each calendar quarter, and provide public notification in advance of Code List updates. We stated that, if finalized, advance notification would be posted on the CMS website on March 1, June 1, September 1, and December 1 of each year, with corresponding Code List updates effective on April 1, July 1, October 1, and January 1, respectively. We also proposed a 30-day public comment period following the posting of each advance notification of the upcoming quarterly Code List update. We stated in the proposed rule that we would provide information on our website regarding the process for submitting public comments through *www.regulations.gov* and address all public comments on the Code List on the CMS website. We stated that we anticipate that most comments would be addressed within 90 calendar days of the effective date of the Code List update to which they pertain; however, we indicated that a longer timeframe might be necessary to address complex comments or those that require coordination with external parties. We also stated that this new process and schedule would begin with the update effective April 1, 2022. Based on the comments, we are not finalizing our proposal to update the Code List more frequently. The Code List that is effective January 1, 2022 is included in this final rule and will continue to be updated on an annual basis as described below.

In addition, we proposed to publish the Code List solely on the CMS website (commencing after the publication of the January 1, 2022 Code List in this final rule). In the proposed rule, we stated that we believe that publication via the CMS website would facilitate compliance with the physician self-referral law and allow ready access to the most up-to-date Code List. We proposed corresponding revisions to the definition of ''List of CPT/HCPCS Codes'' at § 411.351 and to update the URL that indicates where the Code List is published on the CMS website. We are finalizing our proposal to publish the Code List solely on the CMS website (commencing after the publication of the January 1, 2022 Code List in this final rule). We are finalizing the definition of ''List of CPT/HCPCS Codes'' at § 411.351 to mean the list of CPT and HCPCS codes that identifies those items and services that are designated health services under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually and posted on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.*

We received the following comments regarding our proposals and our responses follow:

Comment: Some commenters, including a representative of a large number of stakeholders, expressed concern that more frequent Code List updates would impose a significant burden on the industry and increase its risk of noncompliance with the physician self-referral law. These commenters urged CMS to continue to update the Code List on an annual basis only. By way of example, one commenter stated that quarterly adjustments to the Code List would create confusion and add another level of administrative burden to physician self-referral law compliance efforts. This commenter was concerned that certain compensation arrangements with physicians could inadvertently fall out of compliance with the physician self-referral law with more frequent changes to the Code List. Another commenter stated that more frequent Code List updates would require more frequent review and modification of arrangements with physicians in order to ensure compliance with the physician self-referral law. The commenter further stated that publishing more frequent Code List updates would require more resources to review and comply with the physician self-referral law. In contrast, several commenters generally supported our proposal to update the Code List more frequently, but did not articulate the rationale for their support.

Response: Our proposal to update the Code List quarterly was intended to

[149] *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.*

benefit stakeholders by providing updates to the Code List at intervals that align more closely with the current coding cycles. We are persuaded by the commenters that the increased administrative and compliance burden outweighs the benefit of more frequent updates and are not finalizing our proposal to update the Code List quarterly. We will continue to update the Code List on an annual basis.

Comment: All the commenters that addressed our proposal to publish the Code List solely on the CMS website supported website-only publishing.

Response: After consideration of the comments, we are finalizing our proposal to publish the Code List solely on the CMS website. We continue to believe that publishing the Code List on the CMS website will facilitate compliance with the physician self-referral law and provide easier access to the most up-to-date Code List. Commencing after the publication of the January 1, 2022 Code List in this final rule, the Code List will be updated annually and published on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.*

Comment: Several commenters stated that a 30-day advance notice and comment period for Code List updates is sufficient.

Response: We agree that 30 days advance notice is sufficient prior to the publication of the annual Code List updates. Beginning with the Code List that is effective January 1, 2023, no less than 30 consecutive calendar days prior to the effective date of a Code List update, we will provide advance notice of the updated Code List on the CMS website. We will also provide for a 30-day public comment period for each update using *www.regulations.gov,* and publish instructions for submitting comments on the CMS website. We will address all public comments that we receive through this process on the CMS website. We anticipate that most comments will be addressed within 90 calendar days of the effective date of the Code List update to which they pertain; however, a longer timeframe may be necessary to address complex comments or those that require coordination with external parties.

5. Annual Update to the List of CPT/HCPCS Codes

a. General

As described in section III.P.1. of this final rule, unless an exception applies and its requirements are satisfied, the physician self-referral law prohibits a physician from making a referral for the furnishing of certain designated health services if the physician has a financial relationship with the entity to which the referral is made. Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following items and services are designated health services:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

b. Annual Update to the Code List

i. Background

In § 411.351, we specify that the entire scope of four categories of designated health services is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibitions:

- EPO and other dialysis-related drugs (§ 411.355(g)).
- Preventive screening tests, immunizations, and vaccines (§ 411.355(h)).

The definition of ''designated health services'' at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically included in the statutory or regulatory lists of items and services that are designated health services and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not designated health services and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

ESRD-related oral-only drugs, which are drugs or biologicals with no injectable equivalents or other forms of administration other than an oral form, were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. On December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and, thus, are designated health services.

As previously stated, because the Federal Government purchased the initial supply of COVID–19 vaccines, Medicare does not make payment for COVID–19 vaccines at this time, and COVID–19 vaccines do not fall within the definition of ''designated health service'' at § 411.351. However, should COVID–19 vaccines become payable by Medicare, unless the requirements of an applicable exception to the physician self-referral law are satisfied, the physician self-referral law's prohibitions under section 1877(a)(1) of the Act and § 411.353(a) and (b) will apply to the referral and billing of COVID–19 vaccines.

In the CY 2021 PFS final rule, we added COVID–19 vaccines to the list of immunization and vaccine codes to which the exception at § 411.355(h) is applicable (85 FR 84954 through 85955). We did so to ensure that the physician self-referral law will not impede the availability of COVID–19 vaccines for Medicare and other patients if they become payable by Medicare (85 FR 84955). We also included language in the CY 2021 Code List to ensure that any COVID–19 vaccine to which a CPT or HCPCS code applied prior to the publication of the CY 2022 Code List would qualify for the exception at § 411.355(h). Specifically, we stated that the physician self-referral prohibitions do not apply to CPT code 90749 (unlisted vaccine/toxoid) when it is used to identify a COVID–19 vaccine or

to any future CPT or HCPCS code designated for a COVID–19 vaccine. We continue to include this language in the CY 2022 Code List. The inclusion of CPT code 90749 on the Code List is not intended and should not be considered to direct or approve the use of CPT code 90749 for the identification and billing of any COVID–19 vaccine.

As stated in section II.J. of this final rule, monoclonal antibody products used to treat COVID–19 are currently covered and paid for under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act. We make a separate payment for the products (when not given to the provider or supplier for free by the government) and for the service to administer them. As ''vaccines,'' the products are designated health services for purposes of the physician self-referral law. Monoclonal antibody products covered and paid under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act are included in the January 1, 2021 list of codes that are eligible for the exception at § 411.355(h) as ''any future CPT or HCPCS code designated for a COVID–19 vaccine.'' Accordingly, the physician self-referral prohibitions do not apply to them, provided that all requirements of the exception at § 411.355(h) are satisfied. Effective January 1, 2022, we are including in the list of codes that are eligible for the exception at § 411.355(h) the existing specific HCPCS codes for monoclonal antibody products that are covered and paid under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act. The general descriptor on the Code List will apply to any future CPT or HCPCS codes for monoclonal antibody products that are covered and paid for under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act. For more information regarding monoclonal antibodies, please refer to our website at *https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion.*

Since the PHE for COVID–19 is still ongoing, we remind readers that tests for COVID–19 identified in the Code List fall within the ''clinical laboratory services'' category of designated health services.

The Code List was last updated in Tables 58 and 59 of the CY 2021 PFS final rule (85 FR 84956 through 84957).

ii. Response to Comments

We received no comments relating to the Code List that became effective January 1, 2021.

iii. Revisions Effective for CY 2022

The updated, comprehensive Code List effective January 1, 2022, is available on our website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.*

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 41 and 42 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2022. Tables 41 and 42 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

BILLING CODE 4120–01–P

TABLE 41: Additions to the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
0017M Onc dlbcl mrna 20 genes alg
0229U Bcat1 promoter mthyltn alys
0230U Ar full sequence analysis
0231U Cacna1a full gene analysis
0232U Cstb full gene analysis
0233U Fxn gene analysis
0234U Mecp2 full gene analysis
0235U Pten full gene analysis
0236U Smn1&smn2 full gene analysis
0237U Car ion chnlpthy gen seq pnl
0238U Onc lnch syn gen dna seq aly
0239U Trgt gen seq alys pnl 311+
0242U Trgt gen seq alys pnl 55-74
0244U Onc solid orgn dna 257 genes
0245U Onc thyr mut alys 10 gen&37
0246U Rbc dna gnotyp 16 bld groups
0250U Onc sld org neo dna 505 gene
0258U Ai psor mrna 50-100 gen alg
0260U Rare ds id opt genome mapg
0261U Onc clrct ca img alys w/ai
0262U Onc sld tum rtpcr 7 gen
0264U Rare ds id opt genome mapg
0265U Rar do whl gn&mtcdrl dna als
0266U Unxpl cnst hrtbl do gn xprsn
0267U Rare do id opt gen mapg&seq
0268U Hem ahus gen seq alys 15 gen
0269U Hem aut dm cgen trmbctpna 14
0270U Hem cgen coagj do 20 genes
0271U Hem cgen neutropenia 23 gen
0272U Hem genetic bld do 51 genes
0273U Hem gen hyprfibrnlysis 8 gen

0274U Hem gen pltlt do 43 genes
0276U Hem inh thrombocytopenia 23
0277U Hem gen pltlt funcj do 31
0278U Hem gen thrombosis 12 genes
0282U Rbc dna gntyp 12 bld grp gen
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
98966 Hc pro phone call 5-10 min
98967 Hc pro phone call 11-20 min
98968 Hc pro phone call 21-30 min
98970 Qnhp ol dig assmt&mgmt 5-10
98971 Qnhp ol dig assmt&mgmt 11-20
98972 Qnhp ol dig assmt&mgmt 21+
98975 Rem ther mntr 1st setup&edu
98976 Rem ther mntr dev sply resp
98977 Rem ther mntr dv sply mscskl
98980 Rem ther mntr 1st 20 min
98981 Rem ther mntr ea addl 20 min
G2250 Remot img sub by pt, non e/m
G2251 Brief chkin, 5-10, non-e/m
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
77089 Tbs dxa cal w/i&r fx risk
A9592 Copper cu 64 dotatate diag
A9593 Gallium ga-68 psma-11 ucsf
A9594 Gallium ga-68 psma-11, ucla
A9595 Piflu f-18, dia 1 millicurie
RADIATION THERAPY SERVICES AND SUPPLIES
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
PREVENTIVE SCREENING TESTS AND VACCINES
90671 Pcv15 vaccine im
90677 Pcv20 vaccine im
90759 Hep b vac 3ag 10mcg 3 dos im
91302 Sarscov2 vac 5x10^10vp/.5mlim
91303 Sarscov2 vac ad26 .5ml im
91304 Sarscov2 vac 5mcg/0.5ml im
91305 Sarscov2 vac 30 mcg trs-sucr
91306 Sarscov2 vac 50mcg/0.25ml im
91307 Sarscov2 vac 10 mcg trs-sucr
G0327 Colon ca scrn;bld-bsd biomrk
Q0240 Casirivi and imdevi 600 mg
Q0243 Casirivimab and imdevimab
Q0244 Casirivi and imdevi 1200 mg
Q0245 Bamlanivimab and etesevima
Q0247 Sotrovimab
Q0249 Tocilizumab for covid-19

[1]CPT codes and descriptions only are copyright 2021 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 42: Deletions from the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
76101 Complex body section x-ray
76102 Complex body section x-rays
C9407 Iodine i-131 iobenguane, dx
G0297 Ldct for lung ca screen
C9068 Copper cu-64, dotatate, dx
RADIATION THERAPY SERVICES AND SUPPLIES
C9408 Iodine i-131 iobenguane, tx
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
PREVENTIVE SCREENING TESTS AND VACCINES

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BILLING CODE 4120–01–C

Q. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. SUPPORT Act Requirements

Section 2003 of the SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to exceptions, which the Secretary may specify. Section 2003 of the SUPPORT Act requires that the Secretary use rulemaking to specify circumstances and processes by which the Secretary may waive the Electronic Prescribing for Controlled Substances (EPCS) requirement, and provides the Secretary with authority to enforce and specify appropriate penalties for non-compliance with EPCS. The SUPPORT Act specifies some circumstances under which the Secretary may waive the electronic prescribing requirement with respect to controlled substances that are covered Part D drugs and permits HHS to develop other appropriate exceptions. Since the statute states that the Secretary shall, through rulemaking, specify circumstances and processes by which the Secretary ''may waive'' the EPCS requirement, we consider the list of circumstances to be illustrative. The circumstances that are listed in the statute under which the Secretary may waive the EPCS requirement are at section 1860D–4(e)(7) of the Act, as added by section 2003 of the SUPPORT Act, and include:

- A prescription issued when the practitioner and dispensing pharmacy are the same entity;
- A prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, which is the SCRIPT 2017071 standard;
- A prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed 1 year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;
- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;
- A prescription issued by a practitioner prescribing a drug under a research protocol;
- A prescription issued by a practitioner for a drug for which the FDA requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;
- A prescription issued by a practitioner—
  - ++ For an individual who receives hospice care under title XVIII of the Act; and
  - ++ That is not covered under the hospice benefit under title XVIII of the Act; and
- A prescription issued by a practitioner for an individual who is—
  - ++ A resident of a nursing facility (as defined in section 1919(a) of the Act); and
  - ++ Dually eligible for benefits under title XVIII and title XIX of the Act.

2. Previous Regulatory Action

To begin the process of implementing section 2003 of the SUPPORT Act, in August 2020, we released a Request for Information entitled ''Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)'' (85 FR 47151) (hereinafter referred to as the August 2020 RFI). In August 2020, we released the CY 2021 PFS proposed rule (85 FR

50074) (hereinafter referred to as the CY 2021 PFS proposed rule), which proposed that Part D prescribers be required to use the NCPDP SCRIPT 2017071 standard for EPCS prescription transmissions. We proposed that this mandate would not become effective until January 1, 2022.

We received a combined total of 155 timely comments in response to the August 2020 RFI and the CY 2021 PFS proposed rule. Most commenters supported implementing EPCS and use of the NCPDP SCRIPT 2017071 standard. Comments were mixed as to when compliance actions for EPCS should begin. Some commenters requested that CMS adhere to the January 1, 2021 date specified in the SUPPORT Act because of the many safety benefits associated with EPCS articulated in the proposed rule. Some prescriber groups supported the proposed January 1, 2022 date, while others requested even more time for implementation. To balance the needs of prescribers who wanted more time to implement EPCS and commenters who wanted adherence to the January 1, 2021 date, we finalized this provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022 in the CY 2021 Physician Fee Schedule final rule (85 FR 84472) (hereinafter referred to as the CY 2021 PFS final rule). Due to the consensus among commenters that the NCPDP SCRIPT 2017071 standard was the best choice for EPCS, we required in the CY 2021 PFS final rule that Part D prescribers use this standard.

3. Current EPCS Environment

A variety of Part D medications are classified as controlled substances by the Drug Enforcement Administration (DEA). Among these are medications used for the treatment of acute and chronic pain, (for example, hydrocodone, fentanyl, codeine, methadone), and stimulant medications (for example, Adderall®, Ritalin®). *Buprenorphine* (for example, Suboxone®) is one of only three drugs approved by the FDA to treat opioid use disorders (OUD) including in outpatient settings, and is a Schedule III drug. Benzodiazepines and sedative-hypnotics (including Xanax®, Valium®, Ativan®, Restoril®, Midazolim®, and Halcion®) are used for sleep, agitation, and seizure disorders. Anabolic steroids (for example, Depo-testosterone®) are used to treat impotence, delayed puberty, hormonal imbalance, and inoperable breast cancers.

As discussed in the CY 2021 PFS proposed and final rules, we noted that electronic prescribing of controlled substances provides multiple advantages over the traditional processing of paper prescriptions. These advantages include, but are not limited to, improved workflow efficiencies; deterring and detecting prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes; enhanced patient safety through patient identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions; and providing more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions. By allowing for the direct transmission of prescriptions for controlled substances between prescribers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions among staff, patients, facilities, other care sites, and pharmacies. EPCS can also assure prescribers' identity more easily and may permit a single workflow for prescribing both controlled and non-controlled drugs, improving the overall prescribing process.

From the patient standpoint, EPCS may reduce the logistical burden on patients and caregivers who may otherwise be required to make multiple trips between prescribers and pharmacies to transport paper prescriptions when filling time-sensitive prescriptions, while in pain, or otherwise in need of medical treatment with controlled substances. EPCS can lessen the time needed to obtain prescriptions by minimizing trips to the prescriber to pick up paper prescriptions for refills and minimize transportation costs to and from the prescriber's office. EPCS's identity and security requirements assure prescribers, patients, and pharmacies that prescriptions are processed as intended. In addition to helping with the reduction in fraud previously described, EPCS minimizes the likelihood that prescriptions have been tampered with, since electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, which minimizes the likelihood of exposure to patients or other third parties. During the PHE for COVID–19, EPCS also helps parties maintain social distancing.

It is due to these advantages, coupled with the SUPPORT Act's EPCS mandate, that we encourage all prescribers to conduct EPCS as soon as is feasible for them. We believe that although EPCS is ultimately more efficient, implementing EPCS does take additional time and resources. Prescribers must follow DEA guidance for EPCS, which is summarized at *https://deadiversion.usdoj.gov/ecomm/e_rx/*. Prescribers must first ensure that their current e-prescribing software can support EPCS and meet DEA requirements pursuant to 21 CFR part 1311. Further, DEA also requires prescribers to have their identities verified prior to being issued the authentication credentials needed to sign and issue electronic controlled substance prescriptions. For individual prescribers, identity proofing (that is, verification that the prescriber is who he or she claims to be) is conducted by a credential service provider (CSP) or certification authority (CA). Institutional practitioners, as defined under 21 CFR 1300.01, have the option of conducting in-house identity proofing of the practitioners authorized to use the institution's e-prescribing software. Alternatively, institutional practitioners may require their practitioners to undergo identity proofing by a CSP or CA. Once their identities have been confirmed, prescribers may be issued their authentication credentials. The authentication credentials must be two-factor, meaning that prescribers must be required to supply two factors to confirm both their identity and their authorization to access the e-prescribing software. The factors may be something the prescriber knows (such as a password or PIN), something the prescriber has (such as a smartcard or token), or a biometric (such as a fingerprint). For institutional practitioners, the authentication credentials may be issued by an entity within the institution that is separate from the entity that conducted identity proofing, if identity proofing was conducted in-house. Otherwise, authentication credentials are issued by a CSP or CA. Once a prescriber has received his or her two-factor authentication credentials, the prescriber must be granted access to sign and issue electronic controlled substance prescriptions using the e-prescribing software. This step is completed by certain individuals specifically designated to manage the e-prescribing software's logical access controls. Prior to granting a prescriber access, the individuals managing logical access controls must verify that the prescriber's State authorization to practice and, where applicable, State authorization to prescribe controlled substances, are valid. Additionally, for

individual prescribers (those prescribers not prescribing under an institutional practitioner's DEA registration), the individuals managing logical access controls must verify that the prescriber's DEA registration is valid. This step is required even if the prescriber is already prescribing controlled substances on paper. After being granted access, prescribers may sign and issue electronic prescriptions for controlled substances using their two-factor authentication credentials. The EPCS application must require two-factor authentication for each transaction. Software and workflow training are available for each step of the process. When writing prescriptions, the prescriber may wish to talk with the patients and/or caregivers about electronic prescribing, so there is awareness of the general mechanics of how the prescription(s) will be conveyed to the pharmacy.

We recognize that section 2003(c) of the SUPPORT Act tasked the Department of Justice (DOJ) with updating the requirements for the biometric component of multifactor authentication. As shown on the Spring 2021 Unified Agenda,[150] rulemaking to address this mandate is currently in progress. After reviewing comments on the August 2020 RFI and CY 2021 PFS proposed rule and talking with industry stakeholders, we recognize that commenters believe that an update to the DOJ requirements should allow prescribers to start conducting EPCS with greater ease.

The comments also stated that prescribers have felt strained by the COVID–19 pandemic. Prescribers reported feeling financially strained, worried about their own health and the health of their employees, and concerned about having to make rapid changes during a time when they are continuing to cope with the effects of the COVID–19 pandemic on their practices and their patients. Despite the strain that has been experienced by prescribers, we have noted an increase in EPCS during this PHE. Based on data from the first quarter of CY 2021, EPCS increased to 70 percent of all prescription drug events (PDEs) for controlled substances as compared to 38 percent in CY 2019.[151] We believe that social distancing is likely to be at least partly responsible for the increase in EPCS during this PHE for COVID–19. With the use of electronic prescribing, one potential prescriber-patient interaction in which COVID–19 could be transmitted is eliminated, and any necessary prescriptions can be electronically transmitted to the pharmacy without the prescriber and patient having to see each other in-person and risk transmitting COVID–19. Some insurers, including Part D plans, have been permitting medication refills, including for controlled substances, earlier than usual or for a more extended period of time than is allowed. Pharmacies that were not doing so before the pandemic have been delivering medications, or delivering them at no charge, and communities and individuals have worked together to design ways for beneficiaries to continue to receive access to prescribed medications in tandem with government and private sector flexibilities during the PHE. We believe that these additional flexibilities may have encouraged prescribers to more broadly use EPCS, since it prevented them from having their prescription transmissions automatically denied. The reason for this is that EPCS transaction sets can pull certain pieces of required information for use in their transactions, which prevent the transactions from hitting system edits that would have previously prevented these practices.

4. Timeframe for EPCS Adoption

Section 2003 of the SUPPORT Act mandates that EPCS for Part D controlled substances begin on January 1, 2021. Due to this statutory mandate coupled with the aforementioned advantages provided by EPCS, we encourage all prescribers to adopt EPCS as soon as is feasible for them. However, as stated in our CY 2021 PFS final rule, we recognize that although EPCS is ultimately more efficient, implementing EPCS takes additional time and resources. It is for this reason that, in our CY 2021 PFS final rule, we finalized a policy stating that CMS would not take compliance actions before January 1, 2022.

In developing this policy, we considered responses from commenters encouraging earlier adoption of EPCS, due to its benefits for social distancing, improved patient safety and workflow efficiencies, fraud deterrence, adherence management, and reduced burdens. We agreed with commenters that EPCS has many benefits, which is why we specified an effective date of January 1, 2021 in our regulations, and a compliance date of January 1, 2022.

Since finalizing the CY 2021 PFS final rule, we have received additional prescriber feedback indicating concern with having to implement EPCS rapidly. We have also learned more about the degree to which prescribers have been adversely affected by the COVID–19 pandemic, and that the PHE and the widespread effects of the pandemic may last longer than we had anticipated last year. We want to ensure that our actions do not have unintended consequences, such as the abrupt discontinuation of prescribers' ability to prescribe Part D controlled substances to vulnerable populations, including Part D beneficiaries who need pain treatment or who have substance use disorders (SUDs). In addition, once DOJ has had the opportunity to implement updates to EPCS requirements, such updates will allow prescribers to start conducting EPCS more rapidly and easily. It is for these reasons that in the CY 2022 PFS proposed rule (86 FR 39104) (hereinafter referred to as the CY 2022 PFS proposed rule), we proposed to revise § 423.160(a)(5) to change the date of initial EPCS compliance actions from January 1, 2022 to January 1, 2023. We welcomed comments on this proposal, including whether commenters believe that we should maintain the January 1, 2022 date of initial EPCS compliance actions, given the benefits of EPCS, and the feasibility for prescribers to adopt EPCS for Part D prescriptions by January 1, 2023.

The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported our proposal to delay the start of compliance actions to no earlier than January 1, 2023, rather than January 1, 2022, which is the date that we had finalized in the CY 2021 PFS final rule. In supporting this recommendation, commenters cited the devastating impact that the PHE has had on their practices, stating that the influx of patients, departure of staff, and depletion of financial resources would make it difficult for providers to implement EPCS by January 1, 2022. A few commenters that process or receive electronic prescriptions opposed our proposal to delay the start of compliance actions until January 1, 2023, citing the aforementioned benefits that EPCS has on social distancing and the workflow efficiencies gained from EPCS.

Response: We thank commenters for supporting our proposal to change the earliest date of compliance actions to January 1, 2023. In addition, we appreciate the commenters for confirming our understanding of the benefits of EPCS. We recognize the benefits of EPCS, and it is for this reason that we encourage prescribers to conduct EPCS as soon as possible. In our CY 2021 PFS final rule, we named

[150] *https://www.reginfo.gov/public/do/eAgendaMain.*

[151] Based on Prescription Drug Event data processed through April 6, 2021.

the standard for prescribers to use when conducting EPCS for Part D controlled substances in order to facilitate adoption of EPCS. However, for the reasons stated in the CY 2022 PFS proposed rule, we continue to believe that delaying the start of compliance actions until on or after January 1, 2023 is appropriate.

After consideration of the comments received, we are finalizing our proposal to extend the date of compliance actions to no earlier than January 1, 2023.

For Part D controlled substance prescriptions written for beneficiaries in long-term care (LTC) facilities, we proposed to extend the date on or after which we will pursue compliance actions from January 1, 2022 to January 1, 2025. The intent of this proposed extension was to strike a balance between being responsive to stakeholder concerns surrounding the increased implementation barriers faced by LTC facilities, due to the unique challenges faced by LTC facilities, while at the same time helping ensure that these facilities eventually implement EPCS, due to its aforementioned benefits.

We acknowledged that, in addition to the current challenge of having to manage care for vulnerable residents during the current COVID–19 pandemic, prescribers who work in LTC facilities or who provide care to residents in LTC facilities face technological barriers that other prescribers do not face. One such barrier is that the NCPDP SCRIPT 2017071 standard lacks appropriate guidance for LTC facilities. We understand that this is because early versions of the NCPDP SCRIPT Standard, such as NCPDP SCRIPT Standard versions 5.0 and 8.1, did not support the workflows in the LTC setting that require prescribers to issue a prescription for a patient to a non-prescriber (such as a nursing facility) that in turn forwards the prescription to a dispenser (LTC pharmacy). We nevertheless adopted the NCPDP SCRIPT 2017071 standard in the CY 2021 PFS final rule [85 FR 84807] because it is the most commonly used standard for Part D e-prescribing, and we sought to minimize disruption and provider burden when implementing this statutory mandate. However, we understand that NCPDP is in the process of creating a new version of the SCRIPT standard that would be better suited for use by prescribers serving LTC facilities, which will allow willing partners to enable three-way communication between the prescriber, LTC facility, and pharmacy to bridge any outstanding gaps that impede adoption of the NCPDP SCRIPT 2017071 standard in the LTC setting.

We understand that some LTC settings/services in rural communities do not have sufficient capabilities to support the NCPDP SCRIPT 2017071 standard. This concern is exacerbated by the fact that based on stakeholder feedback and information in several reports,[152] we believe LTC settings often include practitioners and staff serving large numbers of residents across multiple nursing homes. This unique set of circumstances means that some practitioners who primarily practice in suburban or urban areas may have to travel to see residents in rural facilities where there is limited broadband, making EPCS transmission set-ups difficult across LTC facilities. However, we believe that as broadband access increases and the impact of the PHE decreases, prescribers serving beneficiaries in LTCs should be able to more easily conduct EPCS.

As a result, we proposed to revise § 423.160(a)(5) to clarify that the earliest date of compliance actions against prescribers writing prescriptions for Part D beneficiaries in an LTC facility will be January 1, 2025. We did not propose a specific LTC waiver or exception to the EPCS requirement, and we did not anticipate extending the earliest date of compliance actions beyond January 1, 2025. We solicited comments on the benefits, burdens, and challenges of this approach.

We received public comments on the benefits, burdens, and challenges of this approach. The following is a summary of the comments we received and our responses.

Comment: Several commenters suggested that we exempt prescribers writing Part D controlled substance prescriptions for beneficiaries in LTCs from having to conduct EPCS until after version 2022011 of the NCPDP SCRIPT standard has been named, since this standard will contain the necessary three-way communication to facilitate the needs of the LTC community, whereas the current standard lacks such guidance.

Response: We thank commenters for their insights into upcoming versions of the NCPDP SCRIPT standard. However, we are finalizing as proposed that the earliest date of compliance actions against prescribers writing Part D controlled substance prescriptions for beneficiaries in LTCs to be no earlier than January 1, 2025 to allow adequate time for EPCS to be adopted across the industry. We note that this extension of the earliest date for compliance actions is only applicable to the prescriptions written by prescribers for beneficiaries in LTC facilities, since the additional challenges for LTC do not apply when these prescribers are prescribing for beneficiaries who are not in LTC. As we stated in the proposed rule and earlier in this final rule, the intent of extending the date of compliance actions for prescriptions written for beneficiaries in LTC is to strike a balance between being responsive to stakeholder concerns surrounding the increased implementation barriers faced by LTC facilities, while at the same time helping ensure that these facilities eventually implement EPCS, due to its aforementioned benefits. The increased implementation barriers only present themselves when prescribers are writing prescriptions for beneficiaries in LTC, which is why we had only intended for the LTC extension to apply when prescribers are writing prescriptions for beneficiaries in LTC. In this final rule, we have clarified and refined the language at § 423.160(a)(5) to reflect our intent.

As previously stated, EPCS has numerous advantages over manual prescribing, including deterring and detecting prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes; and enhanced patient safety through patient identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions. Given the benefits of EPCS, we decline to further delay taking compliance actions to enforce the EPCS requirements for Part D controlled substance prescriptions written for beneficiaries in LTCs beyond the date by which we believe prescribers in this setting can meet the requirement. Furthermore, we are not persuaded that we should further delay commencing compliance actions to await publication of the NCPDP SCRIPT 2022011 standard. Although we acknowledge that three-way communication is not as seamless in the 2017071 version of the standard as it may be in upcoming versions, it is still possible with some modifications to EPCS, and therefore, we do not believe it would be appropriate to adopt a further delay on this basis. However, we have decided to finalize the extension of compliance actions for prescribers writing prescriptions for beneficiaries in LTC to allow those prescribers the additional

[152] Waters, Rob. The Big Idea Behind a New Model of Small Nursing Homes. Health Affairs. 2021 Mar; 378–383; Levy et al. Physician Practices in Nursing Homes: Final Report. Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2006 Apr; 10–22.

time necessary to make the additional changes necessary to conduct EPCS using the NCPDP SCRIPT 2017071 standard. We also note that CMS does not intend to begin compliance actions for these prescriptions until on or after January 1, 2025. This protracted timeline for commencing compliance actions allows CMS additional time to examine how the industry adopts the new standard for beneficiaries in LTC, and determine the type of compliance actions that would be most appropriate.

Comment: One commenter sought clarification as to whether medication transactions covered under the Part A benefit would be subject to compliance actions starting January 1, 2023 or 2025.

Response: As stated in the CY 2022 PFS proposed rule, this EPCS mandate is only for transactions covered under Part D of the benefit. This mandate implements section 2003 of the SUPPORT Act, which is limited to Part D transactions. It is for this reason that we have not extended this mandate to other parts of the Medicare benefit, such as the Part A benefit.

After consideration of public comments, we are finalizing our proposal at § 423.160(b)(5) to extend the date that we will begin compliance actions based on prescriptions written for a beneficiary in a long-term care facility until January 1, 2025. In order to implement this provision, we will be excluding long term care prescriptions from our counting of compliance actions to help ensure that prescribers writing prescriptions for beneficiaries in these facilities do not have these prescriptions counted against them for purposes of the compliance threshold and the number of prescriptions written per prescriber for purposes of determining who is classified as a small prescriber under § 423.165(a)(5)(ii).

5. Compliance Threshold

The EPCS requirement applies to all controlled substance prescriptions for Part D drugs under a Part D plan, unless an exception to the requirement applies. In order to implement this mandate effectively, we seek to implement it in a manner that balances the mandate with helping ensure that prescribers are not overly burdened, and are able to issue prescriptions for their patients during the rare occurrences when EPCS is not feasible, such as:

- When it would be impractical for the patient to obtain medication(s) prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition,
- When the NCPDP standard does not support transmitting the prescription,
- When the prescriber is unable to meet DEA requirements for identity proofing for reasons beyond their control;
- Where EPCS is not available due to temporary technological failure.

Based on our review of PDE data, the NCPDP standard, and our conversations with Part D stakeholders, we believe that there are very few scenarios under which a prescription could not be transmitted using the NCPDP standard.

We note that section 1860D–4(e)(7)(B)(vi) of the Act provides that the Secretary may grant an exception for a prescription issued for a drug for which the FDA requires a prescription to contain elements that cannot be included in electronic prescribing. However, after reviewing the NCPDP standard implementation guide, we do not believe that there are any such prescriptions under the current standard. The statute gives as an example a drug with risk evaluation and mitigation strategies that include elements to assure safe use (ETASU). Based on our review of the current NCPDP standard, all opioid analgesics intended for outpatient use have a risk evaluation and mitigation strategy with ETASU, and as a result, would fall into the exception if there were one, which would frustrate the purpose of this statute.[153] As a result, we declined to propose to adopt this suggested exception. However, we solicited comment on this decision.

We also stated that there were other reasons that could make EPCS not feasible for prescribers who currently conduct EPCS, such as the aforementioned cases of temporary technological failures or cases where it would be impractical for the patient to obtain medication(s) prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition. However, we did not propose a specific exception for these cases, since based on our stakeholder feedback and review of PDE data, we believe that EPCS is not feasible in no more than an estimated 30 percent of instances due to circumstances such as the ones described previously. We believe that Part D prescribers should be able to conduct EPCS on 70 percent of their Part D controlled-substance prescriptions without being overly burdened or burdening patients. Under section 1860D–4(e)(7)(D) of the Act, we have authority to specify appropriate penalties for non-compliance with the EPCS requirement. It follows, then, that we similarly have the authority to specify a threshold for when we would penalize non-compliance. For this reason, we proposed that in order for prescribers to be considered compliant with the EPCS mandate, they must prescribe at least 70 percent of their Part D controlled substance prescriptions electronically.

Specifically, we proposed to revise § 423.160(a)(5) to specify that 70 percent of all prescribing under Part D for Schedule II, III, IV, and V controlled substances be done electronically per calendar year, excluding from that calculation any prescriptions issued while a prescriber falls within an exception or a waiver. We intend to conduct this calculation by examining PDE data at the end of the calendar year and dividing the number of Part D controlled substances that the prescriber e-prescribed by the total number of Part D controlled substance prescriptions that the prescriber prescribed. We solicited comment on this method and the proposal to make 70 percent the compliance threshold for adherence to the EPCS mandate, and what circumstances would make EPCS not feasible.

We received public comments on this method and the proposal to make 70 percent the compliance threshold for adherence to the EPCS mandate, and what circumstances will make EPCS not feasible. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposal to make 70 percent the compliance threshold for adherence to the EPCS mandate stating that it strikes the appropriate balance between implementing the statute and helping ensure that such implementation does not overwhelm prescribers. Two commenters suggested that we lower our compliance threshold to 50 percent for the first year to avoid overwhelming prescribers.

Response: We agree with the commenters that a compliance threshold of 70 percent is a suitable balance to help ensure that this mandate is implemented while not overwhelming prescribers. Although we understand that a compliance threshold of 50 percent would place less of a burden on prescribers, we believe a compliance threshold in which only a simple majority of a prescriber's prescriptions must be transmitted electronically would not be sufficient to fulfill the statutory mandate.

[153] National Council for Prescription Drug Programs, ''Implementation Guide'' January 2020.

After reviewing the PDE data,[154] we did not find a substantial number of prescribers that transmitted between 50 to 70 percent of their Part D controlled substance prescriptions electronically, which leads us to believe that lowering the compliance threshold would not alleviate much of a burden for prescribers. After consideration of public comments, we are finalizing this provision as proposed, which would require prescribers to prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, except in cases where an exception or waiver applies. We note that, as previously stated, prescriptions for beneficiaries in LTC would be excluded from the calculation of the compliance threshold until the January 1, 2025 compliance threshold calculation is made, which would be using data beginning in January 1, 2024. As we explained in the CY 2022 PFS proposed rule, we will determine compliance with the EPCS requirement by examining PDE data at the end of the calendar year (86 FR 39330), which is why we will begin considering data for Part D prescriptions written for beneficiaries in LTC on January 1, 2024 and continuing through December 31, 2024 for compliance actions that we take on or after January 1, 2025.

6. Classes of Exceptions

a. Prescriptions Issued When the Prescriber and Dispensing Pharmacy are Same Entity

Section 2003 of the SUPPORT Act requires that we specify circumstances by which we may waive the EPCS requirement, and the statute lists several possible circumstances to consider. We listed and sought comment on these circumstances in the August 2020 RFI. The first of these circumstances, which is listed at section 1860D–4(e)(7)(B)(i) of the Act, is when the practitioner issuing the prescription and dispensing pharmacy are the same entity.

All August 2020 RFI commenters who commented on this exception supported it, stating that such an exception would promote patient safety, workflow efficiency, and health IT performance. Several commenters noted that requiring EPCS in this circumstance may create an unwarranted artificial workflow structure. We believe that this may be because the EPCS transactions conducted within an organization are commonly handled by a single database that exists within the organization, and should we not grant this exemption, these entities would be required to reconfigure their own processes, rather than leverage their own integrated databases. Were we to implement a requirement to use the NCPDP SCRIPT 2017071 standard within this closed system, this requirement could increase costs and the rate of performance errors, such as data corruption and patient matching errors, which we understand often happens when an entity is forced to split a unified database into a transaction system that relays information to and from the same entity. We solicited comment on this assumption. However, we did not receive any comments on the assumption.

Therefore, we proposed to adopt at § 423.160(a)(5)(i) the EPCS exception listed in section 1860D–4(e)(7)(B)(i) of the Act, for prescriptions issued where the prescriber and dispensing pharmacy are the same entity. We solicited comment on this proposal.

Comment: All commenters who commented on this proposal supported it.

Response: We thank the commenters for their support. We are finalizing this proposal as proposed.

b. Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions

As we develop regulations to implement section 2003 of the SUPPORT Act, we seek to help ensure that Part D prescribers, including small prescribers, are not overly burdened by our regulation. Based on the comments received from the August 2020 RFI and the stakeholder feedback that we received about EPCS in general, we believe it is appropriate to specify an exception to the EPCS requirement in cases where a prescriber issues a very low volume of controlled substance prescriptions for Part D drugs. For prescribers of very few Part D controlled substance prescriptions, the cost of installing EPCS equipment and software may be unduly burdensome relative to its benefit in terms of improving the security of prescriptions for controlled substances. As noted above, we do not want to disincentivize prescribers from prescribing controlled substances to Part D beneficiaries altogether, especially those who have few beneficiaries who need them.

After reviewing the current PDE data and the costs associated with implementing EPCS, we proposed to exempt prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year. Based on our stakeholder feedback, we understand that EHR companies provide the initial electronic prescribing set-up free of charge, provided the prescribers transmit a minimum number of transactions per year. We estimate that this amount is, on average, 100 Part D controlled substance transactions. In order to do EPCS, prescribers will have to have the capability to e-prescribe more broadly. It is for this reason that we weighed the cost of e-prescribing set-up in general, even though we do not intend to include non-part D prescriptions of controlled or non-controlled substances in our calculation of whether or not prescribers meet the threshold of 100 Part D controlled substance prescriptions per year. Since, based on our conversations with stakeholders, the cost of EPCS transactions is less than the cost of transmitting certain transactions manually, we believe that the initial investment to install EPCS equipment and software is likely justified once prescribers transmit more than 100 Part D controlled substance prescriptions per year. We solicited comment on this assumption and the cost of third-party applications required to conduct EPCS. However, we did not receive any comments on these assumptions.

In order to implement this exception using the data that we have available, we proposed that this exception be given to individual prescribers, regardless of the size of the group practice that they belong to. We also believe that this exception will protect these small prescribers, should they change their place of employment or if their place of employment does not offer support for implementing EPCS.

Based on our examination of PDE data and conversations with stakeholders, we believe that prescribers working under most research protocols will fall under the proposed exception for small prescribers. However, we solicited comment on this assumption. We did not receive any comments on it.

Although we did not propose to adopt the suggested exception listed in section 1860D–4(e)(7)(B)(v) of the Act, which describes an exception for prescribers working under a research protocol, we believe that in most cases prescribers who will fall within this category will be included in the exception for small prescribers or in the exception for cases where the prescriber and dispenser are the same entity. We did not propose to specifically create an exception for prescribers working under a research protocol in the regulations, since we believe that so few prescribers will fall outside of these other exceptions. We believe an exception for prescribers working under a research protocol who do not otherwise meet these exceptions is unnecessary because we believe that

[154] Based on Prescription Drug Event data processed through September 27, 2021.

EHR companies will set up the appropriate EHR equipment, provided around 100 Part D controlled substance prescriptions are transmitted per year.

We proposed to implement this proposal by examining PDE claims as of December 31 of the prior year to determine which prescribers fall within this exception. Prescribers can ascertain whether they meet this exception by looking at how many prescriptions for Part D controlled substances they conducted the prior year or by contacting the CMS contractor responsible for administering the compliance portion of this mandate. CMS and its contractor will be using PDE data from the prior year to determine whether the prescriber qualifies for the exception based on the number of Part D controlled substance claims the prescriber had issued the previous year. CMS will use the previous year's data to determine whether or not the prescriber falls under this exception for the year-in-question. We do not see a compelling reason to exempt prescribers conducting a research protocol on that basis alone.

Based on our conversations with Prescription Drug Plans (PDPs), MA–PD plans, and other organizations with which prescribers are affiliated, we are aware that some are willing to donate the technology and services necessary for prescribers to adopt EPCS. Based on those conversations, we believe that they are more willing to donate these technology and services to prescribers who are working under a research protocol, than to prescribers not working under such a protocol. However, we solicited comment on such an assumption, but we did not receive any comments. We did receive one comment on our decision to not propose an exception for those working under a research protocol. The following is a summary of the comment we received and our response.

Comment: A commenter urged CMS to consider an exception for those working under a research protocol to allow for cases where a research protocol may transmit more than 100 Part D controlled substance prescriptions per year.

Response: We have considered granting an exception to those working under a research protocol. However, we were unable to find a compelling reason to grant such an exception. Further, we reviewed PDE data to determine how many transactions would fall outside of our class of exceptions for cases involving a research protocol, and were unable to find any.[155] For the reasons stated above and in the proposed rule, we decline to adopt a specific exception for those engaging in a research protocol.

We proposed to amend § 423.160(a)(5) by adding § 423.160(a)(5)(ii), which creates an exception for prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using PDE claims data as of December 31st of the preceding year, so that these prescribers will not be required to meet the EPCS requirement. We solicited comment on this proposal, including regarding the maximum number of Part D controlled substance prescriptions a prescriber can issue to be still considered a small prescriber and, so, to fall within this exception.

The following is a summary of the comments we received and our responses.

Comment: All commenters who commented on our proposal to grant an exception for prescribers who issue 100 or fewer Part D controlled substance prescriptions supported the proposal.

Response: We thank commenters for their support of this proposal. After consideration of public comments, we are finalizing this proposal as proposed.

c. Cases of Recognized Emergencies and Extraordinary Circumstances

Section 1860D–4(e)(7)(B)(iii) of the Act, as added by section 2003 of the SUPPORT Act, lists an exception for consideration by the Secretary for cases of exceptional circumstance demonstrated by the prescriber. As stated in our proposal regarding the EPCS compliance threshold, we seek to help ensure that prescribers are able to issue prescriptions for their patients during the rare occurrences when EPCS is not feasible. We believe that the exception listed in the statute, which includes economic hardship, technological limitations that are not reasonably within the control of the prescriber, and other exceptional circumstances, includes prescribers who are overwhelmed due to having to treat patients during a pandemic or a natural disaster such as a hurricane, flood, or earthquake. It is our goal not to penalize prescribers for such circumstances, and we do not want to unduly increase their burden during difficult situations that impact them, and their patients. We solicited comment on what other extraordinary circumstances may prevent prescribers from being able to conduct EPCS.

In order to help ensure that these extraordinary circumstances are accounted for, we proposed two exceptions to the EPCS requirement. The first proposed exception, at § 423.160(a)(5)(iii), is for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. We want to help ensure that the EPCS mandate does not interfere with necessary care for patients, especially during natural disasters or pandemics. As a result, we proposed to exempt prescribers who are issuing prescriptions in areas that are affected by such circumstances. To qualify for this exception, this circumstance will have to arise from an emergency or disaster declared by a Federal, State, or local government entity. We proposed to determine whether a prescriber qualifies for this exception based on whether the prescriber's NCPDP database address is located in the geographic area of an emergency or disaster declared by a Federal, State or local government entity. Since, as stated in the CY 2022 PFS proposed rule, we had intended this exception to avoid unduly burdening prescribers during difficult situations, CMS would like to clarify that this exception would be applicable only if the dispensing date of the medication occurs during the time period that the declared disaster is occurring.

The second proposed exception, at § 423.160(a)(5)(iv), is for prescribers who request and receive from CMS a waiver, which we proposed to grant to prescribers who are facing extraordinary circumstances that prevent them from electronically prescribing a controlled substance to a Part D beneficiary, but who are not in an emergency or disaster area. We would define ''extraordinary circumstance'' for purposes of this exception to mean a situation, other than an emergency or disaster, outside of the control of a prescriber that prevents the prescriber from electronically prescribing a controlled substance to a Part D beneficiary. An example of such a circumstance would be if a prescriber was in a service area that lacks broadband access or EPCS providers refuse to install systems for the prescriber. The prescriber would have to be able to submit evidence of such an extraordinary circumstance to CMS.

For purposes of the exception at § 423.160(a)(5)(iii), prior to imposing any compliance actions on a prescriber, we proposed to ascertain whether there is an emergency or disaster declared by a Federal, State, or local government

[155] Based on Prescription Drug Event data processed through September 27, 2021.

entity for the geographic area associated with the prescriber's address in the NCPDP database.

For purposes of the exception at § 423.160(a)(5)(iv), we proposed that prescribers would be excepted from the EPCS requirements if they request and receive a waiver from CMS. We intend that prescribers will be able to submit a request for a waiver to inform CMS of any extraordinary circumstances that they may be facing and that will prevent the prescriber from conducting EPCS. This waiver could be for any circumstance outside of the prescriber's control and would not require an official declaration by a Federal, State, or local government. To meet the standard for a waiver, prescribers must provide documentation showing the existence of a circumstance beyond their control and that such a circumstance prevents them from conducting EPCS. Section 1860D–4(e)(7)(B)(iii) of the Act, as added by section 2003 of the SUPPORT Act, refers to a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, which suggests a timeframe not to exceed one year, but to be determined by the Secretary.

To implement our proposals for exceptions for exceptional circumstances or disasters, we proposed to amend § 423.160(a)(5) by adding paragraphs (a)(5)(iii) and (iv). Section 423.160(a)(5)(iii) would specify an exception for prescribers in the geographic service area of an emergency or disaster declared by a Federal, State or local government entity. We proposed at section 423.160(a)(5)(iv) that prescribers would be exempt from the EPCS requirements if they have received a CMS-approved waiver certifying that the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. We proposed that in order to receive a CMS-approved waiver, the prescriber will have to submit an attestation using a form, which will be made available on a CMS-supported website, so that prescribers will be able to request a waiver via an online portal.

The following minimum set of information will be required on the attestation:

- Prescriber's first and last name;
- Prescriber's National Provider Identification (NPI);
- Prescriber's taxpayer identification number (TIN) or TIN associated with his or medical practice, when applicable;
- Prescriber's contact information, email address, telephone number, and mailing address; and
- A description of the extraordinary circumstance necessitating a waiver and how it affects the prescriber.

Following receipt of the attestation, we will: (1) Provide a written acknowledgement of receipt of the request using the contact information submitted via the portal; and (2) provide a decision formally granting or denying the waiver using the contact information submitted via the portal. Under the policy, the prescriber will submit their attestation about the circumstance and receive a waiver, if warranted, based on such an attestation. After consideration of public comments, we are finalizing the waiver process as proposed.

The following is a summary of the comments we received on the waiver process and our responses.

Comment: One commenter suggested that we allow a process for waiver requests to be submitted via fax or over the phone, in case a prescriber does not have access to a computer, due to the extraordinary circumstance necessitating such a waiver.

Response: We agree that prescribers should have the ability to submit an attestation using a medium other than a computer. We will make available on the CMS-supported website information to permit prescribers to request a waiver via phone, in addition to via the portal.

Comment: Several commenters mentioned circumstances, such as cybersecurity attacks and technological failures, which may prevent prescribers from conducting EPCS. They stated that these circumstances should be eligible for a CMS waiver.

Response: We agree that these events could be considered circumstances that would prevent prescribers from being able to conduct EPCS. We believe that in most cases, these events should not preclude a prescriber from meeting the 70 percent compliance threshold required by the regulation, and in some cases, prescribers may fall under an exception. However, should prescribers experience these events, we urge prescribers to submit an attestation detailing such an event. As described in subsequent paragraphs, should prescribers be unable to prescribe electronically, prescribers are able to submit an attestation of such. Should a waiver be granted, it would be for a term of up to one year.

Comment: One commenter suggested that we include a waiver for any time certain doctors prescribe *buprenorphine,* since there are certain pharmacies that do not have much *buprenorphine* available to them. The commenter noted that this makes conducting EPCS difficult, since physicians are then required to re-route their electronic prescriptions when the pharmacy runs out of the prescription, which creates an administrative burden for prescribers.

Response: Although CMS understands that this could create an additional burden for prescribers, CMS is not aware of, nor does the commenter explain, why this would not be an issue in cases where prescriptions are not transmitted electronically. However, CMS did seek to more fully examine this concern and reviewed PDE data to determine how often *buprenorphine* is prescribed in Part D.[156] After reviewing this information, we discovered that *buprenorphine* prescriptions make up less than 2 percent of all Part D Schedule II, III, IV, and V prescriptions. It is for this reason that prescribers who experience difficulties electronically prescribing *buprenorphine* should still be able to meet the compliance threshold that allows prescribers to be considered fully compliant with EPCS if they electronically prescribe 70 percent or more of their Part D prescriptions. As a result, we do not believe that an exception for this purpose is necessary. However, should a prescriber find that *buprenorphine* unavailability prevents the prescriber from utilizing EPCS, we encourage the prescriber to submit an attestation form about such events to request a waiver due to circumstances beyond the prescriber's control, which we will consider. In addition, we will continue to monitor PDE data for trends, including whether certain prescriptions are more frequently prescribed using paper prescriptions. If CMS finds that this is the case, we can take action, such as granting exceptions, to help ensure that EPCS is not becoming overly burdensome for these prescriptions.

d. Individuals in Hospice and Nursing Facilities

Section 2003 of the SUPPORT Act, in adding section 1860D–4(e)(7)(B)(vii) to the Act, tasked the Secretary to consider whether prescriptions for individuals under the Part D benefit for an individual enrolled in the Medicare Part A hospice benefit should be exempt from the EPCS requirement. After considering this issue, we believe that an exception for a prescription made for an individual enrolled in hospice would be inappropriate for several reasons. First, when electing hospice, patients have chosen to move from a curative model of care to a holistic palliative model of care. Regulations at 42 CFR 418.202(f) stipulate that the Medicare hospice benefit covers only drugs and

[156] Based on Prescription Drug Event data processed through September 27, 2021.

biologicals used primarily for the relief of pain and symptom control for the terminal illness and related conditions. Under section 1860D–2(e)(2)(B) of the Act, a drug is excluded from Part D coverage if payment for such drug, as prescribed and dispensed for the beneficiary, is available under Medicare Part A or Part B. Thus, in cases where, with respect to a beneficiary, the hospice benefit covers a drug or biological used primarily for the relief of pain or symptom control for the terminal illness or related conditions, such drug is excluded from Part D coverage under section 1860D–2(e)(2)(B) of the Act. The HHS OIG worked with CMS and the National Hospice and Palliative Care Organization (NHPCO) to identify four common categories of prescription drugs that are typically used to treat symptoms often experienced during the end of life, regardless of an individual's terminal diagnosis.[157] The OIG has found that these categories of drugs should generally be paid under the hospice benefit.[158] Thus, there may be very few instances in which a controlled substance prescribed for a Part D enrollee who has elected hospice could be covered under Part D. We believe an exception that will apply only in these rare instances could be confusing and burdensome for prescribers who furnish care to some Part D beneficiaries who are enrolled in hospice and for some who are not because to qualify for the exception they will have to determine when a particular enrollee has elected hospice. Further, a beneficiary is free to elect the hospice benefit and cancel that election as they choose, which will make it difficult for a prescriber to be sure at any point in time whether a beneficiary is, or is not, currently enrolled in hospice, and therefore, whether a paper prescription is permitted. We note that we did not propose for the EPCS requirement to apply to any prescriptions for Part A or Part B controlled substances in any event.

Further, were CMS to provide an exception for prescriptions for Part D-covered controlled substances for hospice enrollees, it would pose an operational challenge to accurately match prescription data records with hospice enrollment data where the patient's hospice status can be fluid. It would be operationally challenging to ensure that paper prescriptions were only issued for beneficiaries enrolled in hospice (which would be permitted), and not for patients not enrolled in hospice (where EPCS will be required). We believed the cost of this potentially confusing and laborious analysis for the small number of prescriptions dispensed for beneficiaries enrolled in hospice but covered under Part D exceeds the benefit creating the exception would provide to prescribers.

Therefore, we did not propose an exemption for prescribers issuing prescriptions for individuals enrolled in hospice. However, we solicited comment on this decision. We did not receive public comments on this provision. As proposed, we are not creating an exemption for prescribers issuing prescriptions for individuals enrolled in hospice.

Section 1860D–4(e)(7)(B)(viii) of the Act suggests an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits. We sought stakeholder feedback on this exemption in our August 2020 RFI and discussed it with our Federal partners at the DEA, and have been informed that there are situations where nursing facilities experience or are at risk of drug diversion. This stakeholder feedback did not inform us of any compelling reasons to include an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits. We have also seen the severe impact that the COVID–19 pandemic has had on nursing facility residents, who are at high risk for infection, serious illness, and death from COVID–19, as well as other infectious diseases including clostridium difficile and the seasonal flu. It is for these reasons that we did not propose an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits. We solicited comment on this issue, but we did not receive public comments on this provision. As proposed, we are not creating an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits.

7. Fraud and Abuse Laws

We are aware that PDPs, MA–PD plans, or other organizations with which prescribers are affiliated may wish to assist prescribers with satisfying the mandate for electronic prescribing of controlled substances for a covered Part D drug by providing technology and services necessary to effectuate the electronic prescribing of such drugs. Such assistance may implicate the payment and fraud and abuse laws that govern the financial relationships in the health care industry. Specifically, the donation of free or below-fair market value electronic prescribing technology or services to a practitioner (or any other person) may implicate the physician self-referral law and the Federal anti-kickback statute. However, there is an exception to the physician self-referral law's prohibition and a corresponding safe harbor under the Federal anti-kickback statute that will permit certain donations in the form of items or services (not including cash or cash equivalents) necessary and used solely to receive and transmit electronic prescription information if all requirements of the applicable exception or safe harbor are satisfied. In addition, other exceptions to the physician self-referral law and safe harbors under the Federal anti-kickback statute may apply.

Section III.P.1. of this final rule provides a general discussion of the application of, prohibitions of, and exceptions to the physician self-referral law. For information specific to the exception for donations of electronic prescribing items and services, we refer readers to our August 8, 2006 final rule entitled ''Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements'' (71 FR 45140) and found at *https://www.govinfo.gov/content/pkg/FR-2006-08-08/pdf/06-6667.pdf,* and the regulations interpreting the physician self-referral law, including additional exceptions to its prohibitions, which are found in 42 CFR part 411, subpart J. Information regarding the Federal anti-kickback statute and its applicable safe harbors can be found at *www.oig.hhs.gov.*

We received several comments regarding the fraud and abuse laws, which we have summarized below.

Comment: Some commenters asked CMS to examine the regulations that set forth exceptions to the physician self-referral law and safe harbors under the Federal anti-kickback statute to determine whether revisions are necessary to permit PDPs, MA–PD plans, and other organizations to donate technology and services necessary for prescribers to adopt EPCS.

Response: We did not propose to revise the existing physician self-referral law exception for electronic prescribing items and services at 42 CFR 411.357(v)

[157] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/2014-PartD-Hospice-Guidance-Revised-Memo.pdf.*

[158] *https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf.*

or any other exceptions to the physician self-referral law that may apply to donations of technology and services that parties may believe are necessary for prescribers to adopt EPCS. Any revisions to our regulations would occur only through notice and comment rulemaking. Stakeholders requesting revision of regulations issued by the HHS Office of Inspector General (OIG) should contact OIG.

8. Penalties

Section 1860D–4(e)(7)(D) of the Act gives the Secretary the authority to enforce and specify appropriate penalties for non-compliance with the EPCS requirement. We sought stakeholder feedback on whether CMS should impose penalties and if so, what those penalties should be. We have also examined State EPCS requirements and their accompanying penalties. However, because these requirements have only been recently implemented and most States do not have penalties for failing to adopt EPCS, we have not been able to evaluate what type of penalties have been effective for State mandates.

In implementing the EPCS requirement, we seek to help ensure that we do not place too much of a burden on prescribers, as we do not want this requirement to have an unintended consequence of incentivizing prescribers to stop prescribing controlled substances to Part D beneficiaries, as appropriate, should they not have EPCS set-up. We also need sufficient time to gather more stakeholder feedback on the most effective and most appropriate type of penalties.

Therefore, we proposed that with respect to compliance from January 1, 2023 through December 31, 2023, CMS compliance actions will consist of sending letters to prescribers that we believe are violating the EPCS requirement during that period of time. These letters will consist of a notification to prescribers that they are violating the EPCS requirement, information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver. We will re-evaluate whether further compliance actions will be necessary and what those compliance actions will be in future rulemaking. We solicited comment on this proposal, including what type of compliance action may be appropriate after the initial period described above, including whether any penalties should be phased in over time.

We received public comments on this proposal, which we have summarized below, along with our responses to them.

Comment: Most commenters supported our proposal to limit compliance actions in the first year to sending letters to prescribers, rather than imposing a penalty on the prescribers. These commenters encouraged the use of these letters in order to avoid overly burdening prescribers during the PHE. However, some commenters suggested that we impose penalties on prescribers who do not conduct EPCS, since these commenters stated that it will hasten EPCS implementation.

Response: We agree that sending letters to prescribers, rather than imposing penalties, may avoid overly burdening prescribers who cannot meet the EPCS mandate in 2023. We will consider adopting penalties in future rulemaking. As previously noted, our intent is to avoid overly burdening prescribers, especially during this critical time during the PHE. In addition, we would like to further examine other EPCS programs and the effects that these penalties have had on EPCS in their States before imposing penalties on prescribers.

After consideration of public comments, we will finalize our proposal to limit the 2023 compliance actions to a compliance letter.

R. Open Payments

1. Background

a. Open Payments Policies

The Open Payments program is a statutorily-mandated program that promotes transparency by providing information to the public about the financial relationships between the pharmaceutical and medical device industry, and certain types of health care providers. Section 1128G of the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as ''applicable manufacturers''), as well as applicable group purchasing organizations (GPOs), to annually submit information for the preceding calendar year about certain payments or other transfers of value made to ''covered recipients,'' currently defined as physicians, teaching hospitals, PAs, NP, CNSs, certified registered nurse anesthetists (CRNAs), anesthesiologist assistants (AAs), and certified nurse-midwives (CNMs).

Payments or other transfers of value that must be reported include, but are not limited to, such things as research-related payments, honoraria, gifts, travel expenses, meals, grants, and other compensation. The type of information required to be reported includes, but is not limited to, the date and amount of the payment or other transfer of value, identifying information about the covered recipient, and details about products associated with the transaction. When a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name of that covered drug, device, biological or medical supply also must be reported. The estimated burden of these reporting requirements, as outlined under OMB control number 0938–1237, is approximately 1.9 million hours over the course of 1 year.

Section 1128G of the Act establishes certain minimum dollar thresholds for required reporting of individual and aggregate payments or transfers of value. To determine if multiple small individual payments or other transfers of value made to a covered recipient exceed the *de minimis* reporting threshold, applicable manufacturers and applicable GPOs must aggregate all individual payments made across all payment categories within a given reporting year. The statutory threshold established in 2013 was $10 for individual payments and $100 for aggregated payments, and this amount has increased with the consumer price index each year. For CY 2021, the annual reporting thresholds for individual payments or other transfers of value is $11.04 and the aggregate amount is $110.40.

The Open Payments program yields information for the general public about providers, as well as information that researchers may use to look into potential correlations between financial relationships and provider behaviors. Between August 2013 and the June 2020 publication, more than 76 million records have been disclosed under the Open Payments program, enabling significant transparency into applicable exchanges of value. We have been committed to stakeholder engagement in an effort to limit the burden in the Open Payments program reporting processes and improve clarity for the public. Additional background about the program and guidance, including frequently asked questions, regarding how the program works and what type of information is required to be reported is available at *www.cms.gov/OpenPayments.*

In the February 8, 2013 **Federal Register** (78 FR 9458), we published regulations implementing section 1128G of the Act and establishing the Open Payments program. Section 1128G of the

Act requires applicable manufacturers and applicable GPOs to submit information annually about certain payments or other transfers of value made to covered recipients during the course of the preceding calendar year. Additionally, section 1128G of the Act defines covered drugs, devices, biologicals, or medical supplies as those covered under Medicare, a State plan under Medicaid, or the Children's Health Insurance Program (CHIP) (or a waiver of either such State plan), and requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or physicians' immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Under section 1128G(e)(10)(A) of the Act, the term ''payment or other transfer of value'' refers to a transfer of anything of value, though some exclusions apply.

In the CY 2015 PFS final rule with comment period (79 FR 67548), we amended the regulations by standardizing reporting in the Open Payments program. Specifically, we: (1) Deleted the definition of ''covered device''; (2) removed the special rules for payments or other transfers of value related to continuing education programs; (3) clarified the marketed name reporting requirements for devices and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

In the CY 2017 PFS proposed rule (81 FR 46395), we solicited information from the public on a wide variety of topics regarding the Open Payments program. Since the implementation of the program and changes made in the CY 2015 PFS final rule with comment period, various commenters have provided us feedback. Consequently, we identified areas in the rule that might benefit from revision and solicited public comments to inform future rulemaking. We sought comment on whether the payment categories listed at 42 CFR 403.904(e)(2) are adequately inclusive to facilitate reporting of all payments or transfers of value, as well as ways to streamline or make the reporting process more efficient while facilitating our role in oversight, compliance, and enforcement, along with posing other program-specific questions. A summary of the comments we received was published in the CY 2017 PFS final rule (81 FR 80428 through 80429).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271) was signed into law. Section 6111 of the SUPPORT Act amended the definition of ''covered recipient'' under section 1128G(e)(6) of the Act with respect to information required to be submitted on or after January 1, 2022, to include PAs, NPs, CNSs, CRNAs, and CNMs, in addition to the previously listed covered recipients of physicians and teaching hospitals. In the CY 2020 PFS final rule, we codified the Open Payments provisions of the SUPPORT Act and addressed public comments received from the CY 2017 PFS proposed rule by simplifying the process for reporting data by adjusting the Nature of Payment categories, and standardized data on reported covered drugs, devices, biologicals, or medical supplies.

In the CY 2022 PFS proposed rule, we proposed to clarify existing Open Payments requirements, as well as add provisions that program stakeholders have requested and that we agree would improve the quality of the data. We proposed the following revisions effective for data collection beginning in CY 2023 and reporting in CY 2024: (1) Adding a mandatory payment context field for records to teaching hospitals; (2) adding the option to recertify annually even when no records are being reported; (3) disallowing record deletions without a substantiated reason; (4) updating the definition of ownership and investment interest; (5) adding a definition for a physician-owned distributorship as a subset of applicable manufacturers and group purchasing organizations, for the purposes of Open Payments program reporting only, which definition would not apply for purposes of any other laws or regulations, including, but not limited to, section 1128B of the Act (the Federal anti-kickback statute), the regulations at 42 CFR 1001.952, and materials interpreting the anti-kickback statute, such as Special Fraud Alerts; and section 1877 of the Act and the regulations at 42 CFR part 411, subpart J (collectively, the physician self-referral law); (6) requiring reporting entities to update their contact information; (7) disallowing publications delays for general payment records; (8) clarifying the exception for short-term loans applies for 90 total days in a calendar year, regardless of whether the 90 days were consecutive; and (9) removing the option to submit and attest to general payment records with an ''Ownership'' Nature of Payment category. We noted that we believed these changes would increase the usability of the data, address concerns we have heard from stakeholders, and we believe our proposed implementation timeline allows reporting entities adequate time to prepare for changes to their data collection and reporting procedures.

We received public comments on our proposals that would be effective for data collection beginning in CY 2023 and reporting in CY 2024. We received 11 comments on the Open Payments proposals. Commenters generally submitted neutral or supportive comments with a few suggestions, which are individually outlined in section c below. We thank the commenters and after consideration of public comments, we are finalizing as proposed.

b. Legal Authority

Four legal authorities from the statute ground our provisions:

- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1861 of the Act, which defines providers and suppliers.
- Section 1128G of the Act, as amended by section 6111 of the SUPPORT Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals, and to PAs, NPs, CNSs, CRNAs, and CNMs for information required to be submitted under section 1128G of the Act on or after January 1, 2022.

c. Provisions of the Regulations

(1) Payment Context Field for Teaching Hospitals

We have received feedback from teaching hospitals during informal interviews that Open Payments submissions do not contain sufficient information to identify reported payments or transfers of value in their own records. This means that teaching hospitals are unable to verify records during the review and dispute process and must dispute the record in order to obtain additional information, which causes additional and unnecessary work for both teaching hospitals and reporting entities.

To reduce the burden created by disputes for both reporting entities and teaching hospitals, we proposed a mandatory context field for payments or transfers of value attributed to teaching hospitals, which would contain information to better identify the

payment as deemed appropriate by the applicable manufacturer or GPO. Examples of data that the reporting entity may choose to include are: the check number or electronic wire number for the payment; related department of the hospital; or other pieces of relevant information.

We received public comments on our proposal for a teaching hospital context field. The following is a summary of the comments we received and our responses.

Comment: We received several comments on this proposal, which were evenly split in support and opposition. Commenters who agreed expressed support for our belief that the proposal would enhance communication between reporting entities and teaching hospitals in a proactive way, thereby reducing the need for disputes. One commenter suggested that additional inputs may include whether education was involved and which services were provided, and that CMS should expand the list of suggestions to avoid limiting reporting entities' inputs. Commenters who disagreed with the proposal stated that the field would increase burden without decreasing disputes, and the lack of standardization would be problematic since reporting entities would not have direction on what to input and teaching hospitals might not understand the additional context.

Response: We believe that the additional field will be a minimal burden on reporting entities, but that the new field will give needed context to the payments based on feedback from both reporting entities and teaching hospitals. The integrity of the data is our highest priority, and this additional information will help ensure accuracy. We also believe that the flexibility regarding the field's contents will be much easier for reporting entities than specifying a mandatory piece of information. We hope to continue to minimize dispute-related issues, and we consider this new field to be a positive step to address both reporting entities' and covered recipients' communication concerns. Therefore, we are finalizing this provision as proposed.

(2) Optional Annual Recertification

Over the course of the program, several entities have provided feedback that they would like the ability to attest that they have no reportable records for a particular year. At this time, an entity that does not have reportable payments or transfers of value does not need to recertify in Open Payments, but it also does not have a way to communicate to CMS that it believes it is still compliant even though it has not reported.

We proposed to make it optional for an entity that does not have reportable payments or transfers of value for the program year to recertify its registration in Open Payments and attest that it does not have any records to submit, which would give peace of mind to reporting entities that are appropriately not reporting records. We believe this optional recertification for entities without reportable transactions will be a low burden to reporting entities, but will be invaluable to ensuring the integrity of the data. We proposed adding the following language to an option for entities that are recertifying without submitting records:

''1. I attest that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer equivalent authorized representative for the reporting applicable manufacturer or applicable group purchasing organization with the authority to attest to the information submitted in the Open Payments system.

2. I attest that, to the best of my knowledge, belief, and ability, my organization does not have any reportable payments or transfers of value or ownership and investment interest to report for the current program year.

3. If I become aware of any information that my entity is required to report, I will submit this information to CMS as required per 42 CFR 403.908(h)(1), which states that ''if an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.''

We received public comments on optional recertification for entities without reporting requirements. The following is a summary of the comments we received and our responses.

Comment: We received two comments on this proposal, both of which were generally supportive although one included questions on how the new attestation would function. The commenter expressed concerns that the attestation would lead to additional consequences if later reportable records were discovered, and inquired as to whether CMS would add a notification functionality so that when the Submitter enters that the entity did not have any reportable records, the Attester would be notified.

Response: We clarify that this optional activity is for the purpose of communication to the Open Payments program for the benefit of reporting entities, and is not intended as a method of penalization. We will continue to carefully evaluate instances of potential non-compliance, including weighing mitigating and aggravating factors, as our regulations currently require. Furthermore, this attestation will not prevent reporting entities from submitting later-discovered records. We will further consider the system's functionality specific to the various roles, such as Submitter and Attester, but do not believe the detail of this functionality is relevant to rulemaking. Therefore, we are finalizing as proposed.

(3) Defining a Physician-Owned Distributorship

The preamble to the 2013 Open Payments final rule (78 FR 9458) discusses physician-owned distributorships (PODs), as a subset of group purchasing organizations (GPOs), but does not provide a specific definition for this type of entity. Reporting entities currently have the ability to self-identify as a POD when registering with Open Payments, but due to the lack of a definition of the term ''physician-owned distributorship'' or ''POD,'' this designation is not required. We believe that the disclosure of an entity's status as a POD is essential to the transparency that is central to the program, and will also help clear up confusion about whether PODs are required to report. Accordingly, we proposed to include the definition of a POD as set out at § 403.902 as a subset of either an applicable manufacturer or applicable GPO.

We also proposed to include language at § 403.908(c)(4) to require PODs to self-identify when registering or recertifying.

Furthermore, to better align the Open Payments program with the updated definition of ownership and investment interest at § 411.354(b)(3) (see 85 FR 77587), we included the exceptions for titular ownership and employee stock ownership programs (ESOPs) that are qualified under IRS regulations for consistency in application.

In addition, we emphasized that:

- The proposed definition of a physician-owned distributorship does not apply for purposes of any other laws or regulations, including, but not limited to, section 1877 of the Act, the regulations at 42 CFR part 411, subpart J, section 1128B of the Act, or the regulations at 42 CFR 1001.952.
- ''Ownership or investment interest'' is defined at § 403.902 of the Open Payments regulations and would not include publicly traded securities or mutual funds.
- To be considered a physician owner(s), the owner would have to hold

at least one active professional license to practice as a physician issued by a U.S. State or territory.

- If a company with common ownership reports in a consolidated report with the POD, the reporting company would only be required to register as a POD if it meets the 5 percent ownership requirement when ownership of all entities in the report is calculated.
- The POD would be required to report ownership and investment interest as required by existing Open Payments requirements. Ownership or investment interest is defined at § 403.902 to include, but is not limited to: stocks, stock option(s) (other than those received as compensation, until they are exercised); partnership shares, both limited and non-limited; limited liability company memberships; loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue. This definition explicitly excepts titular ownership and ESOPs that are qualified under IRS regulations.
- The POD would be required to identify as a POD whether or not the physician has a controlling interest in the reporting entity (for example, a silent partner whose only role is to provide capital and is not involved in the company's operations would still meet requirements for reporting).
- Five percent interest would be calculated as 5 percent of the total dollar value in USD of all ownership in the POD as of December 31, or the latest date that the ownership was held, as of the calendar year proceeding the Program Year. For example, if reporting ownership in a POD for Program Year 2022, the ownership will be calculated as of December 31, 2022, or the latest date in the calendar year that the physician held the ownership or investment interest.
- Indirect ownership interest would also have to be reported as required by § 403.902. Indirect ownership is often the result of the use of holding companies and parent/subsidiary relationships.
- Any entity meeting this definition would be required to identify itself as a POD when submitting and attesting to its records. For example, if an applicable manufacturer meets the definition of a POD, it may not choose to identify itself simply as an ''Applicable Manufacturer'' but will have to choose its business type as ''Applicable Manufacturer—Physician Owned Distributorship.''
- We believed that this proposed definition should not increase industry burden because it is a subset of existing definitions, but should clarify confusion about PODs being outside of reporting requirements.

We received public comments on the requirement that physician-owned distributorships (PODs) self-identify when registering or recertifying.

The following is a summary of the comments we received and our responses.

Comment: We received several comments on this proposal, all of which expressed general support for the creation of a POD definition, although some provided suggestions on additional details to include. Two commenters noted that they believed that the proposed definition was not narrow enough to address concerns around PODs. One commenter suggested that CMS update the language to clarify that a POD may sell to a single entity, such as a hospital.

Response: Many commenters' suggestions fell outside CMS' bounds of rulemaking authority, as statutory language limits the changes we may make to the program definitions. We do not believe we need to specify that the definition may include PODs that have a single customer as long as the definition does not exclude these entities. We therefore finalize the definition as proposed.

(4) Disallowing Record Deletion Without Reason

While we have not seen evidence of the following conduct, we believe that our existing regulations might allow entities to be compliant by reporting and attesting to records, then deleting those records so that they are never publicly available. We proposed to prevent reporting followed by deletion by adding language at § 403.904(a)(3) that will state that an entity that has reported payments or transfers of value under the scope of this rule may not remove, delete, or alter the records in the Open Payments system unless it discovers an error in the information furnished, or the record is otherwise believed to meet existing exceptions for reporting that were previously unknown.

An example of a properly deleted record would be the deletion of ownership records that were reported for a publicly traded company, since publicly traded companies are not required to report ownership and investment interest. We will add a dialogue box in the system for reporting entities to provide a reason for record deletion. We noted that deletions will continue to undergo additional scrutiny to ensure the integrity of the data.

We received public comments on the requirement that a reporting entity provide a reason when deleting a record. The following is a summary of the comments we received and our responses.

Comment: Some commenters were supportive of our proposal, while others were skeptical. These commenters mostly submitted system suggestions that would reduce burden, including: creating pre-filled options for deletion reasons instead of a free form text box; creating a threshold at which the reason for deletion would be required; and having the reason automatically populate as ''dispute'' if the deletion was on a disputed record.

Response: We clarify that while we have not seen evidence of reporting entities reporting and deleting records to avoid publication, we believe our proposed language is nonetheless important to ensure such conduct is proscribed. Furthermore, CMS and reporting entities both currently bear an administrative burden– created when CMS needs documentation to confirm that a deletion is legitimate since attestation had previously been made as to the record's timeliness, completeness, and accuracy—when records are deleted without context. With proper reporting methodologies in place, deletions should be relatively rare and burden should be minimal, especially with respect to undisputed records. We believe that the proposed requirement will afford a needed layer of integrity to the data and we finalize it as proposed. However, we appreciate the feedback on logistical options and will take them into consideration as much as possible as we implement this requirement so as to minimize burden.

(5) Disallow Publication Delays of General Payments

Delayed publication is permitted for Open Payments records based on concerns that the information provided in the record details may reveal proprietary information about an entity's research activities. According to § 403.910, only payments that are made in connection with the following are allowed to be delayed from publication: (1) Research or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply; or (2) Clinical investigations regarding a new drug, device, biological, or medical supply. As of December 26, 2020, there were 20,930 general records with a value of $26.4M that were delayed from publication for at least one Program Year, and based on the information

provided in the current format required for the submission of general records, we are unable to verify these records' connection with research or clinical investigations. Therefore, we proposed to eliminate the ability to delay general payments from publication and only permit publication delay of research payments, whose formatting does require the appropriate information to be provided, the details of which are specified at § 403.904(f).

Reporting entities may hesitate to include records that are currently being delayed as general payments because they are associated with a research study, but are not directly outlined in that research agreement. For example, a company may pay for an airline ticket for a physician to conduct research that is associated with a research agreement, but that travel was not explicitly outlined in that agreement. However, we do not believe that the current requirements for a research payment would exclude these types of payments from being reported as research payments, as long as they are made in connection with, and subject to, a research agreement.

We received public comments on the removal of the ability to delay general payments. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive or neutral. One commenter asked CMS to clarify whether payments associated with research but not explicitly outlined in the written agreement should be reported as research payments instead of general payments.

Response: We believe that our proposal is clear that as long as a payment is made in connection with a written research agreement, it may be reported as a research payment even if it was not explicit in that agreement. We finalize this proposal as it was proposed, and we will update our guidance, including FAQs, to be aligned with this final rule.

(6) Short-Term Loans

The 2013 Open Payments final rule makes a reporting exception for short-term equipment loans. A short-term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient. The Open Payments regulations also clarify that for a single product, the total number of days for the loan should not exceed 90 days for the entire year, regardless of whether the 90 days are consecutive. We believe that this aligns with the intention to limit the loan period to 90 days and not allow a new loan to start at the end of the previous loan period, thus avoiding the reporting requirements. We proposed to clarify this by stating that short-term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 cumulative days per calendar year or a quantity of 90 cumulative days of average daily use per calendar year, to permit evaluation of the device or medical supply by the covered recipient.

We received one public comment on the proposal to clarify the definition of a short-term loan. The following is a summary of the comment we received and our responses.

Comment: One commenter requested that this proposal be withdrawn on the basis that this behavior is not occurring and could impact the product evaluation process.

Response: This proposal is merely a clarification of the existing regulatory requirement, and we are finalizing it as proposed.

(7) Remove General Ownership Records

We currently have two ways for an entity to report ownership: entities may submit an ownership record; or a general record with a Nature of Payment category of ''Ownership.'' We proposed to remove the ''Ownership'' Nature of Payment category. The statute requires special rules for the reporting of ownership interest, including dollar amount invested and value of interest, which is not captured by the general payment with the Nature of Payment category of ''Ownership.'' Furthermore, this would create a cleaner and more consistent data set.

We received one public comment on the proposal to remove the ability to submit general ownership records.

Comment: One commenter supported this proposal.

Response: We will finalize as proposed.

(8) Updated Contact Information

When sending communications to entities, the Open Payments program often finds that their contact information is outdated, especially if the entity has not recertified recently. To ensure data integrity, including in instances where we might discern irregularities or potential noncompliance, it is important that the Open Payments program be able to contact reporting entities. We proposed to require that a company that has had reportable payments or transfers of value within the past 2 calendar years keep current its contact information within the Open Payments system. For example, if an applicable manufacturer or group purchasing organization had reported records in Program Years 2018 and 2022, but did not have records for Program Years 2019, 2020, or 2021, it would be required to keep updated contact information in the system during Program Years 2019 and 2020. The applicable manufacturer or group purchasing organization would not have to update its contact information for Program Year 2021. In Program Year 2022, since it once again had reportable records, it would be required to recertify and update its contact information as usual. We proposed to include this requirement at § 403.908(c)(3).

We received public comments on the requirement for reporting entities to keep their contact information updated. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported the proposal. One commenter expressed concern that the contact field would not be able to be updated in the event that a company goes out of business.

Response: We acknowledge that the requirement to keep contact information updated, along with any other requirements, will be impossible to enforce if, for example, a company goes out of business. We will finalize as proposed.

IV. Summary of the Quality Payment Program Proposed Provisions, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

A. CY 2022 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the final rule sets forth changes to the Quality Payment Program starting January 1, 2022, except as otherwise noted for specific provisions. The CY 2022 performance period/2024 MIPS payment year of the Quality Payment Program continues to build on the first few years of implementation of the Quality Payment Program to focus more on our measurement efforts, refine how clinicians will be able to participate in a more meaningful way and encourage participation in

Advanced Alternative Payment Models (APMs).

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is an incentive program that includes two participation tracks, the Merit-based Incentive Payment System (MIPS) and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. The weights of those four performance categories are specified in statute. For CY 2022, those weights are as follows: 30 percent for the quality performance category, 30 percent for the cost performance category, 15 percent for the improvement activities performance category, and 25 percent for the Promoting Interoperability performance category. If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) status, they are excluded from the MIPS reporting requirements and payment adjustment. Those that are qualifying APM participants (QPs) for the year receive a 5 percent lump sum incentive payment during the corresponding payment year through CY 2024, or a differential payment update under the PFS for payment years beginning in 2026.

Participation in the Quality Payment Program slightly rose in the fourth year with 99.9999 percent comparing with 99.8989 percent in the third year. We saw 99.9999 percent of MIPS eligible clinicians participate in MIPS in 2020: 933,549 MIPS eligible clinicians received a payment adjustment and 933,547 MIPS eligible clinicians participated by reporting at least one measure or activity. This was a slight increase from our 2019 participation rates where 954,670 MIPS eligible clinicians received a payment adjustment and 954,573 MIPS eligible clinicians participated by reporting at least one measure or activity. Therefore, participation in MIPS did not meaningfully change in 2020 as compared to 2019. We did see a slight decrease in the number of MIPS eligible clinicians receiving a payment adjustment with 933,549 MIPS eligible clinicians in 2020 compared to 954,670 in 2019. In addition, 90.6 percent of MIPS eligible clinicians received a positive payment adjustment for 2022 based on CY 2020 performance period/2022 MIPS payment year results. Please note that results for the CY 2020 performance period/2022 MIPS payment year are subject to change as a result of the targeted review process which began on August 2, 2021 and will conclude on November 29, 2021 at 8:00 p.m., eastern standard time. For more information on the targeted review process for 2020 please see our announcement from September 27th at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1631/2020%20Scoring%20Updates_EUC%20Reweighting%20Requests%20Extension_Listserv.pdf.*

Regarding performance in Advanced APMs, for the 2020 QP Performance Period, 237,315 eligible clinicians earned Qualifying APM Participant (QP) status while another 10,609 eligible clinicians earned partial QP status.[159] We note that due to the Public Health Emergency (PHE) for COVID–19, 192,344 (or about 20.60 percent of 933,549) MIPS eligible clinicians received reweighting for CY 2020 performance period/2022 MIPS payment year of one or more MIPS performance categories due to our MIPS extreme and uncontrollable circumstances policy.

We plan to continue developing Quality Payment Program policies that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are moving forward with MIPS Value Pathways (MVPs) as MVPs allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population. The MVPs will include the Promoting Interoperability performance category as a foundational element and incorporate population health claims-based measures, as feasible, along with relevant measures and activities for the quality, cost, and improvement activities performance categories. To provide clinicians and third party intermediaries with sufficient time to prepare for a shift to this new participation framework, in this rule, we proposed to begin transitioning to MVPs in the CY 2023 performance period/2025 MIPS payment year.

As we make long-term improvements, evolve MIPS policies, and plan to implement MVPs in the future, we remain committed to our program goals. We are aligning with broader CMS initiatives, such as the CMS Quality Measure Action Plan (*https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf*), to unify strategic efforts to adopt measures most critical to providing high quality care and accelerate strategic improvements for quality programs and measures. The vision for the CMS Quality Measure Action Plan is to use impactful quality measures to improve health outcomes and deliver value by empowering patients to make informed care decisions while reducing burden to clinicians. This plan supports CMS' work to identify activities for transformation of quality measurement and value-based programs and recognizes the need to modernize the current quality ecosystem of measurement and programs. Additionally, it will encourage further reductions to the burden of quality measure reporting and address the current lack of alignment. These efforts will also support identifying activities that are driving better patient outcomes at lower costs. The planned implementation of MVPs aligns with many of the objectives and goals the CMS Quality Measure Action Plan will strive to achieve.

Through the proposals we describe below, we intend to transform and simplify the MIPS program through MVPs, promote the use of connected measures and activities, reward clinicians for providing high value care, and help all clinicians improve care and engage patients. We also intend to gather information from stakeholders to help guide efforts to advance health equity throughout CMS quality programs.

b. Summary of Major Provisions

(1) Major MIPS Provisions

The MIPS program aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. Within MIPS we intend to pay for health care services in a way that drives value by linking performance on cost, quality, and the patient's experience of care.

We have heard from clinicians that MIPS requirements are confusing, burdensome, and that it is difficult to choose measures from the several hundred MIPS and QCDR quality measures that are meaningful to their practices and have a direct benefit to patients. We have also heard concerns from stakeholders that MIPS does not allow for sufficient differentiation of performance across practices due in part to clinician quality measure selection bias. These aspects detract from the

[159] QPP Participation in 2019: Results at-a-Glance released 10/27/2020 at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1190/QPP%202019%20Participation%20Results%20Infographic.pdf.*

program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. MVPs are intended to lead to a simplified MIPS clinician experience, improve value, reduce burden, and better inform patient choice in selecting clinicians. We noted that the MVP framework will connect measures and activities across the 4 MIPS performance categories, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. We intend to focus the future of MIPS on MVP development and implementation.

Additionally, we have heard from patients, clinicians, and other stakeholders that they would like more comprehensive and granular reporting from the MIPS program. To that end, we proposed to establish voluntary subgroup reporting to help provide patients and clinicians information that is clinically meaningful at a more granular level.

We issued a request for information (RFI) to address the Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs; please refer to section IV.A.1.c. of this rule for more information. We also issued an RFI to address Closing the Health Equity Gap in CMS Clinician Quality Programs as discussed in section IV.A.1.d. of this rule.

(a) Basis and Scope

At § 414.1300, we previously codified the basis and scope of the MIPS and APMs. In order to support the continued application of voluntary reporters, we proposed to revise the basis and scope at § 414.1300(a)(2) to remove reference to section 1848(a) of the Act—Payment for Physicians' Services Based on Fee Schedule and instead redesignate the text at § 414.1300(a)(3) to § 414.1300(a)(2) to state section 1848(k) of the Act—Quality Reporting System. At § 414.1400(a)(3), we also proposed to add new language to state section 1848(m) of the Act—Incentive Payments for Quality Reporting.

We did not receive public comments on this proposal, and therefore, we are finalizing it as proposed.

(b) MIPS Value Pathways and APM Performance Pathway

We recognize that the transition to MVPs will take time and we will continue to evaluate the readiness of clinicians in making this transition, while balancing our strong interest in improving measurement and making MIPS more focused on value.

As discussed in section IV.A.3.b. of this final rule, for MIPS Value Pathways (MVPs) we are finalizing our proposals:

- To define who can report MVPs, through the term MVP Participant.
- A delay to the CY 2023 performance period/2025 MIPS payment year: MVP implementation and subgroup reporting timelines. After considering public comments, we are finalizing the proposal with a modification such that multispecialty groups will be required to form subgroups in order to report MVPs beginning in the CY 2026 performance period/2028 MIPS payment year, instead of the CY 2025 performance period/2027 MIPS payment year as proposed.
- An introductory set of 7 MVPs to be available beginning with the CY 2023 performance period/2025 MIPS payment year.
- MVP reporting requirements that account for the four MIPS performance categories.
- During the CY 2023, CY 2024 and CY 2025 performance periods/2025, 2026 and 2027 MIPS payment years, voluntary subgroup reporting within MIPS limited to reporting through MVPs or the APP. For the MIPS program, eligibility, special status determination, and QP determination will continue to be determined at the group level for subgroup participants. Subgroup performance will be assessed at the subgroup level for three performance categories (the quality, cost, and improvement activities performance categories) and will be assessed at the group level for one performance category (the Promoting Interoperability performance category). Additionally, subgroups will continue to be included in group level reporting but will receive scores separate from their affiliated group.
- MVP scoring policies closely align with those used in traditional MIPS, with few exceptions.
- MVP scoring policies including policies for scoring administrative claims measures, including population health measures, scoring only the cost measures specified in the MVP, assigning 20 points for each medium-weighted and 40 points for each high-weighted improvement activity specified in the MVP, scoring subgroups on their affiliated group's data for the Promoting Interoperability performance category, reweighting performance categories for subgroups in certain circumstances, and requirements that the quality performance category be scored with few exceptions for reweighting. While we are finalizing these policies as proposed, we may consider additional incentives to report MVPs in future rulemaking.
- To provide comparative feedback within performance feedback, comparing the performance of like clinicians who report on the same MVP.

We also discuss in section IV.A.3.b. of this final rule, future considerations and goals of the MIPS program:

- We requested comment on the timeline to sunset traditional MIPS in the future, and to eventually make MVP reporting mandatory. Note: we are referring to the established MIPS participation options collectively as traditional MIPS (85 FR 84844).
- Through the MVP development work, gradually implement MVPs for all specialties and subspecialties that participate in the program.

As discussed in section IV.A.3.c. of this final rule, for the APM Performance Pathway, to create stability within the APP, we did not propose any major changes to the APP.

(c) Other MIPS and APM Policies

We are finalizing our proposals for the following provisions for MIPS beginning with the CY 2022 performance period/2024 MIPS payment year:

- As discussed in section IV.A.3.d. of this final rule, for the MIPS Performance Measures and Activities, we are finalizing our proposals and finalizing with modification our proposals regarding the data completeness threshold for the CY 2023 performance period/2025 MIPS payment year and the quality measure set for the CY 2023 performance period/2025 MIPS payment year:

++ In section IV.A.3.d.(1) of this final rule, for the quality performance category, to maintain the data completeness criteria threshold at 70 percent for the CY 2021 and 2022 performance periods/2023 and 2024 MIPS payment years; maintain the data completeness criteria threshold at 70 percent for the CY 2023 performance period/2025 MIPS payment year; extend the availability of the CMS Web Interface as a collection and submission type for the CY 2022 performance period/2024 MIPS payment year; establish a set of 200 MIPS quality measures; and solicited public comments through a request for information (RFI) regarding the draft COVID–19 Vaccination by Clinicians measure specifications.

++ In section IV.A.3.d.(2) of this final rule, for the cost performance category, to establish 5 new episode-based cost measures for implementation into MIPS, which adds to the 2 global or population-based measures and 18

episode-based measures. Additionally, we are finalizing a process for stakeholders to develop cost measures, outside the current measure development process where all cost measures are developed by CMS' measure development contractor.

In section IV.A.3.e.(2) of this final rule, in regard to calculating the final score, we are finalizing our proposal on formulas for the complex patient bonus with two separate components (one for medical complexity and one for social complexity) and an overall cap of 10 bonus points. Lastly, we are finalizing our proposal on updating the formulas for the bonuses to base them on standardized scores and to reward those who fall in higher quintiles and not reward those who fall below a cut-off point.

- As discussed in section IV.A.3.f. of this final rule, beginning with year 6 of MIPS (2024 MIPS payment year), the performance threshold must be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period. We are finalizing our proposal to establish the performance threshold using the mean and the CY 2017 performance period/2019 MIPS payment year data, which will result in a performance threshold of 75 points. In addition, for the CY 2022 performance period/2024 MIPS payment year, the additional performance threshold must be set at either (1) the 25th percentile of the range of possible final scores above the performance threshold, or (2) the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to a prior period. We note that under section 1848(q)(6)(C) of the Act, the additional MIPS payment adjustment factors for exceptional performance are available through the CY 2022 performance period/2024 MIPS payment year, making this the last year of the additional performance threshold and the associated additional MIPS payment adjustment factors for exceptional performance. We are also finalizing our proposal to establish an additional performance threshold of 89 points. This is the 25th percentile of actual final scores from the CY 2017 performance period/2019 MIPS payment year at or above 75 points.
- As discussed in section IV.A.3.h. of this final rule, for Third Party Intermediaries, we are finalizing our proposals to modify third party intermediary requirements, remedial actions and termination policies. Specifically, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs, qualified registries, and health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs, qualified registries, and, health IT vendors may also support the APP. We also are finalizing our proposal to require QCDRs, qualified registries, health IT vendors, and CMS-approved survey vendors to support subgroup reporting beginning with the CY 2023 performance period/2025 MIPS payment year. Although we did not address any changes to the QCDR measure testing requirement at § 414.1400(b)(3)(v)(C)(1) in the CY 2022 PFS proposed rule, based on public comments received on our proposals, we are considering proposing in next year's rulemaking to further delay this requirement for traditional MIPS until the CY 2024 performance period/2026 MIPS payment year, instead of the CY 2023 performance period/2025 MIPS payment year as previously finalized.
- As discussed in section IV.A.3.i. of this final rule, for Public Reporting on Compare Tools hosted by the U.S. Department of Health and Human Services (Compare Tools), we are finalizing our proposal to publicly report clinician affiliations to certain types of facilities (for example, LTCHs, IRFs, etc.). We also solicited comments through a RFI to inform the ways in which utilization data may be useful to patients and caregivers for their health care decisions. In order to give MIPS eligible clinicians time to familiarize themselves with MVPs and subgroup reporting, we are finalizing our proposal to delay public reporting of new improvement activities and Promoting Interoperability measures and attestations reported via MVPs by 1 year, and begin publicly reporting subgroup-level performance information in PY 2024, on the compare tool hosted by the U.S. Department of Health and Human Services. We also are finalizing our proposal to create a separate subgroup workflow that would allow subgroup performance information to be publicly reported in an online location that can be navigated to and from an individual clinician or group profile page. This also aligns with the historical approach to report performance information at the level that it is submitted.
- As discussed in sections IV.A.4.b. and IV.A.4.c. of this rule, we are finalizing our proposal on a change to the APM Incentive Payment payment hierarchy to include at each level payment to one or more TINs associated with the QP during the payment year.

c. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs—Request for Information

We aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As also detailed in the FY 2022 Hospital Inpatient PPS proposed rule (86 FR 25549 through 25554), as part of this modernization of our quality measurement enterprise, we are issuing this request for information (RFI). The purpose of this RFI is to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contains five parts:

- *Background.* This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides a summary of recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- *Definition of Digital Quality Measures (dQMs).* This part provides a potential definition for dQMs. Specific requests for input are included in the section.
- *Use of Fast Healthcare Interoperability Resources (FHIR®) for current electronic clinical quality measures (eCQMs).* This part provides information on current activities underway to align CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), and contrasts this approach to current eCQM standards and practice.
- *Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025*. This part introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- *Solicitation of Comments.* This part lists all requests for input included in the sections of this RFI.

(1) Background

As required by law, we implement quality measurement and value-based purchasing programs across a broad range of inpatient acute care, outpatient, and post-acute care (PAC) settings

consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2020, we launched the CMS Quality Measure Action Plan.[160] One key goal of the plan is to improve the efficiency of quality measures by a transition to digital measures and use of advanced data analytics. Our objective is to use data and information as essential aspects of a healthy, robust healthcare infrastructure to allow for payment and management of accountable, value-based care and development of learning health organizations.[161] Consistent with the CMS Quality Measure Action Plan, we aim to move fully to digital quality measurement by 2025. We acknowledge providers within the various care and practice settings covered by our quality programs may be at different stages of readiness, and therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting data for quality measurement via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[162] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and associated regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health information technology (IT) as defined in section 4003 of the Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified Health Level 7 (HL7®) FHIR Release 4.0.1 as the standard to support Application Programming Interface (API) policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care providers, and health IT developers HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule, ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[163] The ONC 21st Century Cures Act final rule also requires health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard.[164] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[165]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and issuers of certain Qualified Health Plan [QHP] on the Federally-facilitated Exchanges [FFEs]) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available certain data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule). These certain data include data concerning claims and encounters, with the intent to ensure access to their own health care information through third-party software applications. The rule also established new Conditions of Participation for Medicare and Medicaid participating hospitals and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred if the hospital or CAH utilizes an electronic medical records system or other electronic administrative system which is conformant with the content exchange standard at 45 CFR 170.205(d)(2) (85 FR 25603). In the CY 2021 PFS final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act final rule. Under this policy, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce longstanding barriers to quality measurement. Currently, health IT

[160] *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

[161] CMS Quality Measure Action Plan: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

[162] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[163] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

[164] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[165] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid–19 Public Health Emergency. Available at *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.*

developers are required to implement individual measure specifications within their health IT products. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[166] This may be further complicated by systems that integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these structured data to be easily accessible for quality measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

(2) Definition of Digital Quality Measures

In this section we seek to refine the definition of digital quality measures (dQMs) to further operationalize our objective [167] of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems.'' (85 FR 84845) In this RFI, we solicited input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

We discuss one potential approach to developing dQM software in section IV.A.1.c of this final rule. In this section, we solicited comments on the potential definition of dQMs in this RFI.

We also solicited feedback on how leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability programs.[168] These fully digital measures continue to be important drivers of interoperability advancement and learning. As discussed in the next section, CMS is currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. CMS intends to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

(3) Use of FHIR for Current eCQMs

Since we adopted eCQMs in our hospital and clinician quality programs, we have heard from stakeholders about the technological challenges, burden, and related costs of reporting eCQM data. The CMS eCQM Strategy Project engaged with stakeholders through site visits and listening sessions with health systems and provider organizations to learn about their experiences. This stakeholder feedback identified recommendations to improve processes related to alignment; development; implementation and reporting; certification; and communication, education, and outreach. Over the past 2 years, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring FHIR® (*http://hl7.org/fhir*) as a framework for measure structure and data submission for quality reporting programs, specifically for eCQMs. FHIR is a free and open source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health information technology. FHIR allows systems to communicate and information to be shared seamlessly, with a lower burden for hospitals, providers, clinicians, vendors, and quality measurement stakeholders. Specifically, for quality reporting, FHIR enables representing the data in eCQMs, as well as provides a structure for eCQMs and reporting, using FHIR as the standard for all. Whereas today, multiple standards being used to report eCQMs is challenging and burdensome.

We are working to convert current eCQMs to the FHIR standard. We are currently testing the exchange of data elements represented in FHIR to CMS through ongoing HL7 Connectathons and integrated system testing by using and refining implementation guides. Submitting data through FHIR APIs has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. In addition, development of FHIR APIs could decrease provider burden by automating more of the measure data collection process. We continue to explore and expand potential applications of the FHIR standard and testing with eCQM use cases, and we are considering a transition to FHIR-based quality reporting with the use of the FHIR standard for eCQMs in quality and value-based reporting programs. As we move to an all-dQM format for quality programs, we are depending on testing results and community readiness to improve interoperability, reduce burden, and facilitate better patient care. We will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement.

(4) Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that

[166] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

[167] Centers for Medicare and Medicaid Services. 2021 CMS Quality Conference: CMS Quality Measurement Action Plan. 2021. *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

[168] eCQI Resource Center, *https://ecqi.healthit.gov/.*

are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and health care and produce the rich set of data needed to enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support, care coordination and care decision support, which impacts health care and care quality.

We solicited comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

(a) Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated implementation guides) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825) including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to collect all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of electronic data submitted to the Hospital IQR Program with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning (82 FR 38398 through 38402). These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We solicited feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We also solicited feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcome comment on approaches for testing data quality and validity.

(b) Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s), and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions—

++ Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD);

++ Calculate the measure score according to measure logic; and

++ Generate measure score report(s).

- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation, as well as diffusion of quality measurement and related quality improvement and clinical tools through, for example, the use of open-source core architecture.

We solicited comments on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We are also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

(c) Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Health IT vendors that meet the requirements of a Qualified Clinical Data Registries (QCDRs) and qualified registries that report quality measures for eligible clinicians in the MIPS program are potential examples [169] at section IV.A.3.g. of this final rule and can also support measure reporting.

We solicited feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations. We also solicited feedback on the role data intermediaries can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

(d) Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, Federal and State agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and State agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, and care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (Department of Defense and Veterans Affairs [DoD/VA]); the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's Adapting Clinical Guidelines for the Digital Age initiative; Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, National Quality Forum (NQF), provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, State, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures, as well as the requirements of other agencies and payers.

We solicited feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards).

[169] Calendar Year (CY) 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

We also seek to identify opportunities to collaborate with other Federal agencies, States, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

(5) Solicitation of Comments

As noted previously, we solicited input on the future development of the following:

(a) Definition of Digital Quality Measures

We solicited feedback on the following as described in section IV.A.1.c. of this final rule:

- Do you have feedback on the dQM definition?
- Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.

(b) Use of FHIR for Current eCQMs

We solicited feedback on the following as described in section IV.A.1.c. of this final rule:

- Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers? Please explain if you do not agree.
- Would access to near real-time quality measure scores benefit your practice? How so?
- What parts of the current CMS QRDA IGs cause the most burden (please explain the primary drivers of burden)?
- In what ways could a CMS FHIR Reporting IG be crafted to reduce burden on providers and vendors?

(c) Changes Under Consideration To Advance Digital Quality Measurement

Actions in Four Areas to Transition to Digital Quality Measures by 2025.

- We solicited feedback on the following as described in section IV.A.1.c. of this final rule:

++ Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR Implementation Guides suggested for consideration?

++ How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

++ What are possible approaches for testing data quality and validity?

- We solicited feedback on the following as described in section IV.A.1.c. of this final rule:

++ What functionalities, described in section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

++ How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

- We solicited feedback on the following as described in section IV.A.1.c. of this final rule:

++ What are key policy considerations for aggregation of data from multiple sources being used to inform measurement?

++ What role can or should data aggregators play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

- We solicited feedback on the following as described in section IVA.1.c. of this final rule:

++ What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

++ We also seek to identify opportunities to collaborate with other Federal agencies, States, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

Commenters should consider provisions in the CMS Interoperability and Patient Access final rule (85 FR 25510), CMS CY 2021 PFS final rule (85 FR 84472), and the ONC 21st Century Cures Act final rule (85 FR 25642).

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will not be responding to specific comments submitted in response to this Request for Information in the CY 2022 PFS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions may be addressed through separate and future notice-and-comment rulemaking, as necessary.

We thank commenters for the feedback received through this request for information. We may consider this information to inform future rulemaking.

d. Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information (RFI)

Persistent inequities in health care outcomes exist in the United States, including among Medicare patients.[170] In recognition of persistent health disparities and the importance of closing the health equity gap, we request information on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for hospitals, providers, and patients. The following is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies (86 FR 25554 through 255561).

Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level, is often associated with worse health outcomes.[171] [172] [173] [174] [175] [176] [177] [178] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown

[170] Ochieng N, Cubanski J, Neuman T, Artiga S, Damico A. Racial and Ethnic Health Inequities and Medicare. KFF. February 2021.

[171] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[172] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[173] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[174] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[175] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[176] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[177] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[178] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[179] [180] [181] [182] [183] [184]

We are committed to achieving equity in health care outcomes for Medicare beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[185] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities who have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [186] We note this definition was recently established and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, State, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[187] The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of health disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[188] The CMS Quality Strategy [189] and Meaningful Measures Framework [190] also include elimination of racial and ethnic disparities as central principles. Our efforts aimed at closing the health equity gap to date have included providing transparency of health disparities, supporting providers with evidence-informed solutions to achieve health equity, and reporting to providers on gaps in quality as follows:

- The *CMS Mapping Medicare Disparities Tool* which is an interactive map which identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[191]
- *The Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report*, which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.[192]
- *The Rural-Urban Disparities in Health Care in Medicare Report* which details rural-urban differences in health care experiences and clinical care.[193]
- *The Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588)
- *The CMS Innovation Center's Accountable Health Communities Model* which includes standardized collection of health-related social needs data.
- *The Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews set of activities which can help hospital leaders reduce readmissions in diverse populations.[194]
- *The CMS Disparity Methods* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmissions Reduction Program (see 84 FR 42496 through 42500 for a discussion of using stratified data in additional measures).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine (NASEM) [195] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [196] which have examined the influence of social risk factors on several of our quality programs. In this RFI, we discuss

[179] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[180] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[181] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[182] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[183] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[184] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[185] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[186] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[187] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[188] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[189] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[190] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[191] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[192] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[193] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[194] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[195] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[196] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

initiatives specific to further bridging the health equity gap within the MIPS track of the Quality Payment Program.

In Appendix 2: Improvement Activities of this final rule, we discussed an improvement activity titled ''create and implement an anti-racism plan''. This improvement activity acknowledges it is insufficient to gather and analyze data by race, and document disparities by different population groups. Rather, it emphasizes systemic racism is the root cause for differences in health outcomes between socially defined racial groups. Further, we also proposed to modify five existing improvement activities to address health equity. We note that some improvement activities within our current Inventory already aim to improve equity. We believe further modifying them can more explicitly link the activity to health equity without changing the core activity. In other cases, our proposals to modify an activity fundamentally shifts the activity to focus on health equity specifically.

Additionally, in the CY 2022 PFS proposed rule (86 FR 39439 through 39446), we proposed to update the complex patient bonus formula. We specifically refer to ASPE's second report, Social Risk and Performance in Medicare's Value-Based Purchasing Programs, which was publicly-released in May 2020.[197] The second report builds on the analyses included in the initial report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs. More specifically, the report has a 3-pronged strategy approach to: Measure and report quality; set high, fair quality standards; and reward and support better outcomes for beneficiaries with social risk. As a part of this 3-pronged strategy, the report supports use of the complex patient bonus in MIPS, explaining that it is well supported because this policy gives additional points to clinicians with a higher share of medically and socially complex patients and does not lower the standard of care. Hence, although, ASPE's reports to Congress support the use of a complex patient bonus at the final score level, we respond to other findings reported in other literature studies by identifying ways to make the complex patient bonus more targeted for clinicians caring for high risk and complex patients and to mitigate differences in resources that affect MIPS scores. Hence, the proposed formula is based on standardized scores and to reward only those clinicians who fall in higher quintiles in order to focus the bonus on those serving a higher proportion of more complex and vulnerable patients.

Lastly, we acknowledge that small practices within the MIPS program often face challenges in many ways. More specifically, as noted in section IV.A.3.e.(2) of this final rule, the Quality Payment Program gives an advantage to large organizations because such organizations have more resources invested in the infrastructure required to track and report measures to MIPS (82 FR 53776). In response to the feedback on the potential burden on small practices, we have established special policies available for small practices including the small practice bonus and special scoring policies. For example, in the CY 2018 QPP final rule (82 FR 53682 through 53683), we established a significant hardship exception for small practices for the Promoting Interoperability performance category. To further alleviate the burden on small practices and reduce this disparity between large and small practices, we proposed in section IV.A.3.d.(4) to automatically redistribute the Promoting Interoperability performance category weight for any small practice that does not submit data for the performance category, and in section IV.A.3.e.(2), we proposed different redistribution weights for small practices.

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[198] We have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We solicited public comments on two potential future expansions of the CMS Disparity Methods, including: (1) Future potential stratification of quality measure results by race and ethnicity, and (2) improving demographic data collection.

(1) Future Potential Stratification of Quality Measure Results by Race and Ethnicity

The Administration's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal programs. As summarized previously, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications. We are considering expanding the disparity methods to include stratification of the condition/procedure-specific readmission measures by race and ethnicity. The 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, outlines the racial and ethnic categories which may potentially be used for reporting the disparity methods, which we note are intended to be considered as social and cultural, and not biological or genetic.[199] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.[200] Another example, the ''Race & Ethnicity—CDC'' code system in PHIN Vocabulary Access and Distribution System (VADS) [201] permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB

[197] Social Risk and Performance in Medicare's Value-Based Purchasing Programs. ASPE Second Report. May 2020. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[198] Centers for Medicare Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[199] Executive Office of the President Office of Management and Budget, Office of Information and Regulatory Affairs. Revisions to the standards for the classification of Federal data on race and ethnicity. Vol 62. **Federal Register**. 1997:58782–58790.

[200] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[201] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. ONC includes both the CDC and OMB standards in its criterion for certified health IT products.[202] For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using *any* of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system in the Public Health Information Network (PHIN) Vocabulary Access and Distribution Systems (VADS), as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. However, CMS currently does not consistently collect self-reported race and ethnicity for the Medicare program, but instead gets the data from the Social Security Administration (SSA) and the data accuracy and comprehensiveness have proven challenging despite capabilities in the marketplace via certified health IT products. Historical inaccuracies in Federal data systems and limited collection classifications have also contributed to the limited quality of race and ethnicity information in our administrative data systems.[203] In recent decades, to address these data quality issues, we have undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive racial and ethnic identification.[204] [205] Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying white and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander (API) and American Indian/Alaskan Native race.[206] Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with public and private partners to better collect and leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection [207] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information when it is absent.[208] The Office of the National Coordinator for Health Information Technology (ONC) included social, psychological, and behavioral standards in the 2015 Edition health information technology certification criteria (2015 Edition), providing interoperability standards (LOINC [Logical Observation Identifiers Names and Codes] and SNOMED CT [Systematized Nomenclature of Medicine—Clinical Terms]) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health information exchange for EHR fields, as well as proposals to expand the ICD–10 (International Classification of Diseases, Tenth Revision) z-codes, the alphanumeric codes used worldwide to represent diagnoses.[209]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirect estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on hospitals as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[210] Indirectly estimated data are most commonly used at the population level (such as the hospital or health plan-level) where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[211]

As described earlier, we previously supported the development of two such methods of indirect estimation of race

[202] See *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity*. For more information about the certification criterion for ''Demographics'' in the ONC Health IT Certification program, see *https://www.healthit.gov/test-method/demographics.*

[203] Zaslavasky AM, Ayanian JZ, Zaborski LB. The validity of racial and ethnic codes in enrollment data for Medicare beneficiaries. Health Services Research, 2012 Jun (47) (3 Pt 2): 1300–21.

[204] Filice CE, Joynt KE. Examining Race and Ethnicity Information in Medicare Administrative Data. Med Care. 2017; 55(12):e170–e176. doi:10.1097/MLR.0000000000000608.

[205] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[206] Zaslavsky AM, Ayanian JZ, Zaborski LB. The validity of race and ethnicity in enrollment data for Medicare beneficiaries. Health Serv Res. 2012 Jun;47(3 Pt 2):1300–21.

[207] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[208] *https://pubmed.ncbi.nlm.nih.gov/18567241/*, *https://pubmed.ncbi.nlm.nih.gov/30506674/*, Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Financ Rev.* 2008; 29(3):27–42. Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res.* 2019; 54(1):13–23. doi:10.1111/1475–6773.13099.

[209] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[210] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[211] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

and ethnicity among Medicare beneficiaries. One indirect estimation approach developed by our contractor uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, State of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or API.[212] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.[213]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C and D performance data for Medicare Advantage Plans by race and ethnicity.[214] Validation testing reveals concordance of 0.88–0.95 between indirectly estimated and self-report among individuals who identify as White, Black, Hispanic and API for the MIBSG version 2.0 and concordance with self-reported race and ethnicity of 0.96–0.99 for these same groups for MBISG version 2.1.[215] [216] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.[217] Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the hospital-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration, there remains the small risk of unintentionally introducing measurement bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We believe this amount of bias is considerably less than would be expected if stratified reporting was conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We are interested in learning more about, and solicited comments about, the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

(2) Improving Demographic Data Collection

Currently self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[218] Collection and sharing of a standardized set of social, psychological, and behavioral data by clinicians, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[219] This could potentially include expansion to additional social factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We note that clinicians participating in the Medicare Promoting Interoperability Program must use certified EHR technology (CEHRT) that has been certified to the 2015 Edition of health IT certification criteria. As noted previously, the certification criterion for Demographics under the 2015 Edition (at 45 CFR 170.315(a)(5)) supports collection of data using both the OMB standards for collecting data on race and ethnicity, as well as the more granular ''Race & Ethnicity—CDC'' standard. In the 2020 ONC 21st Century Cures Act final rule, ONC also adopted a new framework for the core data set which certified health IT products must exchange, called the United States Core Data for Interoperability (USCDI) (85 FR 25669). The USCDI incorporates the demographic data and associated code sets finalized for the 2015 Edition certification criteria.

As noted previously, ONC also finalized a certification criterion in the 2015 Edition which supports a certified health IT products ability to collect social, psychological, and behavioral data (at 45 CFR 170.315(a)(15)). However, this functionality is not included as part of the certified EHR technology required by the Promoting Interoperability performance category. While the technical functionality exists to achieve the gold standard of data

[212] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[213] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research*, 54:13–23 and Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[214] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[215] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[216] MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G. Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[217] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13– 23. *https://doi.org/10.1111/1475-6773.13099.*

[218] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[219] The Office of the National Coordinator for Health Information Technology. United States Core Data for Interoperability Draft Version 2. 2021. *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

collection, we understand challenges and barriers exist in using the technologies with these capabilities.

We are interested in learning about, and solicited comments on, current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), language preference, tribal membership, and disability status). Further, we are interested in potential challenges facing clinicians with collecting a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [220]) and standards for interoperable exchange (such as the United States Core Data for Interoperability incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria [221]). Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation of this demographic information into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported, information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

Therefore, based on our current and newly proposed policies, we solicited comments on other efforts we can take within the MIPS program to further bridge the equity gap. We plan to continue working with ASPE, clinicians, the public, and other key stakeholders on this important issue to identify policy solutions to achieve the goals of attaining health equity for all patients and minimizing unintended consequences. We look forward to receiving feedback on these topics and note for readers that responses to the RFI will not directly impact payment decisions. We also note our intention for additional RFI or rulemaking on this topic in the future. While we will not be responding to specific comments submitted in response to this Request for Information in the CY 2022 PFS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance.

We thank commenters for the feedback received through this request for information. We may consider this information to inform future rulemaking.

2. Definitions

At § 414.1305, we proposed definitions of the following terms:

- Collection type (revision).
- Meaningful EHR user for MIPS (revision).
- MIPS determination period (revision).
- MIPS eligible clinician (revision).
- Multispecialty group (addition).
- MVP Participant (addition).
- Population health measure (addition).
- QCDR measure (addition).
- Single specialty group (addition).
- Special status (addition).
- Subgroup (addition).
- Submission type (revision).

These terms and definitions are discussed in detail in the relevant sections of this final rule.

3. MIPS Program Details

a. MIPS Eligibility

(1) MIPS Eligible Clinician Definition

In the CY 2017 Quality Payment Program final rule (81 FR77040 through 77041), we defined a MIPS eligible clinician at § 414.1305, as identified by a unique billing TIN and NPI combination used to assess performance, as any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act), a PA, NP, and CNS (as such terms are defined in section 1861(aa)(5) of the Act), a CRNA (as defined in section 1861(bb)(2) of the Act), and a group that includes such clinicians. We established at § 414.1310(b) and (c) that the following are excluded from this definition per the statutory exclusions defined in section 1848(q)(1)(C)(ii) and (v) of the Act: (1) QPs; (2) Partial QPs who choose not to report on applicable measures and activities that are required to be reported under MIPS for any given performance period in a year; (3) low-volume threshold eligible clinicians; and (4) new Medicare-enrolled eligible clinicians. In accordance with sections 1848(q)(1)(A) and (q)(1)(C)(vi) of the Act, we established at § 414.1310(b)(2) that eligible clinicians (as defined at § 414.1305) who are not MIPS eligible clinicians have the option to voluntarily report measures and activities for MIPS. Additionally, we established at § 414.1310(d) that in no case will a MIPS payment adjustment apply to the items and services furnished during a year by eligible clinicians who are not MIPS eligible clinicians, as described in § 414.1310(b) and (c), including those who voluntarily report on applicable measures and activities specified under MIPS. In this final rule, we are finalizing our proposal to amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to include certified nurse midwives (CNMs) (as defined in section 1861(gg)(2) of the Act) and clinical social workers (as defined in section 1861(hh)(1) of the Act).

Section 1848(q)(1)(C)(i)(II) of the Act provides the Secretary with discretion, beginning with the 2021 MIPS payment year, to specify additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) as MIPS eligible clinicians. Such clinicians may include physical therapists, occupational therapists, or qualified speech-language pathologists; qualified audiologists (as defined in section 1861(ll)(3)(B) of the Act); CNMs (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); clinical psychologists (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietitians or nutrition professionals. Therefore, in the CY 2019 PFS proposed rule (83 FR 35883 through 35884), we proposed to amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a PA, NP, and CNS (as such terms are defined in section 1861(aa)(5) of the Act); a CRNA (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, clinical social worker (as defined in section 1861(hh)(1) of the Act), and clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act. In addition, we solicited comments on specifying qualified speech-language pathologists, qualified audiologists, CNMs, and registered dietitians or nutrition professionals as MIPS eligible clinicians beginning with the 2021 MIPS payment year.

After consideration of comments we received, we finalized to revise our proposal in the CY 2019 PFS final rule (83 FR 59722 through 59727) and amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess

[220] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[221] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

performance, to mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a PA, NP, and CNS (as such terms are defined in section 1861(aa)(5) of the Act); a CRNA (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians.

In the CY 2022 PFS proposed rule (86 FR 39349 through 39350), we proposed to amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to include CNMs (as defined in section 1861(gg)(2) of the Act) and clinical social workers (as defined in section 1861(hh)(1) of the Act). The new definition would mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a PA, NP, and CNS (as such terms are defined in section 1861(aa)(5) of the Act); a CRNA (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 through 2023 MIPS payment years, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; beginning with the 2024 MIPS payment year, CNMs (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); and a group that includes such clinicians.

In order to assess whether these additional eligible clinicians (CNMs and clinical social workers) could successfully participate in MIPS, we evaluated whether there would be sufficient measures and activities applicable and available for each of the additional eligible clinician types. We finalized in the CY 2018 Quality Payment Program final rule (82 FR 53780) that having sufficient measures for the quality performance category means having sufficient measures applicable and available such that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician. For the improvement activities performance category, we believe that all MIPS eligible clinicians have sufficient activities applicable and available, as they are broadly applicable. We focused our analysis on the quality and improvement activities performance categories because these performance categories require submission of data. For the Promoting Interoperability performance category, we do not believe that clinical social workers would have sufficient measures applicable and available to them. We refer readers to section IV.A.3.d.(4)(h)(iv) of this final rule, where we discuss our proposed policy to automatically assign a zero percent weighting for the Promoting Interoperability performance category for the clinical social workers. However, we stated in the proposed rule (86 FR 39426) that for the CNMs we do believe they would have sufficient Promoting Interoperability measures applicable and available to them as many of them have participated in the Medicaid EHR Incentive Program and have experience with the adoption or use of CEHRT. Therefore, the CNMs score would not be reweighted automatically for the Promoting Interoperability performance category. However, under § 414.1380(c)(2)(i)(C)(*2*), if a clinician believes they were subject to extreme and uncontrollable circumstances that caused their CEHRT to be unavailable, they may apply for a hardship exception for the Promoting Interoperability performance category. We did not focus as part of our analysis on the cost performance category because we are only able to assess cost performance for a subset of eligible clinicians—specifically, those who are currently eligible as a result of not meeting any of the current exclusion criteria. We do not believe there are cost measures that would apply to the care that clinical social workers or CNMs tend to provide. The current set of episode-based measures in the cost performance category focuses on a range of acute inpatient medical conditions and procedures, and the two population-based cost measures assess inpatient and primary care. Therefore, we anticipate the cost category would be reweighted in accordance with § 414.1380(c)(2) for the majority of these clinician types. The impact of the cost performance category for these additional eligible clinicians would continue to be considered but is currently not a decisive factor for successful participation in MIPS. From our analysis, we found that improvement activities would generally be applicable and available for each of the additional eligible clinician types. For the quality performance category, we found that the additional eligible clinician types would have sufficient MIPS quality measures applicable and available. Since the CY 2019 PFS final rule, we have increased the quality measures that we believe are applicable to clinical social workers to 15 quality measures, which includes 2 outcome measures and 8 high priority measures. In the CY 2021 PFS final rule (85 FR 85069 through 85071), we finalized a Clinical Social Worker Specialty Measure Set. For CNM, we believe there are 7 quality measures which includes 2 outcome measures and 5 high priority measures available for reporting in the CY 2022 performance period. In Appendix 1, Table Group BA of this final rule, we are adopting a Certified Nurse-Midwives Specialty Set. In addition, we received correspondence from the clinical social workers national associations requesting to be included in MIPS. Finally, amending the definition of a MIPS eligible clinician to include clinical social workers and CNMs would align with § 414.1305 definition of an eligible clinician utilized by MIPS APMs for eligibility determinations.

We solicited comments on our proposal.

We received public comments on MIPS eligibility. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported including clinical social workers as MIPS eligible clinicians beginning January 1, 2022. One commenter stated their belief that clinical social workers should be regarded as core members of the clinical care team and becoming MIPS eligible clinicians promotes shared responsibility among the entire care team. Another commenter stated their belief that clinical social workers are an important part of the oncology care team. Another commenter referenced that there should be clear guidelines on how clinical social workers will be able to work with physicians on care coordination efforts and navigate interoperability issues. A few commenters stated their support of adding CNMs as MIPS eligible clinicians as of the CY 2022 performance period. One commenter suggested working with the NQF to determine social work and CNM metrics.

Response: We will work to develop educational materials for clinical social workers to help them successfully participate in MIPS. While we believe

that there are sufficient quality measures for clinical social workers and CNMs, we plan to continue to work with NQF to determine if additional measures are appropriate and to make sure that these measures evolve over time.

Comment: One commenter did not support adding CNMs as a MIPS eligible clinician type as they believe that CNMs provide a majority of obstetrics related services and may not qualify for the low-volume threshold due to limited services they would provide to Medicare populations. Another commenter did not support adding clinical social workers as MIPS eligible clinician type because, as they stated, they believe that there is limited relevance in the categories of MIPS for clinical social workers. A few commenters suggested deferring the MIPS eligibility of clinical social workers by one additional year due to concerns related to the PHE and further burden.

Response: Clinicians and practices must exceed the low-volume threshold to be eligible for MIPS; therefore, if a CNM is below the threshold, they would not be required to participate in MIPS. As for clinical social workers, we did find that there are sufficient measures and activities that would be applicable and available for them (86 FR 39350). We also did receive a comment from the clinical social workers national association requesting that clinical social workers be included in MIPS. In regards to the concerns about the PHE, we note that we have a number of flexibilities in place for MIPS eligible clinicians that are impacted by the COVID–19 pandemic, and refer readers to our COVID–19 resources on our website at *https://qpp.cms.gov/resources/covid19.*

Comment: One commenter suggested recognition of pharmacists' care contributions as they stated under MIPS there is no mechanism for attributing pharmacists' contributions to achieving metrics, and further suggested that a significant number of measures are related to or impacted by medications and would benefit from appropriate medication use and pharmacist-provided services.

Response: We agree that pharmacists are an important component of the health care system but are unable to include them in MIPS since pharmacists are not included in the definition of a MIPS eligible clinician at section 1848(q)(1)(C) of the Act.

Comment: One commenter supported the expansion of MIPS eligible clinician types as it will facilitate the program's growth as quality and performance measurement become an increasingly valuable piece of information in evaluating provider networks offered by health plans. The commenter added that when this information is made available to consumers, it will aid in the identification of high-performing providers using a consistent and evidence-based standard.

Response: We thank the commenter for their support of our proposal and will continue to post performance data on Compare Tools.

After consideration of public comments, we are finalizing our proposal to amend § 414.1305 to modify the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of following (excluding those identified at § 414.1310(b)): For the 2019 and 2020 MIPS payment years, a physician (as defined in section 1861(r) of the Act); a PA, NP, and CNS (as such terms are defined in section 1861(aa)(5) of the Act); a CRNA (as defined in section 1861(bb)(2) of the Act); for the 2021 through 2023 MIPS payment years, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; for the 2024 MIPS payment year and future years, a CNMs (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); and a group that includes such clinicians.

(2) MIPS Performance Period

In the CY 2019 PFS final rule (83 FR 59745 through 59747) we finalized to amend § 414.1320(d)(1) that for purposes of the 2022 MIPS payment year and future years, the performance period for the quality and cost performance categories will be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. In addition, we finalized at § 414.1320(d)(2) that for purposes of the 2022 MIPS payment year and future years, the performance period for the improvement activities performance category will be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

In the CY 2021 PFS final rule (85 FR 84873), we finalized the performance period for the quality and cost performance categories at § 414.1320(d)(1) as follows: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1). However, the quality, cost, and improvement activities performance period for the 2022 MIPS payment year, formerly at § 414.1320(d), was inadvertently deleted, and the amended language regarding administrative claims measures was not expressly retroactive. We recognize that the application of this policy for the 2020 MIPS performance period would be retroactive. To the extent that the application of this policy for the 2020 MIPS performance period will be retroactive, section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively will be contrary to the public interest. We believe that failure to reinstate the inadvertently deleted language retroactively will be contrary to the public interest because the performance period establishes the timespan for the collection of performance data, assessment of performance, and computation of the MIPS payment adjustment, to which clinicians have already committed valuable time and resources. In addition, many of the MIPS policies such as the MIPS determination period and the low-volume threshold determinations utilize the performance period as an integral part of the policy, without which we will be unable to operate the MIPS program as required by statute. Therefore, we solicited comments on our technical amendment to reinstate the inadvertently deleted language, with a modification to state ''For purposes of . . .'' rather than ''Beginning with . . .''. The proposed text stated, for purposes of the 2022 MIPS payment year, the performance period for: (1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year; and (2) The improvement activities performance categories is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year (86 FR 39350 through

39351). Lastly, we proposed to redesignate current § 414.1320(d) through (g) to § 414.1320(e) through (h), respectively.

We did not receive public comments on these proposals, and we are finalizing them as proposed: For purposes of the 2022 MIPS payment year, the performance period for: (1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year; and (2) The improvement activities performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. We are redesignating current § 414.1320(d) through (g) to § 414.1320(e) through (h), respectively.

(3) Modifications to Small Practice Groups Reporting Medicare Part B Claims Measures

In the CY 2019 PFS final rule (83 FR 59753), we established that beginning with the 2019 performance period, Medicare Part B Claims will be an available collection type and submission type for the quality performance category for small practices reporting as individuals or a group. We also stated that in circumstances where only Medicare Part B claims were submitted, that we intended on calculating the quality performance category for the practice as both a group and as individuals and apply the quality performance category score that is the greater of the two. We considered requiring an election for assessment as a group but believed this would be unduly burdensome on small practices (83 FR 59752).

Although we stated we would take the highest of the individual or group score for MIPS eligible clinicians in small practices, we now recognize that this policy has had an unintended impact for clinicians in a small practice who did not submit Medicare Part B quality claims and would not otherwise be eligible for MIPS. Once we receive a Medicare Part B submission, both an individual score and a group score is created. Once a group score is created, a clinician who was individually excluded from MIPS for being under the low-volume threshold, may now be eligible if the group exceeds the low-volume threshold. These clinicians will receive the MIPS final score based on the Medicare Part B submissions, even if the group did not intend to report to MIPS as a group. While we still perform an analysis to only provide to the clinicians the highest final score available, clinicians who are only MIPS eligible by the act of exceeding the low volume threshold as a group are receiving final scores that are unintended. This issue will continue to be further exacerbated as the performance threshold continues to increase, so does the likelihood that a final score from the quality performance category alone (or quality and cost as cost does not have submission requirements) could be below the performance threshold for a group. We therefore now believe it is important for the group to clearly signal its intention to report to MIPS as a group before we expand potential eligibility to other members of the group.

We have existing policies under MIPS that require clinicians to indicate to us when to utilize a group submission. For example, in the CY 2019 PFS final rule (83 FR 59862), we stated that submission of data on improvement activities or Promoting Interoperability measures will indicate that the clinicians in that group wanted to be scored as a group for the purposes of facility-based measurement. Therefore, we believe a similar policy would be appropriate for small practices to indicate they wish to submit Medicare Part B claims for a group quality performance category score. We proposed that starting with the CY 2022 MIPS performance period/2024 MIPS payment year, small practices, excluding those participating in MIPS as part of a virtual group, must submit data as a group in any performance category to indicate that they wish to be scored as a group for Medicare Part B claims (86 FR 39351). This means a group will need to submit data as a group to the improvement activities, Promoting Interoperability performance categories, or to the quality performance category via another submission mechanism as a group (for example, a group that submits MIPS CQMs in addition to Medicare Part B claims data). Once the group submits data to MIPS as a group, we will consider any available Medicare Part B claims measure submissions in calculating their quality performance category score.

We believe using the choice to submit data as a group will indicate the group's intention to participate and be measured as a group. The proposal would preserve and respect the choices made by clinicians and groups by not inadvertently expanding eligibility unwittingly to other clinicians. We note that this proposal will not apply to small practices participating in MIPS as part of a virtual group, because clinicians signal their intent to be scored as a virtual group through the virtual group election process.

We received public comments on our proposal for modifications to small practice groups reporting Medicare Part B claims measures. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to have small practices to submit data as a group in any performance category starting in the CY 2022 performance period to indicate that they wish to be scored as a group for Medicare Part B claims. One commenter suggested that we apply this policy retroactively to the 2020 and 2021 performance periods.

Response: We appreciate the support for this proposal. Unfortunately, we are not able to apply this policy retroactively because we did not propose to do so. Further we believe that if applied retroactively, it would harm certain MIPS eligible clinicians by reducing their payment adjustments.

Comment: One commenter questioned the intersection of the proposed policy requiring small practice groups reporting on Medicare Part B claims measures to report for the improvement activities or promoting interoperability performance category as a group to be assessed as a group, and the policy that deals with circumstances where a clinician has more than one final score. This commenter encouraged CMS to retain the policy that allows clinicians to receive the better of the two results (scoring as an individual or a group) for their final score. This commenter noted that small practices who submit measures via Medicare Part B claims have significant challenges predicting their final MIPS scores while those using registries are able to analyze their data before submission and predict a final score.

Response: We thank the commenter for their support. We note that the final score hierarchy still provides the MIPS eligible clinician with their highest final score, with a few exceptions. More details on this policy is available in section IV.A.3.f. of this final rule.

After consideration of public comments, we are finalizing this policy as proposed. Specifically, starting with the CY 2022 MIPS performance period/2024 MIPS payment year, small practices, excluding those participating in MIPS as part of a virtual group, must submit data as a group in any performance category to indicate that they wish to be scored as a group for Medicare Part B claims.

b. Transforming MIPS: MIPS Value Pathways

(1) Overview

We are moving to MIPS Value Pathways (MVPs) to improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to facilitate movement into APMs (84 FR 40732 through 40734 and 85 FR 84844 through 84845). We intend to promote high value care by paying for health care services by linking performance on cost, quality, and the patient's experience of care. The MVP framework will move MIPS forward on the path to value by connecting the MIPS performance categories, better informing and empowering patients to make decisions about their healthcare, and by helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability.

Stakeholders have supported the MVP framework and our MVP guiding principles, which aim to reduce complexity and burden, move towards more meaningful measurement, capture the patient voice, and move to higher value care (84 FR 62946 and 85 FR 84845). We believe MVP reporting will reduce selection burden with choosing MIPS quality measures and improvement activities to submit; reduce reporting burden by requiring submission of fewer MIPS quality measures than the traditional MIPS participation method; and further align across performance categories the measures and activities identified by specialists and patients as being meaningful and relevant. We believe MVPs developed in coordination with stakeholders with an established process in which clinician and patient perspectives are incorporated (85 FR 84850) can result in more meaningful performance data, reduced complexity of the MIPS program, and lowered clinician burden to participate.

MVPs will make MIPS more meaningful by allowing a more cohesive participation experience; by standardizing performance measurement of a specialty, medical condition, or episode of care; and by reducing the siloed nature of the traditional MIPS participation experience. We intend for MVPs to drive value and help clinicians and practices prepare to take on and manage financial risk, as in Advanced APMs, as they build out their quality infrastructure components (measurement tracking, performance improvement processes, interoperability and data information systems) that align with the MIPS performance categories and gain experience with cost measurement (84 FR 40733). Performance measure reporting for specific populations, such as in MVPs, encourages practices to build an infrastructure with capabilities to compile and analyze population health data, a critical capability in assuming and managing risk. The experience with MVPs, in which there is aligned measurement of quality (of care and experience of care) and cost, continuous improvement/innovation within the practice, and efficient management and transfers of information will help clinicians deliver higher value care and remove barriers to APM participation. Combining linked performance measures and activities with more standardization of measures in MVPs will produce data that can better assist patients in comparing clinician performance and selecting clinicians from which to seek care. As more clinicians have applicable MVPs, the performance data available to patients will expand, and in the future, information for specialists in multispecialty groups will become more available on our Compare Tools, enabling patients to make more informed choices for their care.

We continue our efforts to improve the healthcare of Medicare patients by allowing clinicians to focus on providing care for their patients and report on measures and activities that best reflect their care. As we finalize our initial MVP implementation policies in this final rule, we continue to consider critical factors that will contribute to and demonstrate MVP success and the desired characteristics of the future overall MVP portfolio. We look forward to continuing to work with stakeholders to improve the program and implement the vision of MVPs.

(2) MVP Framework and Implementation Considerations

In the CY 2022 PFS proposed rule (86 FR 39352 through 39355), we requested public comments regarding several issues involving the overall implementation of MVPs and how we can most effectively meet our MVP goals, which include driving value and care improvements. We outlined in the CY 2022 PFS proposed rule several MVP framework and implementation considerations, as well as limitations and challenges we are working with stakeholders to address. As discussed in previous rules (CY 2020 PFS proposed and CY 2021 PFS final rules (84 FR 40732 through 40734, 85 FR 50279 and 85 FR 84844 through 84845 respectively)), our MVP framework calls for linking the MIPS quality, cost, and improvement activities performance categories with a foundation of the Promoting Interoperability and population health claims-based measures. We noted that we are considering how to best implement an MVP portfolio that balances our MVP goals for transformative change and our five MVP guiding principles (85 FR 84845) within current capabilities. We noted there are constraints related to the ability to implement significant program changes including statutory restrictions on the structure of MIPS, and limitations of the current quality and cost measure inventories.

(a) MVP Framework Request for Comments

Stakeholders have largely supported our MVP goals, but a few commenters continue to voice concerns regarding whether our goals to drive value, reduce burden, and derive comparative data can be achieved via the MVP framework (85 FR 84845 through 84847). We noted in the CY 2022 PFS proposed rule that the statutory requirements at section 1848 of the Act may constrain our ability to adopt certain changes (86 FR 39353). These requirements include but are not limited to: The use of four MIPS performance categories (quality, cost, improvement activities and Promoting Interoperability); setting the performance threshold; the call for measures and annual quality measure selection process; and the prescribed performance category weights. Conversely, the statute does provide limited flexibilities in some other areas, so we are interested in exploring any existing MIPS flexibilities that will assist us in implementing MVPs. As we begin MVP implementation, a portfolio of MVPs will be developed with a focus on our end goals while adhering to statutory requirements.

We requested comments on more innovative approaches to help achieve our desired MVP results that we should consider as we build our MVP portfolio (86 FR 39353 through 39354). MVPs aim to improve value, reduce burden, help patients compare clinician performance to inform patient choice in selecting clinicians, and reduce barriers to movement into APMs. We received several comments with feedback on MVP portfolio concepts, overall types of MVPs the portfolio should include, quality and cost measure considerations for meeting MVP objectives, and approaches to measuring and driving value. While we are not summarizing and responding to the comments we received in this final rule, we thank the commenters for their responses and may take them into account as we develop

future policies for the MVPs. We also are interested in continuing to engage with stakeholders on additional ways to drive value, engage the patient perspective, stimulate practice improvement processes, and reduce burden in the MIPS program, through our MVP framework. For example, in the context of MVPs, we are interested in solutions that drive care improvements, measure value through meaningful performance measurement, and reduce burden across all 4 MIPS categories. We are considering how measure development approaches and technology, such as Fast Healthcare Interoperability Resources (FHIR) and dQMs, can help us meet our MVP objectives and improve health equity. We intend to continue a dialogue with stakeholders on these important MVP topics and may consider convening public forums, webinars, and office hours or using additional opportunities such as the pre-rulemaking process to further understand what is important to clinicians, patients, and stakeholders and obtain further input as we develop our MVP portfolio.

Our approach to developing the portfolio of MVPs must balance objectives for having MVPs available for the diverse range of MIPS eligible clinicians, the variety of health conditions affecting Medicare patients, and the patient's needs for relevant, meaningful information. While the proposals finalized in this final rule demonstrate important progress toward realizing the MVP guiding principles (86 FR 39354), challenges remain for CMS in developing an overall portfolio of MVPs that achieves our vision for MVPs. As we finalize our first set of MVPs and begin to implement our guiding principles, we continue to strive to fully implement MVPs and an overall MVP portfolio to drive value, obtain comparative performance data, and elevate the patient voice while reducing clinician burden.

We thank commenters for their responses to our above-referenced requests for comment in the proposed rule. We may consider these responses to inform future rulemaking.

(b) MVP Participant

(i) MVP Participant Definition

As we look ahead to implementing MVPs, we believe it is important to clearly define who can participate in MIPS through MVPs. We believe that defining MVP participation will help stakeholders better understand how our policies affect them, as well as provide clarity and simplicity for readers.

At § 414.1305 we have previously finalized definitions for a MIPS eligible clinician, group, and APM Entity. While we did not propose to change these definitions, and are using these existing terms, we sought to clarify who can participate in MVPs. We proposed a new opportunity for clinicians to participate in MVPs, as a subgroup. We refer readers to section IV.A.3.b.(3)(b)(ii) of this final rule, where we discuss our proposal to define a subgroup. In addition, we believe it would be helpful to distinguish the types of groups that participate in MIPS, and how they could participate in MVPs. Therefore, we refer readers to section IV.A.3.b.(3)(b) of this final rule, where we discuss our proposals to define single specialty group, multispecialty group, and special status, to provide further clarity for stakeholders as they seek to understand how they can participate in MVPs.

In keeping with MVPs broader aim of cohesive participation, at § 414.1305 we proposed the term MVP Participant to mean: An individual MIPS eligible clinician, multispecialty group, single specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2025 MIPS performance period/2027 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. The proposed definition of MVP Participant accounts for the gradual transition to requiring multispecialty groups to form subgroups if they want to report MVPs. We believe this is important because multispecialty groups report on the same set of measures, which may not be relevant or meaningful to all specialists that participate within the multispecialty group, to make improvements in the care they provide to patients. We refer readers to section IV.A.3.b.(2)(c) of this final rule for discussion of subgroup implementation, including requiring multispecialty groups forming subgroups to report MVPs. We recognize that in some limited instances, there are specific policy proposals that are more narrow or expansive than the term MVP Participant allows for. In those cases, we will continue to clarify which specific participants a given policy applies to, rather than using the new term. For example, if we have policies regarding what is required during subgroup registration, as discussed below, we would specify that these policies would be specific to subgroups rather than use the term MVP Participants. In another example, as discussed in section IV.A.3.b.(4)(d)(vi) of this final rule, we proposed Promoting Interoperability performance category scoring policies that apply to individual MIPS eligible clinicians, groups, and APM Entities, but do not apply to subgroups. In this example, we would clarify that the policy applies to MVP Participants, except subgroups. In addition, if we determine a given policy proposal is applicable to groups, regardless of whether they are single specialty or multispecialty, we may simply refer to them as groups. We believe stakeholders would welcome the simplicity that using the term MVP Participant would provide. It is an important step forward for the program that would promote clarity and consistency of policy drafting and compliance by stakeholders. We solicited public comment on the proposal.

The following is a summary of the comments we received on the MVP participant definition and our responses.

Comment: One commenter supported the proposed MVP participant definition, specifically supporting the inclusion of multispecialty groups to participate as subgroups. Several commenters supported the proposal to implement voluntary subgroup reporting in the CY 2023 performance period. The commenters expressed their appreciation for 2 years of voluntary subgroup reporting for multispecialty groups and believed that subgroup reporting encourages representation of specialists within a group and allows clinicians to report measures meaningful to their practice as part of a multispecialty group. One commenter expressed their opinion that subgroup reporting is essential for clinicians in multispecialty groups and believed that under the current group reporting option, specialists in multispecialty groups are unable to use MIPS performance feedback to improve patient care since the reported measure set chosen by the group does not reflect the care provided by the specialists. Another commenter appreciated CMS for tackling the operational and implementation hurdles to implement subgroup reporting.

Response: We thank the commenters for their support. To clarify, as described at § 414.1305, the proposed MVP participant definition would not allow for multispecialty group reporting indefinitely. As described in section IV.A.3.b.(2)(c)(ii) of this final rule, the finalized policy requires, multispecialty groups to form subgroups in order to

report MVPs, beginning with the CY 2026 performance period.

Comment: Several commenters did not support the proposed definition of an MVP participant, specifically the proposed exclusion of multispecialty practices from being able to report an MVP at the group level beginning in the CY 2025 performance period due to the burden associated with having to form subgroups given the limited timing in which they have to prepare for subgroup reporting, particularly during the PHE. They noted that requiring these groups to report by subgroups will increase burden and diminish the effectiveness of subgroup reporting.

Response: We disagree. While we understand the increased reporting burden to multispecialty practices related to forming and reporting as subgroups, we believe that subgroup reporting would lead to clinicians in a multispecialty group reporting on measures and activities that are meaningful to their practice. We understand that requiring multispecialty groups to report by subgroups will increase burden, but believe the benefits of requiring multispecialty groups to report through subgroups justify the burden and will not diminish the effectiveness of subgroup reporting. The data submitted by multispecialty groups for quality reporting is not always directly attributable to every clinician within that multispecialty group. For example, we do not believe a nephrologist in a multispecialty group can make meaningful improvements in the care they provide based on the primary care measure data that is submitted on behalf of their multispecialty group. It is difficult to ascertain whether specialists can make improvements in the care they provide, leading to improved patient outcomes, when the data submitted does not directly represent the care they provide. Therefore, we believe there is value in pursuing subgroup reporting, particularly for multispecialty groups and that the MVP participant definition should effectuate this transition. As described in the CY 2022 PFS proposed rule (86 FR 39357), the intent of the subgroup reporting proposals is to move away from large multispecialty groups reporting on the same set of measures, which may not be relevant or meaningful to all specialists that participate within a multispecialty group. Data submitted at the subgroup level would provide increased data granularity that patients and caregivers could use in making data-driven decisions regarding the involvement of specialists in their care. In addition, we believe that transitioning multispecialty groups to subgroup reporting will address some of the inherent gaming risks that are apparent when we have multi-specialty groups report on measures that are not necessarily representative of the care provided by all clinicians within the group, where clinicians in a group may rely on the performance of other clinicians (of a different specialty) within the group to meet quality reporting requirements. While our intent is to solve for the potential gaming risks associated with group reporting through our subgroup policies, we do continue to support clinicians who practice leveraging the team-based care model and plan to address team-based care through future rulemaking. We understand that multispecialty groups may need additional time to prepare for this transition and transitioning during the PHE is difficult, for those that are not prepared to make a transition during the PHE, they can continue to report traditional MIPS. However, we do encourage multispecialty practices to adopt subgroup reporting practices as early as feasible, to allow clinicians sufficient time to orient themselves to MVP policies and reporting ahead of the eventual sunset of traditional MIPS.

Comment: One commenter recommended CMS should explore options to allow multispecialty groups to report the same MVP instead of requiring them to form subgroups to report an MVP.

Response: We disagree. The intent of the subgroup reporting is to move away from large multispecialty groups reporting on measures that are not relevant or meaningful to the specialists that participate within a multispecialty group. From the MIPS perspective, we believe there is more value from a quality improvement standpoint or opportunity to improve patient outcomes through subgroup reporting than through multispecialty group reporting. We do acknowledge there may be circumstances where more than one subgroup within a multispecialty group could select and report on the same MVP, if the MVP is relevant and applicable to the clinicians within the subgroups. While our intent is to have more meaningful reporting and solve for the potential gaming risks associated with group reporting through our subgroup policies, we do continue to support clinicians who practice leveraging the team-based care model and plan to address team-based care through future rulemaking.

Comment: One commenter suggested that CMS work with stakeholders to understand the issues and barriers to subgroup reporting before making them mandatory. The commenter also does not believe there will be sufficient MVPs available by 2025 to accommodate multispecialty groups.

Response: We have continued to solicit stakeholder feedback on the MVP framework, including subgroup reporting for the past few years. In the CY 2020 PFS final rule (84 FR 62946 through 62948) we solicited public comments on the MVP framework. We have held several listening sessions, through the CMS Quality Conference related to the MVP framework and subgroup reporting. In addition, on January 7th, 2021 we held a MVP Town Hall in which we also listened to stakeholder feedback on our MVP vision at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1290/MIPS%20Value%20Pathways%20Town%20Hall%20Slide%20Deck.pdf.* We continue to be open to understanding stakeholders' points of view with regards to MVPs and subgroup reporting. We believe our policy proposals already include enough flexibility to allow multispecialty groups to determine when they are prepared to transition to MVP reporting, and ultimately subgroup reporting. We acknowledge that it is unlikely that we will have MVPs available for all clinicians who participate in MIPS by the CY 2025 performance period. As we continue to expand the portfolio of MVPs available over the next few years, clinicians within a multispecialty group that do not have a relevant MVP for reporting could continue to report through traditional MIPS. We plan to time any future proposal to sunset traditional MIPS with the implementation of an appropriate portfolio of MVPs that are relevant to specialists that participate in the MIPS program.

We understand that stakeholders such as multispecialty groups, healthcare organizations, and vendors are rightfully prioritizing the care of patients during the PHE, which may impact the timing of when they can prepare for and implement subgroup reporting. Since it is unclear as to when the COVID–19 PHE may ultimately end, we believe it is sufficient to delay mandatory subgroup by 1 year. The additional year serves as a buffer to allow multispecialty groups, healthcare organizations, and vendors time to plan and prepare to transition to subgroup reporting. This is in addition to the proposed 2-year period in which subgroup reporting would be voluntary, giving multispecialty groups 3 years in total to transition to subgroup reporting. We intend on continuing to monitor the PHE, and would address the mandatory

subgroup reporting timeline through future rulemaking if we believe additional delay is needed-depending on the status of the PHE and other relevant circumstances at the time. Therefore, after consideration of public comments, we believe it is appropriate to delay the requirement for multispecialty groups to form subgroups in order to report MVPs by 1 year. We are finalizing the definition of MVP participant with modification at § 414.1305 to mean: an individual MIPS eligible clinician, multispecialty group, single specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 MIPS performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. Table 43 serves to summarize which MVP Participants can report an MVP in the future:

TABLE 43: Who Can Report MVPs

Who Can Report MVPs	
CY 2023- CY 2025 MIPS Performance Period	Individual MIPS eligible clinicians, single specialty groups, multispecialty groups*, subgroups, and APM Entities.
CY 2026 MIPS Performance Period, and Future Years	Individual MIPS eligible clinicians, single specialty groups, subgroups*, and APM Entities.

*Multispecialty Groups will be required to report as subgroups in order to report MVPs beginning with the CY 2026 MIPS performance period/2028 MIPS payment year.

(ii) Opt-In Participants, Voluntary Participants, and Virtual Groups

As discussed in the CY 2022 PFS proposed rule (86 FR 39355), we proposed that for the implementation of MVPs, certain clinicians would not be able to participate. These include, voluntary reporters, opt-in eligible clinicians, and virtual groups, who would have their participation in MVPs delayed. We refer readers to section IV.A.3.b.(3)(c)(iv) of this final rule for discussion of the participation rates of opt-in and voluntary participants.

The following is a summary of the comments we received on our proposal to exclude opt-in participants, voluntary participants and virtual groups from the MVP participant definition and our responses.

Comment: A few commenters did not support the exclusion of opt-in participants, voluntary participants, and virtual groups from the definition of MVP participants. They believed that allowing these clinicians to participate in MVP reporting would help them prepare for the potential sunset of traditional MIPS and would allow voluntary reporters to gain experience with MVP reporting. One commenter shared their belief that excluding these clinicians could potentially hinder the development and refinement of MVPs.

Response: We understand the need for opt-in participants, voluntary participants, and virtual groups to prepare for the potential sunset of traditional MIPS by experiencing and orienting themselves to MVP policies and reporting; however, we disagree with the commenters that these clinician types should not be excluded from the definition of an MVP participant for the time being. As described in section IV.A.3.b.(3)(c)(iv) of this final rule, based on historical data, a significantly low number of clinicians have utilized the opt-in, voluntary, and virtual group participation options in MIPS. We believe there are several considerations, such as implementation burden for stakeholders and CMS, value of MVP reporting for these clinicians versus burden, scoring policies, etc. that must be addressed prior to allowing clinicians in these categories to participate in reporting MVPs. Additionally, we believe we need to consider the downstream impacts of including these clinicians when considering the intersection of subgroups and virtual groups. As described at § 414.1305 of this final rule, a subgroup is defined as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI and will not be applicable for clinicians in a virtual group because a virtual group is a combination of two or more TINs, resulting in exclusion of clinicians in virtual groups from participating as subgroups for reporting MVPs. Additionally, we acknowledge the potential for multispecialty virtual groups and the issue of whether they would need to be required to form subgroups in order to report MVPs, similar to multispecialty groups. Overall, there are several factors that need to be planned for before we consider the inclusion of these clinician types. We do intend on revisiting this policy through future rulemaking and prior to the beginning of MVP reporting. We request stakeholder feedback on how to mitigate these implementation issues to expand the MVP participant definition to include these clinician types. Lastly, we disagree that excluding these clinician types could potentially hinder the development and refinement of MVPs. We do not believe there is a mutually exclusive relationship between the MVP development and maintenance processes and the exclusion of opt-ins, voluntary participants, or virtual groups. MVPs are developed around specific clinical conditions, specialties, procedures, or episodes of care and are not developed exclusively for these clinician types.

After consideration of public comments, we are finalizing this policy as proposed.

(d) MVP and Subgroup Implementation Timeline

(i) MVP Implementation Timeline

Since the finalization of the MIPS Value Pathways framework through the CY 2020 PFS final rule (84 FR 62946 through 62949), stakeholders have provided feedback on our implementation timeline through multiple methods, including public comment through rulemaking, meetings, and the MVP Town Hall that held in January 2021. Associated resources related to the MVP Town Hall are available for stakeholder review through the Quality Payment Program Resource Library are available at *https://qpp.cms.gov/resources/webinars.*

Through the MVP Town Hall, we have heard stakeholders encourage MVPs be implemented through a

gradual process that provides MVP participants and third-party intermediaries with time to adapt to the changes in policy, requirements, and programming updates that would need to occur in technological systems. Therefore, we believe it is appropriate to delay the implementation and availability of the MVPs, as described in Appendix 3: MVP Inventory of this final rule, until the 2023 performance period/2025 MIPS payment year, of the MIPS program. We proposed at § 414.1365(a)(1), that for the 2023 MIPS performance period/2025 MIPS payment year, and future years, we use MVPs included in the MIPS final inventory of MVPs established by CMS through rulemaking to assess performance for the quality, cost, improvement activities, and Promoting Interoperability performance categories. Based on the discussion above, we proposed for the CY 2023 MIPS performance period/2025 MIPS payment year, MVP reporting is voluntary.

In addition to proposing a timeline in which MVPs would be first available, we also believe it is important to be transparent with the agency's current vision and solicited public comments on the timing of how long MVP reporting should be voluntary, the transition to mandatory MVP reporting, and the timing for when we should sunset traditional MIPS. While we have heard from stakeholders their request for us to maintain both reporting methods, traditional MIPS and MIPS Value Pathways, we believe it is not a feasible option long term, because of the operational burden, complexity, and costs associated with simultaneously maintaining both versions of the program.

We have also heard from stakeholders (through the MVP Town Hall and from Health Affairs [222]) the importance in continuing this shift to value through MVPs, and doing so by providing as much transparency as possible. In order to foster transparency with our thinking, we solicited public comments on a transition timeline, and are planning to provide stakeholders with information to make informed decisions about their eventual transition to MVP reporting. We believe it is critical to establish a timeline for the awareness of all stakeholders (such as MVP participants, third-party intermediaries, and health systems) so they can plan their work accordingly to coincide with this timeline.

As such, we outline a timeline in which MVP implementation could occur. As stated above, we proposed at § 414.1365(a) that the first year MVP reporting be available is the CY 2023 MIPS performance period/2025 MIPS payment year. Through the remainder of the timeline outlined in Table 44, we seek to lay out our beliefs for the future of the MIPS program, for purposes of transparency, and solicited public comments. We believe moving forward with voluntary MVP reporting in the initial years would provide MVP participants sufficient time to prepare for mandatory MVP reporting. Therefore, as outlined below, we considered MVP reporting would be voluntary for the CY 2023 through the CY 2027 MIPS performance periods/2025 through the 2029 MIPS payment years. Furthermore, we plan for potential future mandatory MVP reporting to coincide with the sunset of traditional MIPS.

TABLE 44: MVP Implementation Timeline

MVP Implementation Timeline	
Proposed:	
CY 2023 MIPS Performance Period	As proposed at § 414.1365 (a), an initial set of MVPs are available for reporting; MVP reporting is *voluntary*.
Request for Comment for Future Consideration:	
CY 2024- CY 2027 MIPS Performance Periods	The existing MVP portfolio would be gradually updated to include newly developed MVPs that are available for reporting. MVP reporting is *voluntary*.
End of CY 2027 MIPS Performance Period and Corresponding Data Submission Period	Considered sunset of traditional MIPS.
CY 2028 MIPS Performance Period, and Future Years	Considered *mandatory* MVP reporting.

As previously described, maintaining both traditional MIPS and MVPs is not a feasible long-term approach for the agency. As such, we are thinking of sunsetting traditional MIPS by the end of the CY 2027 performance period/2029 MIPS payment year. We like to note that we did not propose the timeframe in which MVP reporting would no longer be voluntary (by the end of the CY 2027 performance period/2029 MIPS payment year), and the future sunset of traditional MIPS at this time; any proposal to sunset traditional MIPS would be made in future rulemaking. Our discussion of the MVP implementation timeline is an effort to be transparent with our long-term vision of the MIPS program.

We solicited public comments on this incremental timeline to transition to mandatory MVP reporting, including the timing of the sunset of traditional MIPS. Specifically, are there concerns with this timeline? Is there an alternative timeline we should consider and why? In addition, what factors should CMS monitor to determine stakeholder's readiness to sunset traditional MIPS and transition to MVPs? We understand that some clinicians who participate in MIPS practice in highly specialized clinical areas and subspecialties, where they may believe there is not an MVP applicable to their highly specialized practice. Therefore, we also solicited comments on what should happen in instances where highly specialized

[222] ''Medicare Should Transform MIPS, Not Scrap It,'' Health Affairs Blog, March 2, 2021. DOI: 10.1377/hblog20210226.949893.

clinicians cannot identify an applicable and relevant MVP.

The following is a summary of the comments we received on the MVP implementation timeline and our responses.

Comment: Several commenters supported a gradual transition to and implementation of MVPs. One commenter supported the proposal to introduce MVPs and a subgroup reporting option in 2023. The commenter appreciated CMS identifying innovative approaches to measuring value through MVPs, and supported CMS in soliciting stakeholder recommendations on changes to established MVPs for patient-facing and non-patient facing specialties, through the MVP maintenance process.

Response: We thank the commenters for their support.

Comment: One commenter voiced their appreciation of the delay to implement MVPs until 2023 and suggests CMS to finalize this policy as proposed. The commenter commended CMS for developing the MVP framework to create a more cohesive MIPS program and believes it will facilitate more meaningful comparison of care by allowing providers to report on fewer, more relevant measures.

Response: We thank the commenter for their support.

Comment: Several commenters supported CMS' move to MVPs including the proposal to offer MVPs as an optional reporting pathway beginning in the 2023 performance period. The commenters commended CMS for listening to stakeholders during the creation of the MVP process, and introducing the MVP framework as an optional reporting method initially and not a mandatory reporting method.

Response: We thank the commenters for their support.

Comment: Some commenters voiced support for MVPs but suggested that CMS consider delaying the implementation of the MVPs until 2024 or later after the end of the PHE. A few commenters stated that initial voluntary reporting would allow clinicians and groups to familiarize with the structure and scoring of MVPs, evaluate the proposed MVPs and adopt and prepare for reporting an MVP.

Response: We disagree with the commenters that there is a need to further delay the implementation of MVPs. While we certainly understand the need to consider the impact to clinicians and organizations during the PHE, we have built in some flexibilities into our policy proposals. The delayed implementation of the proposed MVPs to the CY 2023 performance period/CY 2025 MIPS payment year, as described in section IV.A.3.b.(2)(c)(i), is intended to provide organizations, clinicians, and third-party intermediaries with additional time to prepare for MVP reporting. In addition, we have also proposed flexibility to allow for voluntary reporting of MVPs at the onset of implementation. This flexibility allows organizations and clinicians to determine whether they are ready to make the transition to MVP reporting or continue to report traditional MIPS, considering their resources that are dedicated to caring for patients during the PHE. Since we did not propose a definitive timeframe to which MVP participants must transition to MVP reporting or to sunset traditional MIPS, we believe our proposed policies include sufficient flexibilities for organizations and clinicians. In addition, we agree with commenters who state that the initial voluntary reporting would provide MVP participants time to familiarize themselves with MVP policies and prepare to adopt and report MVPs that are relevant to their practice.

Comment: One commenter recommended that CMS wait to implement MVPs until a FHIR-based approach to quality measurement can be deployed. The commenter stated this will aid in the transition to MVPs by lowering the cost of multiple program transitions and potentially lower the cost of reporting.

Response: We disagree with the commenter that we should wait to implement MVPs until a FHIR-based approach to quality measurement is deployed. We understand the value in pursuing FHIR to reduce reporting burden and potentially lowering costs, however, we believe it is important to continue to take gradual steps, through the implementation of MVPs, to transform the MIPS program to one of value—where clinicians are able to report on measures and activities relevant to their practice, utilize the results to make improvements in the care provided, and continue to keep our work patient centric. The MVP framework was established prior to the efforts to implement FHIR for quality measurement began. The use of a FHIR-based approach to quality measurement reporting will require additional system development, testing, and notice and comment rulemaking before it is ready to be implemented.

After consideration of public comments, we are finalizing these policies as proposed. We did not propose the remainder of the MVP implementation timeline, and sought public comment on our thinking. We received several comments regarding the future of the MIPS program and the sunset of traditional MIPS. We thank the commenters for their feedback that may be taken into consideration for future rulemaking.

(ii) Subgroup Implementation Timeline

In the CY 2021 PFS final rule (85 FR 84845), we signaled our intent to implement subgroup reporting by finalizing modifications to the MVP guiding principles. We refer readers to section IV.A.3.b.(3) of this final rule for detailed discussion of subgroup proposals; and to section IV.A.3.b.(3)(b) of this final rule and § 414.1305 for the definitions of groups, multispecialty groups, single specialty groups, and subgroups.

From our understanding, groups may be made up of a single specialty or of multiple specialties. We do not believe that single specialty groups, should be required to form subgroups in order to report MVPs. In this scenario, we believe that a single specialty group would be able to report on the same set of relevant and applicable measures for all clinicians within the group, and would be able to ascertain results that may lead to improvements in the patient care provided. Therefore, for now, we do not anticipate the need to require single specialty groups to form subgroups in order to report an MVP.

The intent of the subgroup reporting proposals is to move away from large multispecialty groups reporting on the same set of measures, which may not be relevant or meaningful to all specialists that participate within a multispecialty group. In addition, we have heard from stakeholders over the past few years that large multispecialty groups tend to submit data that is not necessarily representative of all the clinicians that make up that group. For example, a group from a large hospital system, may include various specialties such as primary care, oncology, surgery, anesthesia, and radiology that submit data to CMS on primary care quality measures. We are concerned that these type of group submissions do not accurately reflect the performance of all clinicians within the group, and does not provide all clinicians with results that leads to quality improvement in the care provided. In addition, we do not believe that the other specialties within the group can make data-driven improvements in the quality of patient care provided, when only primary care measure data is submitted to CMS; and the results of that data submission is only relevant to the primary care clinicians. From the patient and caregiver perspective, only receiving

information on primary care measures when searching for a specialist is not helpful. Data submitted at the subgroup level will provide increased data granularity that patients and caregivers could use in making data-driven decisions regarding the involvement of specialists in their care. In addition, we believe that transitioning multispecialty groups to subgroup reporting will address some of the inherent gaming risks that are apparent when we have multi-specialty groups report on measures that are not necessarily representative of the care provided by all clinicians within the group, where clinicians in a group may rely on the performance of other clinicians (of a different specialty) within the group to meet quality reporting requirements. We anticipated that multispecialty groups will need some time to familiarize and prepare themselves for subgroup reporting.

We refer readers to section IV.A.3.b.(2)(b)(i) of this final rule, where we discuss the finalized MVP Participant definition as modified based on public comment. Pursuant to the finalized MVP Participant definition, multispecialty groups and single specialty groups may report as groups or choose to form subgroups to report MVPs for the CY 2023 through the CY 2025 performance period/2025 through the 2027 MIPS payment years. In addition, beginning with the CY 2026 MIPS performance period/2028 MIPS payment year, multispecialty groups would no longer be able to report MVPs. This will mean that if a multispecialty group would like to report MVPs, beginning with the CY 2026 MIPS performance period/2028 MIPS payment year, they could only do so if they form subgroups. We believe this span of time will give multispecialty groups time to familiarize themselves and prepare for subgroup reporting. We encourage multispecialty groups to monitor the implementation of MVPs to determine when to adopt subgroup reporting and transition to MVPs. We encourage groups to adopt MVP and subgroup reporting as early as possible to provide some time to work through any inadvertent operational issues they may encounter as MVP participants prepare for the future of the MIPS program. While we understand that groups may choose between MVP reporting and continuing to participate through traditional MIPS, we highly encourage groups to submit via subgroups if applicable in the first few years of MVP reporting. We believe early adoption of MVPs and subgroup reporting is important for stakeholders, as this will allow clinicians to acclimate to MVP reporting in the event we sunset traditional MIPS in the future.

We understand that some clinicians practice utilizing a team-based care approach, through a multispecialty group. We believe that MVP reporting can continue to foster the utilization of team-based care through subgroup reporting. As such, we describe in section IV.A.3.b.(4)(b)(i)(A) of this final rule, that MVPs may be developed to reflect the team-based care approach used during an episode of care.

In addition, we believe that the delayed implementation of subgroups to the CY 2023 MIPS performance period/2025 MIPS payment year provides third party intermediaries with sufficient time to adapt to the changes in policy, requirements, and programming updates that would need to occur in technological systems to support subgroup reporting. We encourage the early adoption of subgroup reporting to allow groups to gain experience with the future state of the program.

A finalized timeline to implement subgroup reporting is outlined in Table 45.

TABLE 45: Subgroup Implementation Timeline for MVP Reporting

Subgroup Implementation Timeline*	
CY 2023 through CY 2025 MIPS Performance Period/2025 through 2027 MIPS payment years	Groups may voluntarily form subgroups to report MVPs.
CY 2026 MIPS Performance Period/2028 MIPS payment year, and Future Years	Multispecialty groups will be required to form subgroups in order to report MVPs.

* As discussed above, we did not propose that MVP reporting is mandatory. We have outlined and solicited public comments on our future timeline.

As we continue to expand the portfolio of MVPs available over the next few years, MIPS eligible clinicians, groups, and APM entities that do not have a relevant MVP for reporting could continue to report through traditional MIPS. We plan to time the sunset of traditional MIPS with the implementation of an appropriate portfolio of MVPs that are relevant to specialists that participate in the MIPS program. Until that time, there may be instances where some clinicians in a multispecialty group may have a relevant MVP available for reporting, while other clinicians within that same multispecialty group may not. In this scenario, the clinicians within the multispecialty group that have an MVP available may form a subgroup to report the MVP, while the group continues to report traditional MIPS. We refer readers to section IV.A.3.b.(3) of this final rule for additional discussion of subgroup proposals.

We believe there is a need for multispecialty groups to transition to subgroup reporting in order to align with the goals of MVP reporting. That is, to provide more direct attribution of quality measure data and results to all clinicians that participate in the program rather than relying on quality reporting results that can only be attributed to a few clinicians within the group. This direct attribution will lead to more valuable, meaningful, and actionable results that contribute to patient care and improvement. We refer readers to sections IV.A.3.b.(3) and IV.A.3.b.(4)(d) of this final rule for discussion of the finalized subgroup and MVP reporting requirements.

(e) Subgroups Reporting the APM Performance Pathway (APP)

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the availability of the APM Performance Pathway beginning with the CY 2021 performance period. Specifically, we finalized that individual MIPS eligible clinicians who are participants in MIPS APMs may report through the APP at the individual level (85 FR 84860). Furthermore, we finalized that groups and APM Entities may report through the APP on behalf of constituent MIPS eligible clinicians (85 FR 84860). Because we already identify the MIPS eligible clinicians who are MIPS APM participants based on Participation Lists

for each APM, it is unnecessary to require MIPS APM participants to register as subgroups for purposes of reporting the APP. We use Participation Lists to identify each individual APM participant for purposes of MIPS APM participation, as well as application of the Improvement Activities credit for APM participants; beginning with performance year 2023, we will use Participation Lists to identify the MIPS eligible clinicians within a group TIN that should be included in the subgroup of APM participants for purposes of reporting the APP.

(f) Catalyst for Reporting MVPs

(i) Background

Through the MIPS Value Pathways framework, finalized in the CY 2020 PFS final rule (84 FR 62946 through 62949), stakeholders provided feedback, specifically questioning what incentives would MVP Participants have to report on MVPs, when they have the choice to report traditional MIPS instead. We have heard these questions raised through multiple methods, including public comment through rulemaking, meetings, and the MVP Town Hall that was held in January 2021. Through rulemaking, we have proposed MVP policies that we believe act as catalysts to encourage MVP Participants to transition to MVP reporting. This includes reduced reporting requirements, as described in section IV.A.3.b.(4)(d) of this final rule, allowing MVP Participants to report on a smaller, more cohesive subset of measures and activities that are relevant to a given clinical topic, condition, procedure, or episode of care. In addition, as described in section IV.A.3.b.(5)(d)(ii) of this final rule, we are finalizing our proposal to provide MVP Participants who report on MVPs with enhanced performance feedback that allows for meaningful comparison to similar clinicians and provides more useful information to make improvements in the care provided.

Additionally, we understand that clinicians have other requirements that must be met to maintain their licensure and as appropriate board certification status. In many instances, clinicians must comply with Continuing Medical Education (CME) requirements and/or Maintenance of Certification (MOC) requirements. We believe that any alignment between what clinicians must do to maintain their licensures/board certifications and reporting MVPs would be beneficial by reducing burden in terms of the various requirements clinicians must comply with. Therefore, in some cases, it seems possible that offering CME credit or credit towards MOC could be connected with MVPs. We encourage accrediting organizations such as specialty societies, to work with MVP submitters and consider whether CME credit or credit towards MOC could be offered for reporting MVPs. We believe by allowing clinicians to receive CME credit for MVP reporting, there is potential for there to be a reduction in the administrative burden clinicians face when trying to balance meeting CMS program requirements with the requirements of medical licensing or certification.

The incentives for clinicians to report on MVPs in lieu of traditional MIPS may encourage early adoption of MVPs and allows those clinicians to gain experience with the future state of the program. We believe that creating incentives to report MVPs may help MVP participants familiarize themselves with MVP reporting requirements, particularly in cases where clinicians identify an available MVP as relevant to their practice. Through public comment stakeholders have expressed their desire for additional incentives for clinicians to choose to report MVPs over traditional MIPS. We refer readers to section IV.A.3.b.(5) of this final rule where we discuss considerations of additional incentives through future rulemaking.

(ii) Public Reporting of MVP Data

We have heard from stakeholders who expressed hesitancy to partake in the initial transition to MVP reporting citing concerns with what results may be publicly reported. We refer readers to section IV.A.3.i.(1) of this final rule for discussion of our public reporting proposals related to MVP data and subgroup reporting.

(3) Subgroup Composition

(a) Overview

In the CY 2022 PFS proposed rule (86 FR 39355 through 39358), we proposed to establish subgroup reporting as an option for MVP Participants and for those individuals and entities who choose to report the APP. Additionally, we proposed: (1) Definitions for subgroup, single specialty group, multispecialty group, and special status; (2) subgroup eligibility requirements; and (3) application of low-volume threshold and special status designations for subgroups (86 FR 39360 through 39363). We refer readers to section IV.A.3.b.(4) of this final rule, for details on our finalized policies regarding: (1) Subgroup reporting requirements; (2) subgroup election process; and (3) subgroup identification. In section IV.A.3.b.(5) of this final rule, we detail our finalized policies on subgroup scoring.

We refer readers to the CY 2022 PFS proposed rule (86 FR 39359) for information on the background of subgroup reporting and discussion of our proposed policies.

(b) Definitions of a Single Specialty Group, Multispecialty Group, Subgroup, and Special Status

A group is currently defined at § 414.1305 as a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN. As discussed in section IV.A.3.b.(3)(b)(iii) of this final rule, we proposed to use certain characteristics of the group to determine eligibility and special status of the clinicians in the subgroup. To provide clarity, we proposed definitions for single specialty groups, multispecialty groups, subgroups, and special status.

(i) Single Specialty and Multispecialty Groups Definitions

We proposed to add to § 414.1305 to include that a single specialty group is a group as defined at § 414.1305 that consists of one specialty type as identified by eligible clinicians in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) (*https://pecos.cms.hhs.gov/*). In the proposed rule (86 FR 39360), we shared our belief that using clinician specialty information from PECOS would allow us to align data sources and create greater consistency within the program given that PECOS specialty information is publicly reported on Care Tools.[223]

We also proposed to add to § 414.1305 to include that a multispecialty group is a group as defined at § 414.1305 that consists of two or more specialty types as identified by eligible clinicians in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). As discussed in section IV.A.3.b.(2)(c)(ii) of this final rule, beginning in the CY 2026 performance period/2028 MIPS payment year, multispecialty groups will be required to form subgroups to report MVPs.

Additionally, we refer readers to the CY 2022 PFS proposed rule (86 FR 39360), where we discussed the subgroup reporting options for clinicians involved in care across multiple specialties or who may have more than one PECOS specialty

[223] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/About-Physician-Compare-An-Overview.*

designation. At this time, we do not have limitations on which specialty will be considered the primary specialty. However, we will be taking stakeholder feedback into consideration as we craft policies for limiting subgroup composition in the future.

We received public comments on the proposed definitions for single specialty and multispecialty groups. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the use of the PECOS clinician specialty designation to determine the composition of a group or a subgroup. A few commenters shared their concern that PECOS primary specialty designations in many instances do not align with the scope of care provided by a clinician and specifically do not represent the care provided by clinicians in subspecialties. A few commenters recommended that CMS determine specialty by analyzing claims data, specifically specialty taxonomy codes, because they believed that taxonomy codes offer a deeper level of specificity than PECOS specialty codes which could make it clearer which specialties would want to report on a given MVP. One commenter specifically shared their belief that using PECOS to determine clinician specialty may result in the exclusion of NPs, PAs, and other clinician types due to the designation options within PECOS.

Response: As articulated in the CY 2022 PFS proposed rule (86 FR 39365 through 39366), we recognize there are advantages and disadvantages with using PECOS to make specialty determinations. We thank the commenters for sharing their concerns about the use of PECOS clinician specialty designations to determine the composition of a group or subgroup. We recognize that specialty codes on claims data may offer additional information regarding the primary specialty of clinicians in a subgroup. We currently utilize both PECOS and claims data in the Quality Payment Program. For example, we use claims data for determining clinician eligibility for the MIPS program and use PECOS for identifying specialty information on the Compare Tools for doctors and clinicians. Given that PECOS specialty information is also publicly reported on Compare Tools, its use would advance our desire to maintain consistency across the program. Additionally, we agree with the commenter on the importance of ensuring that NPs, PAs, and other clinician types are not excluded from MVP reporting due to their primary designation within PECOS. Therefore, we are finalizing the proposed definitions of single specialty group and multispecialty group with modifications as described in more detail below. We believe that it is critical for CMS to continue to explore the most appropriate data sources and options which can be used to determine whether a group is single specialty or multispecialty, as well as across the MIPS program (for example, when making eligibility determinations, for public reporting).

Comment: One commenter recommended that CMS define a multispecialty group as a group that consists of five or more specialty types as identified by eligible clinicians in PECOS because they believe requiring single specialties to form individual subgroups would be exorbitantly burdensome for large, multispecialty practices which they believe would have to form 50 or more subgroups.

Response: We thank the commenter for their feedback. As discussed in the proposed rule (86 FR 39365 through 39366), we solicited comments on the criteria for defining mandatory subgroup reporting and if a subgroup should be limited to a single specialty. As discussed in section IV.A.3.b.(2)(c)(ii) of this final rule, beginning in the CY 2026 performance period/2028 MIPS payment year, multispecialty groups will be required to form subgroups to report MVPs. To clarify, we did not propose to require any criteria for the composition of subgroups at this time, including limiting subgroup reporting to a single specialty; however, we will be taking public comments into consideration as future subgroup proposals are created. We agree with the commenter that we would not want to create a scenario where a practice would have to create a subgroup for every specialty and subspeciality. As we move from traditional MIPS to MVP reporting, we currently believe defining a multispecialty group as two or more specialties offers simplicity for stakeholders to understand their status.

After consideration of public comments, we are finalizing our proposal to define single specialty groups and multispecialty groups, with modifications. Specifically, we are removing the reference to the use of PECOS within the definitions for single specialty and multispecialty groups at § 414.1305 to allow CMS to explore the data sources and options that can be used across the program, including for identifying primary specialty designations. Given the feedback from commenters, as well as the fact that we utilize both PECOS and claims data in the Quality Payment Program, we do not believe that it is appropriate to specify PECOS as the sole data source for determining specialty information of groups at this time. We recognize that the attribution of a specialty is complex, and we want to avoid unintended consequences that may arise from the use of one data source over another data source when making such attributions.

We also recognize there are different ways for a clinician to identify their specialty and that this results in different information available to CMS (for example, different specialty information available under PECOS and claims data). We believe we need additional time to explore the potential data sources (for example, PECOS and claims) and options that can be used across the program, including for identifying primary specialty designations. Analyzing existing data sources, such as PECOS or claims data, as well as other options will help us ensure we have accurate data on eligible clinicians. We intend to assess available data and systems to ensure that the data is recent and accurately reflects the scope of care provided by clinicians.

Therefore, we are finalizing at § 414.1305 that a single specialty group consists of one specialty type. We are finalizing at § 414.1305 that a multispecialty group consists of two or more specialty types. We encourage stakeholders to provide feedback on their experience with CMS use of separate data sources for MIPS eligibility determination (claims data) and public reporting on Care Compare (PECOS data). Additionally, we request stakeholder feedback on alternate data sources that CMS could consider in addition to the existing data sources (claims data and PECOS) utilized in MIPS.

(ii) Subgroup Definition

We proposed to define a subgroup at § 414.1305 as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI. Groups would identify their affiliated subgroups, and those subgroups would submit data on the MVPs which are clinically meaningful to MIPS eligible clinicians within a subgroup or their patients. We proposed at § 414.1318(b) to state that except as provided under § 414.1317(b), each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance assessment. Additionally, we proposed to amend § 414.1310(e)(1) to state that except as provided under

§§ 414.1315(a)(2), 414.1317(b), 414.1318(b), and 414.1370(f)(2) each MIPS eligible clinician in the group receives a final score based on the group's combined performance assessment. With the inclusion of the exception provided under § 414.1318(b), this would allow for an exception for subgroups to receive a final score based on the subgroup's combined performance.

As discussed in the CY 2022 PFS proposed rule (86 FR 39361), it is possible that more than one final score could be associated with a TIN/NPI for a performance period, and in those situations and as finalized in section IV.A.3.f.(5) of this final rule, we will apply a final score hierarchy for purposes of determining the MIPS payment adjustment for that TIN/NPI. As finalized in section IV.A.3.b.(2)(c)(ii) of this final rule, beginning with the CY 2026 performance period/2028 MIPS payment year, multispecialty groups will be required to form subgroups for reporting MVPs. We believe this will offer clinicians the opportunity to participate in MIPS more meaningfully and will allow patients to have more granular and meaningful information when selecting an eligible clinician. Additionally, we refer readers to the CY 2022 PFS proposed rule for discussion around balancing increased data granularity with team-based care and measuring performance at the subgroup level (86 FR 39361).

As discussed in section IV.A.3.b.(4)(d)(vi) of this final rule, MIPS eligible clinicians in groups who do not have an MVP relevant to their practice would participate in traditional MIPS through group reporting or as an individual. If their group reports through traditional MIPS or an MVP, the clinicians could receive their group's score, if their group submits data. If the group chooses not to report, a MIPS eligible clinician can report as an individual and receive their individual score. While subgroup reporting of MVPs would be voluntary for multispecialty groups until the CY 2026 performance period/2028 MIPS payment year, these groups will continue to report to MIPS for the eligible clinicians (as identified by NPI) under their TIN, including clinicians reporting through subgroups, which is discussed in section IV.A.3.b.(4)(d) of this final rule.

We received public comments on the proposed definition for subgroups. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal for the implementation of subgroup reporting. The commenters shared their belief that the subgroup data would allow for better choice of care by patients and provide additional information for clinicians to improve quality of care provided. One commenter believes subgroup reporting would be crucial to MVPs as it would facilitate meaningful participation for specialists within multispecialty groups, especially clinicians in group practices who are part of episode-based care.

Response: We agree collecting subgroup-level data would allow for better choice of care by patients and provide additional information to clinicians to improve the quality of care they provide. We also believe this policy will allow specialists to participate in the MIPS program more meaningfully.

Comment: A few commenters expressed concern that subgroup reporting may undermine the efficiencies and advantages of the group practice model, specifically detracting from team-based care.

Response: We agree there are tradeoffs that must be considered in the development and implementation of subgroup reporting policies. In addition, we believe transitioning multispecialty groups to subgroup reporting will address some of the inherent gaming risks that are apparent when we have multi-specialty groups report on measures which are not necessarily representative of the care provided by all clinicians within the group, where clinicians in a group may rely on the performance of other clinicians (of a different specialty) within the group to meet quality reporting requirements. While we intend subgroup reporting to be meaningful and relevant to the scope of care provided by the clinicians in the subgroup and allow patients to obtain clinician information at a more granular level, we continue to support clinicians who practice medicine leveraging the team-based care model and plan to address team-based care through future rulemaking. We believe clinicians would be able to participate in the MIPS program more meaningfully if they report measures which are aligned with their scope of care—where specialists directly contribute to the measures and activities they report on. We also encourage the continuation of team-based care and do not intend to prohibit or limit team-based care through the MVP and subgroup policies. Therefore, as discussed in section IV.A.3.i.(1) of this final rule, we believe clinician participation in subgroups would provide meaningful performance feedback for clinicians and also allow patients to choose clinicians relevant to their clinical condition or care needs.

We also agree with commenters that there are many advantages of group practice, and it is critical that team-based care must be accounted for in both subgroup and MVP reporting. Therefore, as finalized in section IV.A.3.b.(2)(c)(ii) of this final rule, we are delaying the implementation of mandatory subgroup reporting of MVPs from CY 2025 performance period/2027 MIPS payment year to CY 2026 performance period/2028 MIPS payment year. We believe the additional time will allow us to craft subgroup reporting policies which will help increase the data available to patients for choosing clinicians, increase the meaningfulness of QPP, and support team-based care.

Comment: One commenter requested that CMS clarify what it means by stating that groups will continue to report to MIPS for their eligible clinicians in their group, including the eligible clinicians who report to MIPS through subgroups.

Response: In section IV.A.3.b.(2)(c)(ii) of this final rule, we finalized the proposal that beginning with the CY 2026 performance period/2028 MIPS payment year, multispecialty groups will only be able to participate in MVP reporting as subgroups. We anticipate there would not be an applicable MVP for all clinicians by the CY 2026 performance period/2028 MIPS payment year. Therefore, those clinicians who do not have a relevant MVP available for reporting would continue to report through traditional MIPS. As we transition to mandatory subgroup reporting, including a State where subgroups may report the Promoting Interoperability measures at the subgroup level, we recognize there will be duplicative reporting during this time to ensure no clinicians are left behind and policies are achievable. Therefore, during the initial years of subgroup reporting, the affiliated group will continue to include subgroup reporters in their traditional MIPS submission across all four performance categories. We refer readers to § 414.1310(e) and the CY 2018 Quality Payment Program final rule (82 FR 53592 through 53593) for a description of our previously established policies regarding group reporting.

After consideration of public comments, we are finalizing these proposals as proposed.

(iii) Special Status Definition

In the CY 2018 Quality Payment Program final rule, we finalized definitions for special status

determinations for ambulatory surgical center (ASC)-based MIPS eligible clinicians, facility-based MIPS eligible clinicians, Health Professional Shortage Areas (HPSA), hospital-based MIPS eligible clinicians, non-patient facing MIPS eligible clinicians, rural area, or small practice status and codified at § 414.1305 definitions for each (82 FR 53479 through 53586). We often refer informally to these as ''special status''; however, we have not previously defined what ''special status'' means. Therefore, we proposed to add to § 414.1305 and define that special status means that a MIPS eligible clinician: (1) Meets the definition of an ASC-based MIPS eligible clinician, facility-based MIPS eligible clinician, hospital-based MIPS eligible clinician, non-patient facing MIPS eligible clinician, or is in a small practice; or (2) is located in an HSPA or rural area. We believe that defining special status will help clinicians better understand the application of subgroup policies.

Comment: One commenter supported the proposed definition of special status because they believe that clinicians who provide their services in ASCs should not be penalized for lack of access to health information technology. They also shared their belief that this aligns with Congressional intent under Section 16003 of the 21st Century Cures Act.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing the proposal as proposed.

(c) Subgroup Eligibility

As described in section IV.A.3.b.(2)(c)(ii) of this final rule, we proposed voluntary subgroup reporting for clinicians beginning with the CY 2023 performance period/2025 MIPS payment year and to define subgroup as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI. During the initial years of MVP implementation, we recognize that there may be an inadequate number of MVPs available for clinicians to participate as subgroups. In the proposed rule, we proposed: (1) Application of a low-volume threshold; (2) application of special status designation; and (3) subgroup inclusions and exclusions (86 FR 39361). Additionally, we solicited comments on subgroup composition and limitations.

(i) Application of Low-Volume Threshold

We considered whether a low-volume threshold for clinicians participating in subgroup reporting should be calculated at the group or subgroup level. In consideration of stakeholder feedback and to minimize changes in eligibility determination for clinicians, we believe it would be optimal to determine the low-volume threshold for clinicians participating in a subgroup at the group level. As we implement subgroup reporting and as clinicians and groups familiarize themselves with this new participation option, we believe we should limit the complexity of the program to the extent that is feasible.

At § 414.1305, one of the ways we determine MIPS eligibility is by defining how the low-volume threshold is applied to individual clinicians and groups. We determine eligibility for MIPS during two different eligibility periods, which include an assessment of: (1) Those who have allowed charges for covered professional services less than or equal to $90,000; (2) those who provide covered professional services to 200 or fewer Part B-enrolled individuals; and (3) those who provide 200 or fewer covered professional services to Part B-enrolled individuals (83 FR 59735) provided by the clinician and group during that time-period. Therefore, we proposed at § 414.1318(a)(1) that except as provided under § 414.1318(a)(2), for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for subgroups are determined at the group level as provided under §§ 414.1305 and 414.1310.

We solicited public comments on this proposal. As MVPs continue to evolve, we anticipate increased opportunities for clinician participation in subgroups, and we also solicited feedback from stakeholders if we should reevaluate, in the future, MIPS eligibility for clinician participation in subgroups at the subgroup level.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal of applying a group's low-volume threshold determination to clinicians in subgroups. One commenter believes finalizing the low-volume threshold determination at the group level for subgroup participants would generally rule out the possibility that multispecialty groups would then exclude clinicians from the program.

Response: We agree with the commenters that assessing the low-volume threshold at the group level would ensure many clinicians are continued to be eligible clinicians in the program.

Comment: One commenter shared their concern that some clinicians may not meet the low-volume threshold by themselves under a scenario where each specialty is required to form and report through subgroup reporting. The commenter shared their belief that MVP reporting for clinicians in small subgroups may not be beneficial for such clinicians and their patients due to inadequate patient outcomes volumes, and therefore, these clinicians should be excluded from MVP reporting. They recommended that CMS instead apply the low-volume threshold at the subgroup level because they believe this would help alleviate burden in large, multispecialty practices and ensure that the subgroup data that patients receive is a valid representation of the care provided.

Response: We understand the commenter's first concern to be that applying the low-volume threshold at the subgroup level would exclude some clinicians who would otherwise be eligible to participate in MIPS. We acknowledge the commenter's concern that subgroup reporting would be burdensome and may not be beneficial due to insufficient patient volume. We agree with the commenter that subgroup reporting may be burdensome, however, we believe that subgroup reporting will provide information about the clinicians at a more granular level to patients, enabling informed decision making for their care needs. We believe that the benefits of providing patients with more information about clinicians outweighs the detriments of the increased reporting burden. We also believe that through subgroup reporting, clinicians will receive performance feedback relevant to the care provided, making the MIPS program more meaningful to both clinicians and patients. To further clarify, we proposed to continue low-volume threshold determinations at the group level, which we believe helps simplify our subgroup policies, limiting confusion around participation status in MIPS. We believe if we determined the low-volume threshold at the subgroup level that this could have unintended consequences such as excluding clinicians from participating in MIPS. We believe by participating in MIPS, clinicians are incentivized to provide higher quality care at a lower cost, which benefits patients. Additionally, we believe assessing the low-volume threshold at the subgroup level could

create loopholes whereby clinicians do not report. This could limit a patient's access to more granular clinician data and could have adverse effects on their care, which is contrary to the goals of MVPs and subgroup reporting. Additionally, as finalized in section IV.A.3.b.(5)(b)(i) of this final rule, for MVP measures to be scored, case minimums are applied and can be reweighted. We believe we will have to find ways for smaller subgroups to meet case minimum on certain quality measures and look forward to working with stakeholders over the coming rulemaking cycles on this issue. We refer readers to this section for more details and discussion of this policy.

After consideration of public comments, we are finalizing this policy as proposed.

(ii) Application of Special Status Designation

Groups in MIPS could have their data submission requirements and scoring affected by special statuses outside of their underlying eligibility for MIPS. Each of these special statuses, described in section IV.A.3.b.(3)(b)(iii) of this final rule, are determined at the time of eligibility determinations.

We proposed at § 414.1318(a)(1) for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status, as defined at § 414.1305, for subgroups is determined at the group level as provided under § 414.1310. We believe it is necessary to explain how special status determinations would work in the context of subgroup reporting. For example, a large, multispecialty group may include subgroups of clinicians that meet the requirements for small practice status, or non-patient facing status, or facility-based status. While we are certain some existing groups could have subgroups that could be eligible at the subgroup level for special status designation as described in section IV.A.3.b.(3)(b)(iii) of this final rule, we do not believe that this determination should be made at the subgroup level at this time. We want to deter construction of subgroups that would inappropriately create special status exemptions, such as subgroups of 15 or fewer clinicians in a large group. Overall, we believe this should help limit the complexity of the program as we implement this new participation option.

We refer readers to the CY 2022 PFS proposed rule for discussion of our plan to not establish limits, at this time, on the number of subgroups that a clinician can be part of (86 FR 39362). We will monitor the ways in which clinicians form subgroups and will revisit this issue in future rulemaking if we discover that clinician participation in multiple subgroups is not what we intended.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to apply a group's special status designation to clinicians in subgroups because they believe it would continue the traditional MIPS exemption policies and offer simplicity for multispecialty statuses, so they are not tracking special status determinations for each subgroup.

Response: We thank the commenters for their support.

Comment: A few commenters requested CMS clarify what special status designation means for healthcare systems, hospitals, and practices which include clinicians with different types of special status designations (hospital-based, non-patient facing, small practice, etc.) under the same TIN.

Response: In the CY 2018 Quality Payment Program final rule (82 FR 53579 through 53586), we finalized definitions for special status determinations for ASC-based MIPS eligible clinicians, facility-based MIPS eligible clinicians, HPSA, hospital-based MIPS eligible clinicians, non-patient facing MIPS eligible clinicians, rural area, or small practice status and codified at § 414.1305 definitions for each. We did not propose a change to how these determinations are made in traditional MIPS or under MVPs. We clarify that our proposal described above would extend these special status designations to subgroup participants so practices would not have to keep track of these designations at a subgroup level. To further clarify our intent, we interpret the commenters' reference to ''healthcare systems' to mean an organization or entity consisting of a group of affiliated hospitals or practices. We note that special status designations are not applicable to healthcare systems and are assigned by CMS to MIPS eligible clinicians at the individual or group level (available via the NPI lookup on *qpp.cms.gov*). Additionally, we note that all the special statuses could apply at the individual or group level, which we believe helps account for different types of eligible clinicians who provide health care under the same practice.

Comment: One commenter did not support the proposal for special status designation to be assessed at the group level for subgroup participants because they believed participation in MVPs may be more difficult for some clinicians if there are no relevant measures or activities available in an MVP.

Response: We believe the commenter misinterpreted the proposed policy for the application of special status designation and may have confused it with our MVP reporting policies regarding the availability and applicability of measures and activities under MVPs, described under section IV.A.3.b.(4) of this final rule.

After consideration of public comments, we are finalizing this policy as proposed.

(iii) Subgroup Composition Limitations

In the CY 2022 PFS proposed rule, we did not propose to require any criteria for the composition of subgroups at this time (86 FR 39362). However, we solicited comments on criteria that we could consider in the future, such as in the CY 2023 PFS rulemaking cycle. We received many comments, and we thank commenters for their feedback. We will take these comments into consideration for future rulemaking.

(iv) Subgroup Inclusions and Exclusions

(A) Subgroup Eligibility—Participants in MIPS APMs

We refer readers to the CY 2022 PFS proposed rule (86 FR 39362 through 39363), where we discuss subgroup reporting eligibility for MIPS APM participants, including how clinicians in APM Entities cannot form a subgroup across multiple TINs at this time. We thank the commenters who provided public comment on potential considerations for allowing APM Entities to form subgroups across multiple TINs and will take this feedback into consideration in future rulemaking.

(B) Subgroup Exclusions—Opt-In Eligible Clinicians and Voluntary Participants

Based on historical data, a significantly low number of clinicians have utilized the following participation options in MIPS: Virtual groups; opt-in eligible clinicians; and voluntary reporters. For example, if the number of opt-in eligible clinicians remains the same as estimated in the CY 2021 PFS final rule (85 FR 85015), we anticipate that an estimated 0.3 percent of the total number of MIPS eligible clinicians would fit into this category. We believe that there are several operational considerations, such as implementation burden for stakeholders and CMS, value of subgroup reporting for these clinicians versus burden, scoring policies, etc. that must be addressed prior to allowing clinicians in these categories to participate as subgroups

for reporting MVPs. Additionally, we believe that the definition of a subgroup consisting of one TIN, as in section IV.A.3.b.(3)(b)(ii) of this rule, would not be applicable for clinicians in a virtual group because a virtual group is a combination of two or more TINs, resulting in exclusion of clinicians in virtual groups from participating as subgroups for reporting MVPs.

Therefore, beginning in the CY 2023 performance period/2025 MIPS payment year, we proposed at § 414.1318(a)(2) that an individual clinician or group electing to participate in MIPS as an eligible clinician in accordance with § 414.1310(b)(1)(iii)(A) or § 414.1310(b)(2) is not eligible to participate as a subgroup. As we consider transitioning to MVPs and retiring traditional MIPS, we will revisit subgroup eligibility for opt-in eligible clinicians, voluntary participants and clinicians in virtual groups in future years. We also solicited feedback from stakeholders on whether clinicians in these categories should be allowed to form subgroups in future years, and if there are additional criteria that should be established.

The following is a summary of the comments we received and our responses.

Comment: One commenter did not support our proposal to exclude opt-in eligible clinicians, virtual groups, and voluntary reporters from subgroup reporting in the CY 2023 performance period/2025 MIPS payment year because they believe allowing these clinician types would help them prepare for the potential sunset of traditional MIPS.

Response: We acknowledge that we will continue to take these types of clinicians into consideration as we continue to build out our subgroup policies in future rulemaking. Additionally, based on historical data, opt-in clinicians, voluntary reporters, and virtual groups make up less than 5 percent of the total number of MIPS eligible clinicians. We believe excluding these clinicians from subgroup reporting would allow CMS to streamline MVP reporting and focus on MVP development for a majority of the clinicians, while reducing burden and complexity for these clinicians during the initial years of MVP implementation. However, as MVP implementation continues, we will reassess if these exclusions should be continued.

After consideration of public comments, we are finalizing this policy as proposed.

(d) Subgroup Examples

In Appendix 3: MVP Inventory of this final rule, we are finalizing seven MVPs for implementation in the CY 2023 performance period/2025 MIPS payment year. We have provided examples below to show how eligible clinicians could choose to participate as subgroups for reporting MVPs if these MVPs are finalized. These examples are not intended to be exhaustive of the eligible clinician types that could participate as subgroup.

Example 1: A group is composed of all anesthesiologists. In this example, all the clinicians in the group have the same primary specialty designation, which is an example for a single-specialty group. We would not anticipate that they would wish to form subgroups but could report the *Patient Safety and Support of Positive Experiences with Anesthesia* MVP as a group.

Example 2: Table 46 illustrates an example of subgroup reporting for a group consisting of anesthesiologists, orthopedic surgeons, and CRNAs. In this example, the group could form a total of three subgroups. The anesthesiologists and CRNAs could form either one or two subgroups for reporting the proposed *Patient Safety and Support of Positive Experiences with Anesthesia* MVP as described in Table G: Proposed Patient Safety and Support of Positive Experiences with Anesthesia MVP Beginning with the CY 2023 performance period/2025 MIPS payment year of Appendix 3: MVP Inventory of this final rule. We believe the measures and activities included in this MVP would be most applicable to clinicians who provide anesthesia services to patients within the surgical setting, are considered anesthesiologists, or are other qualified anesthesia professionals. For instance, the anesthesiologists and the CRNAs could form separate subgroups for reporting on applicable measures and activities in the MVP. Alternatively, the CRNAs and the anesthesiologists could report on the applicable measures and activities in the MVP as one subgroup if this aligns better with how the subgroup would practice and they all report the same measures and activities. The orthopedic surgeons in the group could then form a separate subgroup to report the applicable measures and activities in the proposed *Improving Care for Lower Extremity Joint Repair* MVP.

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TABLE 46: Example to Demonstrate Subgroup Participation

Subgroup Example	Measures and Activities in the MVP
Subgroup #1 (Anesthesiologists): *Patient Safety and Support of Positive Experiences with Anesthesia*	***Quality Performance Category*** Q477: Multimodal Pain Management (MIPS CQMs Specifications) AQI48: Patient-Reported Experience with Anesthesia (QCDR) AQI69: Intraoperative Antibiotic Redosing (QCDR) AQI70: Prevention of Arterial Line-related Bloodstream Infections (QCDR) ***Improvement Activities Performance Category*** IA_BE_22: Improved practices that engage patients pre-visit (Medium) IA_BMH_2: Tobacco use (Medium) ***Cost Performance Category*** Medicare Spending Per Beneficiary (MSPB) Clinician
Subgroup #2 (Certified Registered Nurse Anesthetists): *Patient Safety and Support of Positive Experiences with Anesthesia*	***Quality Performance Category*** Q404: Anesthesiology Smoking Abstinence (MIPS CQMs Specifications) Q424: Perioperative Temperature Management (MIPS CQMs Specifications) Q430: Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (MIPS CQMs Specifications) Q463: Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (MIPS CQMs Specifications) ***Improvement Activities Performance Category*** IA_BE_22: Improved practices that engage patients pre-visit (Medium) IA_BMH_2: Tobacco use (Medium) ***Cost Performance Category*** Medicare Spending Per Beneficiary (MSPB) Clinician
Subgroup #3 (Orthopedic Surgeons): *Improving Care for Lower Extremity Joint Repair*	***Quality Performance Category*** Q350: Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (MIPS CQMs Specifications) Q351: Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (MIPS CQMs Specifications) Q376: Functional Status Assessment for Total Hip Replacement (eCQM Specifications) Q470: Functional Status After Primary Total Knee Replacement (MIPS CQMs Specification) ***Improvement Activities Performance Category*** (~) IA_CC_9: Implementation of practices/processes for developing regular individual care plans (Medium) IA_CC_13: Practice improvements for bilateral exchange of patient information (Medium) ***Cost Performance Category*** Elective Primary Hip Arthroplasty Knee Arthroplasty
Foundational Layer ***Population Health Measures*** **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) ***Promoting Interoperability (PI) Performance Category*** The subgroup submits the affiliated group's Promoting Interoperability performance category data	

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The following is a summary of the comments we received and our responses.

Comment: One commenter disagreed with the subgroup reporting example detailed in Table 33 of the proposed rule, which illustrated how different clinicians could form subgroups and report on the same proposed MVP, Patient Safety and Support of Positive Experiences with Anesthesia. The commenter believes that CMS described how anesthesiologists and nurse anesthetists could report different anesthesia measures and that QCDR measures do not apply to nurse anesthetists. This commenter shared that both the physician anesthesiologist and the nurse anesthetist can, in most cases, report the same quality measures and that there are entities who report QCDR measures to MIPS for their nurse anesthetist clients.

Response: In the illustrative subgroup example under Table 33 of the proposed rule, we provided an example of how different subgroups could report a given MVP. We appreciate the commenter for sharing that CRNAs and anesthesiologists can mostly report the same quality measures and QCDR measures. We believe that the commenter misunderstood our interpretation of subgroup reporting for CRNAs and anesthesiologists in the example. As described in the proposed rule (86 FR 39363), we note the example was not intended to be exhaustive of the measures and activities reported by CRNAs and anesthesiologists. We further clarify that the example was an illustration of the different ways we anticipate the CRNAs and anesthesiologists could report together on the same MVP. We acknowledge that in many cases, CRNAs and anesthesiologists can and do report the same measures, including QCDR measures.

(e) Third-Party Intermediaries for Subgroup Reporting

As described in section IV.A.3.h.(2)(b) of this final rule, we are finalizing at § 414.1400(a)(1) for third-party intermediaries to implement MVPs and subgroup reporting options for MIPS eligible clinicians starting with the CY 2023 performance period/2025 MIPS payment year. Since subgroups will be implemented concurrently with MVPs, we believe that it is important that all third-party intermediaries support subgroup reporting in order for clinicians to meaningfully report MVPs. We refer readers to section IV.A.3.h.(2)(b) of this final rule for additional details on requirements for third-party intermediaries supporting MVPs and subgroups.

(f) Public Reporting of Subgroup Performance Information

As described in section IV.A.3.i.(1) of this final rule, we are finalizing to delay public reporting of subgroup performance information by an additional year. This policy would result in the public reporting of subgroup performance information beginning with the CY 2024 performance period/2026 MIPS payment year and each performance period/MIPS payment year thereafter. We refer readers to section IV.A.3.i.(1) of this final rule for additional details on the finalized policies related to public reporting of subgroup performance information on the compare tool.

(g) Future Vision of Subgroups

In the CY 2022 PFS proposed rule (86 FR 39365 through 39366), we described our vision for the future of subgroup reporting and requested public comment on several policy issues we will consider for future rulemaking. We solicited feedback on: (1) Our vision for data granularity; (2) how subgroup group reporting could function if traditional MIPS is retired; (3) considerations for limiting subgroup reporting to a single specialty; and (4) a request for information on the future vision of subgroup reporting.

To emphasize the main points of our request for comment, under our vision for data granularity, we shared our belief that additional data granularity will help clinicians and patients in making informed health care decisions. Furthermore, additional data granularity would allow CMS to have additional information that we can use to assess gaps in health equity.

In considering how sunsetting traditional MIPS will impact subgroup reporting, since we are finalizing the MVP participant timeline proposal as described in section IV.A.3.b.(2)(c)(ii) of this rule, multispecialty groups would have to report more than 1 MVP beginning in the CY 2026 performance period/2028 MIPS payment year. We reiterate our belief that in order to meet the goals of MVPs, provide enhanced performance feedback to clinicians, and ensure more granular information is publicly available for patients, multispecialty groups must form subgroups to report MVPs. Additionally, we do not believe there will be an MVP that will be applicable to all types of clinicians within multispecialty groups. However, as we work to implement MVPs, we anticipate we will create additional policies to set the rules for how all clinicians will be able to meaningfully participate in the program if traditional MIPS is no longer available.

In considering limitations to subgroup reporting, and specifically, limiting subgroup reporting to a single specialty, we restate our belief that without establishing limitations to subgroup composition prior to implementation, we will not meet the desired programmatic goals of MVPs. We believe in many ways this would replicate our concerns with the current state in traditional MIPS. We considered limiting subgroups to a single specialty, setting a threshold for clinician specialty composition to allow some degree of flexibility under a subgroup, establishing specialty families that would be allowed to form subgroups, and limiting MVP reporting to approved specialties and clinician types rather than placing limits to the subgroup composition itself. As MVPs are implemented, we will consider establishing criteria for how subgroups can be formed for eligible clinicians, group practices, and third-party intermediaries time to make system and workflow updates.

Additionally, we reiterate our belief that team-based care is an essential element to providing high-quality care to patients and acknowledge some of the subgroup policies could be construed to create competition within groups. It is not our intention to create competition, rather, we believe as MVPs continue to be created and evolve, we will include MVPs that are focused on team-based care for some specialties.

We received many comments for our consideration on the vision for data granularity, impact of the sunsetting of traditional MIPS for subgroup reporters, limiting subgroup composition to a single specialty, and future vision of subgroup reporting. We thank commenters for their feedback and will take these comments into consideration in future rulemaking.

(4) MVP Requirements

(a) Overview

In the CY 2020 PFS final rule (84 FR 62948), we finalized at § 414.1305 that MIPS Value Pathway means a subset of measures and activities established through rulemaking. We describe our vision for MVPs to connect the four performance categories while using a foundational layer of population health claims-based measures and interoperability, on which to build, quality, cost, and improvement activity linkages. In the CY 2021 PFS final rule (85 FR 84849 through 84859), we finalized a set of MVP development criteria and a process to receive MVP candidates from stakeholders. In the CY 2022 PFS proposed rule (86 FR 39367 through 39377), we proposed to establish additional MVP related policies to support the implementation and availability of MVPs. In this section, we discuss our proposed: (1) Refinements to the MVP development criteria; (2) a maintenance process for established MVPs; (3) MVP reporting requirements; and (4) the MVP registration process.

(b) MVP Development and Maintenance

(i) MVP Development Criteria

(A) General MVP Structure

As discussed in the CY 2022 PFS proposed rule (86 FR 39367), from the time the CY 2021 PFS final rule

published, we have solicited feedback from several stakeholders who have submitted MVP candidates for CMS consideration utilizing the MVP candidate solicitation process (85 FR 84854 through 84856). Through this feedback, we have understood that the quality and patient improvement priorities of specialists may differ based on the way they practice. There are clinicians who practice utilizing a team-based approach, involving several clinicians of different specialties working together and for that reason, find quality reporting that reflects that approach more meaningful. Team-based health care is defined by the National Academy of Medicine as ''the provision of health services to individuals, families, and/or their communities by at least two health providers who work collaboratively with patients and their caregivers—to the extent preferred by each patient—to accomplish shared goals within and across settings to achieve coordinated, high-quality care.'' [224] Other clinicians may be specialized in a manner where they focus on a limited number of procedures.

For these reasons, we believe there are various ways to approach MVP development, and the method utilized would be dependent on the topic measured by the MVP. One method is to construct MVPs in a manner that is broad, for example, addressing cancer care comprehensively versus the creation of MVPs for each unique diagnosis of cancer care. Another method is to construct MVPs in a more granular manner, for example, addressing a specific procedure, such as hip and knee arthroplasty. A third approach is to structure MVPs in a manner that reflects the team-based healthcare model. This approach considers the patient's care from a holistic perspective, involving various clinicians as needed. One such example is around surgical care, which involves several clinician types, such as surgeons and anesthesiologists. We believe this approach captures the patient experience and outcomes in a manner that is meaningful, that would result in patient improvement. In the CY 2021 PFS final rule (85 FR 84850), we finalized MVP development criteria that accounts for the development of MVPs collaboratively by multiple specialties for this reason. We believe that the team-based healthcare model has an impact to patient outcomes and encourage the use of this approach, as feasible, when developing MVPs.

As described in the CY 2022 PFS proposed rule (86 FR 39370) and in section IV.A.3.b.(4)(b)(ii) of this final rule, we discuss a proposed maintenance process for MVPs. In instances where an MVP is initially implemented, for example, to address a specific procedure, and there is opportunity to evolve the MVP over time to reflect the team-based healthcare model, we would strongly encourage and work towards that transition.

However, we do understand there is not a ''one size fits all'' MVP structure that is suitable for all specialties and believe the use of one of the structure methodologies is appropriate for MVP development.

(B) Selection of Measures and Improvement Activities Within an MVP

As described above, in the CY 2021 PFS final rule (85 FR 84849 through 84850), we established a set of criteria for use in the development and selection of MVPs. Specifically, we had finalized that we were not prescriptive on the number of quality measures that are included in an MVP (85 FR 84850). In the CY 2022 PFS proposed rule (86 FR 39370 through 39372), we proposed reporting requirements for MVPs, and discussed the allowance of clinician choice in selecting which quality measures and improvement activities to report, as described in detail below in section IV.A.3.b.(4)(d) of this final rule. We believe that it is important to provide clarity in our expectations of the number of quality measures and improvement activities that are available for an MVP Participant to choose.

As discussed in the CY 2022 PFS proposed rule (86 FR 39367 through 39368), an MVP should include a sufficient number of quality measures and improvement activities to allow MVP Participants to select measures and report them to meet the reporting requirements outlined in sections IV.A.3.b.(4)(d)(ii) and IV.A.3.b.(4)(d)(iv) of this final rule. To the extent feasible, MVPs should include a maximum of 10 quality measures and 10 improvement activities, to offer MVP Participants some choice without being overwhelming. However, we understand that the total number of measures and activities available in an MVP would depend on the MVP structure. For example, as described in Appendix 3: MVP Inventory of the proposed rule (86 FR 39892 through 39895), we proposed the Optimizing Chronic Disease Management MVP that includes 9 quality measures and 12 improvement activities. Chronic disease can broadly encompass several conditions; therefore, we have selected measures and improvement activities that are closely aligned to the topic and offer clinicians some choice. We refer readers to Appendix 3: MVP Inventory for discussion of our proposed MVPs.

(aa) Requirement of Outcomes or High Priority Measures

As described in the CY 2022 PFS proposed rule (86 FR 39370 through 39371), we proposed MVP quality reporting requirements, that are similar to the requirements of traditional MIPS under § 414.1335. We discuss a proposal to require the reporting of one outcome measure or high priority measure (if an outcome measure is not available). Accordingly, we believe it is important to modify the previously finalized MVP development criteria (85 FR 84849 through 84859), where we describe the criteria for including quality measures in an MVP. We believe we need to update the criteria to ensure MVPs are developed in a manner that accounts for this proposed quality reporting requirement.

(AA) Outcomes Measures Requirement

In the CY 2022 PFS proposed rule (86 FR 39370 through 39371), we proposed that beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, MVPs must include at least one outcome measure that is relevant to the MVP topic, so MVP Participants are measured on outcomes that are meaningful to the care they provide. In addition, beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included. This is important since MVPs are proposed to be constructed in a manner that may include one or more clinician specialties, as described above in section IV.A.3.b.(4)(b)(i)(A) of this final rule, and there should be outcome measures included in the MVP that are relevant to each clinician specialty.

We anticipate over the next few years, there may be opportunities where outcomes-based measures are developed and can be reported utilizing the administrative claims collection type. For example, in the CY 2021 PFS final rule (85 FR 85049 through 85051), we finalized the *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive*

[224] Mitchell, P., M. Wynia, R. Golden, B. McNellis, S. Okun, C.E. Webb, V. Rohrbach, and I. Von Kohorn. 2012. Core principles & values of effective team-based health care. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. *https://doi.org/10.31478/201210c.*

Payment Systems (MIPS) outcome-based administrative claims measure. We proposed to allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP. We believe these measures can be used to meet the outcome measure requirement discussed under the MVP reporting requirements in section IV.A.3.b.(4)(d)(ii) of this final rule. We solicited comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the requirement for MVPs to include at least one outcome measure.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing our policies as proposed.

(BB) Exception When None Are Available

As described in the CY 2021 PFS final rule (85 FR 84850), we are aware that not all specialties and subspecialties may have outcome measures currently available to them in the MIPS program. We are aware of this measurement gap, and believe it is appropriate to allow for the use of high priority measures when outcome measures are not available.

In the CY 2022 PFS proposed rule (86 FR 39368), we proposed that beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, in instances when outcome measures are not available, each MVP must include at least one high priority measure that is relevant to the MVP topic, so MVP Participants are measured on high priority measures that are meaningful to the care they provide. In addition, beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, each MVP must include at least one high priority measure that is relevant to each clinician specialty included. This is important since MVPs are proposed to be constructed in a manner that may include one or several clinician specialties, as described above in section IV.A.3.b.(4)(b)(i)(A) of this final rule. As previously established at § 414.1305, we define high priority measures to include outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measures.

We continue to encourage stakeholders to utilize our established pre-rulemaking processes, such as the Call for Measures: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking,* to develop outcome measures relevant to their specialty if outcome measures currently do not exist and for eventual inclusion in an MVP. We encourage, to the extent feasible, the inclusion of several outcome and/or high priority measures, if available and relevant to the MVP topic. The inclusion of several measures would allow clinicians to have some choice in selecting the most relevant outcome or high priority measure that is meaningful to their specific practice. We solicited comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the requirement for MVPs to include a high-priority measure if an outcome measure is not available.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing our policies as proposed.

(bb) Encouragement To Include Patient-Centered Measures

In the CY 2021 PFS final rule (85 FR 84850), we finalized MVP development criteria that takes into consideration the patient voice. Specifically, we finalized MVP development and selection criteria that considers the inclusion of (to the extent feasible), patient-reported outcome measures, patient experience measures, and/or patient satisfaction measures. Through interactions with stakeholders and presentations, we have referred to these measures as patient-centered measures.

As described in the CY 2022 PFS proposed rule (86 FR 39368), we did not propose any revisions to our previously finalized policy, however, we believe it is important that we rely on a consistent understanding of patient-centered measures. Health Affairs [225] stated the following with respect to such measures, ''Measures should be patient-centered and incorporate new approaches to assessing patient health status and patient experience. Such measures include assessment of clinical outcomes, patient-reported outcome measures, as well as new approaches to evaluation of patient experience.''

We acknowledge that our existing portfolio of patient reported outcome measures is limited and may not be applicable to all specialties and subspecialties. We continue to encourage stakeholders to utilize our established pre-rulemaking processes, such as the Call for Measures, described in the CY 2020 PFS final rule (84 FR 62953 through 62955) to develop patient reported outcome measures relevant to their specialty. In addition, we encourage measure stewards of new and existing quality measures in MIPS to consider updating their measures to include the patient centered approach through the measure maintenance cycle or the development of new measures.

We solicited and received public comments on whether there are other aspects of patient measurement that should be considered as a part of the patient-centered measures definition. We thank commenters for the feedback received through this request for information. We may consider this information to inform future rulemaking.

(cc) Requirements for QCDR Measures Considered for an MVP

In the CY 2021 PFS final rule (85 FR 84857 through 84859), we finalized that QCDR measures that were approved in the previous year may be considered for inclusion within an MVP. In addition, we finalized at § 414.1400(b)(3)(v)(C)(4) that QCDR measures should be fully tested at the clinician level prior to the QCDR measure being included in an MVP. We refer readers to the CY 2021 PFS final rule (85 FR 84857 through 84859) for the specific policies that were previously finalized. In the CY 2022 PFS proposed rule (86 FR 39368 through 39369), we clarified when we would expect a QCDR to prove that their QCDR measure is fully tested before it is implemented within an MVP. QCDRs must self-nominate as a QCDR and submit QCDR measures for CMS consideration within the 60-day self-nomination period that begins on July 1st of the calendar year prior to the applicable performance period and ending on September 1 of the same year. In order to determine whether a QCDR measure may be finalized within an MVP, we will need to receive QCDR measure testing data for review by the end of the self-nomination period, that is no later than September 1 of the year prior to the applicable performance period. We encourage, as feasible, that QCDRs share testing data for their fully tested QCDR measures at the time of MVP candidate submission which may be prior to the September 1st deadline. If a QCDR is unable to submit testing data to demonstrate that their QCDR measure is fully tested at the clinician level by end of the self-nomination period (September 1st) or does not

[225] Higgins, A., D. Safran, N. Fiore, E. Murphy, M. McClellan. 2019. Pathway To Patient-Centered Measurement For Accountability. Health Affairs Blog, Health Affairs. *https://www.healthaffairs.org/do/10.1377/hblog20190910.733376/full/.*

otherwise meet our requirements, we will not finalize the inclusion of the QCDR measure within an MVP.

(C) Foundational Layer

In the CY 2020 PFS final rule (84 FR 62947 through 62948), we establish that the implementation of a foundational population health core measure set using administrative claims-based quality measures that can be broadly applied to communities or populations can result in MVPs that provide more uniformity in how the program measures population health, reduce clinician reporting burden, focuses on important public health priorities, and increases the value of MIPS performance data. In addition, we discuss our beliefs that interoperability is also a foundational element that would apply to all clinicians, regardless of MVP, for whom the Promoting Interoperability performance category is required. Furthermore, we also discuss the importance of the integration of population health measures and Promoting Interoperability measures into MVPs, as they provide a degree of standardization across all clinician types and promotes an infrastructure on which to assess and improve value-based care.

(aa) Population Health Measure

In the CY 2021 PFS final rule, we discuss the inclusion of population health measures calculated from administrative claims-based data as a part of the foundational layer of MVPs, in an effort to improve patient outcomes, reduce reporting burden and costs, and better align with clinician quality improvement efforts. We refer readers to the CY 2021 PFS final rule (85 FR 84856 through 84857) where we discuss population health. In the CY 2022 PFS proposed rule (86 FR 39369), we proposed: (1) To define the term population health measure; and (2) update the population health measure inventory.

(AA) Proposed Definition

In the 2020 CMS Quality Measure Development Plan- 2020 Population Health Environmental Scan and Gap Analysis Report (*https://www.cms.gov/files/zip/2020-mdp-population-health-e-scan.zip*), we conducted an environmental scan to identify gaps in population health measurement within MIPS, specifically for use in the foundational layer of MVPs. Through this environmental scan and gap analysis, we have settled on a definition of ''population health measure''. In addition, as described in the ''Roadmap for Promoting Health Equity and Eliminating Disparities'': *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86046,* developed by the National Quality Forum, health equity continues to be a priority for the agency, we believe it is important to include the measurement of health disparities when measuring population health.

In the CY 2022 PFS proposed rule (86 FR 39369), we proposed to codify this at § 414.1305, such that a population health measure means a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as, access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services. We solicited comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: A few commenters recommended that additional information be provided in the definition to clarify the intended use and attribution approaches to ensure transparency as to CMS' intent for population health measures. One commenter expressed concern for the size of the population or cohort in the proposed definition for population health measures.

Response: The proposed definition of population health was not intended to be comprehensive, and intentionally is flexible. With regards to the attribution, and the size of the population or cohort, we believe these areas may vary depending on the clinical topic of measurement. Standardization of the attribution does not take into consideration the various specialties that participate in MIPS and instances where certain specialties should not be attributed to a population health measure. Furthermore, standardization of a cohort or population size may lead to certain population health conditions being excluded from measurement because the cohort size is not sufficient. We do not believe it is appropriate to limit population health measurement this way. To account for instances where MVP participants may not be attributed to a certain population health measure or when MVP participants may not treat enough patients to meet the population or cohort size within the measure, we have proposed scoring rules for population health measures accordingly. We refer readers to the CY 2022 PFS proposed rule (86 FR 39378 through 39379) and section IV.A.3.b.(5)(b)(i)(B) of this final rule for discussion of the population health scoring rules.

Comment: Several commenters expressed concerns with the population health measures proposed for MVPs, because commenters believe that the measures are too broad and are outside of the control of the clinician. One commenter expressed the belief that the inclusion of population health measures in the foundational layer is essentially creating an entire new MIPS category which is outside the intent of the MACRA legislation. Another commenter believes that population health measures move the MVP away from incorporating the patient's voice, measuring clinical conditions and outcomes, and generating real-time feedback.

Response: The population health measures capture outcomes important to patients (that is, hospitalizations for acute illness) and thus provide meaningful information to clinicians so they can improve their practice. Although administrative claims measures use outcomes that are not directly reported by patients, they measure clinical outcomes that are central to patient well-being since avoidance of acute hospitalization is an important goal of care. They can thus generate feedback to help improve care. We anticipate sharing measure scores with clinicians scored on the measure, in addition to tying reimbursement payment adjustments to these scores, will encourage clinicians to improve care quality and patient outcomes. Each measure is fully tested to ensure that it reflects the quality of care provided by clinicians held accountable for care of their assigned patients.

We disagree with commenters that the inclusion of population health measures in the foundational layer is essentially creating an entire new MIPS category. The population health measures are still considered quality measures, and as described in section IV.A.3.b.(5)(b)(i)(B) of this final rule, are scored and incorporated into the quality score. Therefore, their use does not create a new performance category, rather, the foundational layer of MVPs was created to ensure that important areas of measurement would be reflected within all MVPs.

We also disagree that population health measures move the MVP away from incorporating the patient voice, measuring clinical conditions and outcomes, and generating real time feedback. We believe MVPs can be multi-faceted in covering these important areas, and believe there is importance in measuring the health of communities through population health

in addition to the value in including the patient voice. In addition, MVPs are expected to be developed to cover clinical conditions that are important to the specialties that participate in the program and would include outcome measures to the extent available. Furthermore, as discussed in the CY 2022 PFS proposed rule (86 FR 39383), we proposed to provide enhanced performance feedback to MVP participants within the annual performance feedback that is currently provided through traditional MIPS. We do not believe that reporting on population health measures will impede our ability to provide enhanced performance feedback to MVP participants. At this time, we are not able to provide real time or performance period feedback, as there are complexities that need to be mitigated.

Comment: Several commenters do not support the use of administrative claims-based measures in any of the MVPs. They are concerned that many of the existing administrative claims-based measures have not been tested at the physician level and are based on a retrospective analysis of claims and do not provide granular enough information for physicians to make improvements in practice. Overall, they do not believe that administrative claims-based measures will be appropriate in all MVPs. One commenter believes that the measures should focus on the domain of care that is most relevant to the care the physician provides. One commenter requested confirmation that each measure has a high level of reliability and is fully tested to ensure that the measure can appropriately be assigned to specific physicians or groups. Another commenter recommends the administrative claims-based measures be voluntary.

Response: We disagree. The administrative claims-based measures in MIPS have been tested and have been put forth through the Measures Application Partnership (MAP) process through the National Quality Forum. Each measure is fully tested at the clinician level to ensure that it reflects the quality of care provided by clinicians held accountable for care of their assigned patients. While there may be instances where administrative claims-based measures include a lookback period, many in MIPS are based on performance period dates, that is January 1 through December 31. We refer readers to the CY 2021 PFS final rule (85 FR 85045) and the CY 2022 PFS proposed rule (86 FR 3600 through 39602) for discussion of the data collection periods for these measures.

We believe administrative claims measures capture information related to outcomes that is important to patients (that is, hospitalizations for acute illness) and thus provide meaningful information to clinicians so they can improve their practice. Although administrative claims measures use outcomes that are not directly reported by patients, they measure clinical outcomes that are central to patient well-being since avoidance of acute hospitalization is an important goal of care. They can thus generate feedback to help improve care.

Overall, we believe administrative-claims based measures, such as the population health measures should be included as a facet of MVP measurement, across all MVPs. The clinical topics covered in the population health measures are applicable to most clinicians. However, as described in the CY 2022 PFS proposed rule (86 FR 39378), we are aware there may be instances where the population health measures cannot be calculated, and had proposed to adopt our scoring policies used in traditional MIPS for MVPs, we would exclude the measure from the total achievement points and the total available points if the administrative claims measure does not have a benchmark or meet the case minimum requirement in accordance with § 414.1380(b)(1)(i)(A)(*2*)(*ii*).

We also proposed at § 414.1365(d)(3)(i)(A) that except as provided in paragraph (d)(3)(i)(A)(*1*) each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points. The population health measures in the MIPS program are fully tested, with a reliability of 0.4 with a minimum attributed case size of 20. We consider these measures to be of moderate reliability and believe the reliability thresholds for these measures are sufficient for these measures to be included as quality measures within the MIPS program. In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77171), we identified reliability levels between 0.4 to 0.7 as moderate and reliability levels above 0.7 as high. We aim to measure quality performance for as many clinicians as possible, and limiting measures to reliability of 0.7 would result in fewer individual clinicians with quality performance category measures. In addition, a 0.4 reliability threshold ensures moderate reliability for most MIPS eligible clinicians or group practices that are being measured on quality.

We disagree with the commenter who recommended that administrative-claims based measures, such as the population health measures, be voluntary. Population health measurement has been purposefully included in the foundational layer of all MVPs to be broadly applied to communities or populations and provide more uniformity in how the program measures population health, reduces clinician reporting burden, and focus on important public health priorities.

After consideration of public comments, we are finalizing our policy as proposed.

(BB) Population Health Measures Inventory

In the CY 2022 PFS proposed rule (86 FR 39369) we discussed the population health measure inventory, and the expansion of the number of population health measures available in the foundational layer of MVPs. We also discussed and encouraged stakeholders to pursue population health measure development. As discussed in Appendix 1: MIPS Quality Measures of this final rule, we proposed to include the *Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions* in the MIPS program. As discussed in Appendix 3: MVP Inventory, this measure was proposed for inclusion as an additional population health measure for MVP reporters to choose from as part of the Foundational Layer. We refer readers to Appendix 3: MVP Inventory for the comments received on the specific population health measures and our responses.

(bb) Promoting Interoperability

In the CY 2021 PFS final rule (85 FR 84849 through 84850), as a part of the MVP development criteria, we had finalized that MVPs must include the full set of Promoting Interoperability measures. Any updates made to the set of Promoting Interoperability measures through traditional MIPS will apply to the MVPs. Therefore, we refer readers to section IV.A.3.d.(4) of this final rule where we discuss Promoting Interoperability performance category policies.

(D) Health Equity Measures in MVPs–Request for Information (RFI)

In the CY 2022 PFS proposed rule (86 FR 39369) we requested information regarding the incorporation of health equity measures in MVPs. We thank

commenters for the feedback received through this request for information. We may consider this information to inform future rulemaking.

(ii) Maintenance Process for MVPs

As described in the CY 2022 PFS proposed rule (86 FR 39370), we believe it is important that we implement a maintenance process for established MVPs. Independent of the implementation of MVPs; the individual measures typically undergo annual updates and maintenance for several reasons. These updates may include technical coding updates, changes to clinical guidelines, or modifications to various aspects of the measure specification (such as the numerator or denominator). It will be important that we monitor when changes are made to individual measures to ensure that the updated measure is relevant and should be maintained within the MVP.

Therefore, beginning with the CY 2023 MIPS performance period/2024 MIPS payment year, we proposed an annual maintenance process for finalized MVPs. In order to ensure that various stakeholder perspectives are also considered, we proposed a solicitation process to solicit stakeholder recommendations for potential updates to established MVPs. Under this proposal, beginning in January of the year prior to the performance period, stakeholders could submit their recommendations to revise established MVPs. We would accept stakeholder input on a rolling basis. Any changes to MVPs will be addressed through future notice and comment rulemaking, for example, suggesting the addition or removal of a quality measure or improvement activity. If changes are made to existing individual measures and activities, they would be made under the traditional MIPS performance category policies and criteria for measures and activities and those changes would be reflected within the MVP. We would be unable to communicate with a stakeholder about whether or not their recommendations are accepted ahead of rulemaking, and we would ultimately decide whether updates to the established MVPs should be made. Additional logistical information, such as where to submit recommendations would be provided through the QPP resource library and listserv messaging, prior to the opening of the solicitation process. We stated in the proposed rule that we would consult with the stakeholders who originally nominated the MVP about any publicly recommended changes to that MVP. To be clear, the annual maintenance process for finalized MVPs would be separate from the new MVP candidate solicitation process that was described in the CY 2021 PFS final rule (85 FR 84854 through 84856). We solicited comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: A few commenters believe that it would be beneficial to have all relevant specialties and clinician types provide feedback on any MVP changes, because commenters believe it would generate more buy in and foster collaboration. A few commenters expressed concern for our process to only consult with stakeholders who submitted the MVP regarding changes to the MVP and suggested soliciting recommendations from major contributory stakeholders. Another commenter believes that involving multiple stakeholders in the maintenance of MVPs would make the process more transparent and nimbler to ensure that MVP owners do not unnecessarily prevent appropriate modifications of the MVP from taking place.

Response: We agree that it would be beneficial to have all relevant specialties and clinician types provide feedback on potential changes to established MVPs. To clarify, as discussed in the CY 2022 PFS proposed rule (86 FR 39370), we intend to solicit recommendations for potential changes to established MVPs from all interested parties through an MVP maintenance process, and not just from those stakeholders that submitted the MVP through the initial development process. In addition, the initial implementation of an MVP and any potential changes to an established MVP (for example, the addition or removal of measures) would need to be proposed and finalized in future notice-and-comment rulemaking which enables all interested parties to voice their opinions through the public comment process on any proposed changes to an MVP. We are also open to exploring additional options as to how we can better engage with a broader cohort of stakeholders on MVP maintenance. We would make the determination as to which MVP updates will be proposed and finalized and which will not.

Comment: A few commenters urged CMS to align the MVP maintenance process with timelines for MIPS and QCDR measure updates to minimize the burden on MVP developers.

Response: The timeline for MVP maintenance will coincide with our MIPS rulemaking timelines. As described in the CY 2022 PFS proposed rule (86 FR 39370), any changes to MVPs would be addressed through future notice and comment rulemaking. Unfortunately, we are not able to align with the QCDR self-nomination timeline (July 1st to September 1st) as it does not align with the rulemaking timeline. However, as described in the CY 2022 PFS proposed rule (86 FR 39368 through 39869) we are mindful of the QCDR self-nomination timeline when considering the inclusion of new QCDR measures in existing MVPs. In order to determine whether a QCDR measure may be finalized within an MVP, we will need to receive QCDR measure testing data for review by the end of the self-nomination period, that is no later than September 1st of the year prior to the applicable performance period. If a QCDR is unable to submit testing data to demonstrate that their QCDR measure is fully tested at the clinician level by the end of the self-nomination period or does not otherwise meet our requirements, we will not finalize the inclusion of the QCDR measure within an MVP.

After consideration of public comments, we are finalizing our policies as proposed.

(c) Establishing a Portfolio of MVPs

In the CY 2022 PFS proposed rule (86 FR 39879 through 39907), we proposed seven MVPs on the following topics: Rheumatology, Stroke Care, Ischemic Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia. We refer readers to Appendix 3: MVP Inventory of this final rule for a full description of each MVP, proposal rationales, summary of public comments and our responses. We anticipate that the portfolio of MVPs will continue to grow over the next few years. Through the review of data received through MIPS reporting for the 2019 performance period, we have identified the ten specialties who have the most participants in the MIPS program. These specialties include primary care, emergency medicine, diagnostic radiology, anesthesiology, cardiology, obstetrics and gynecology, orthopedic surgery, psychiatry, general surgery, and ophthalmology.

We believe it is important to develop MVPs that address these specialties, amongst the other specialties that participate in the program. We are, however, aware of the limited availability of relevant cost measures for all specialties and subspecialties. We refer readers to the CY 2022 PFS proposed rule (86 FR 39402 through 39405) and section IV.A.3.d.(2)(c) of this final rule, for discussion of the proposed cost measure development by external

stakeholders process, where we discuss a potential strategy to mitigate the issue of a limited inventory of cost measures that will potentially remove barriers for MVP implementation.

To support MVP development efforts over the next few years, and to ensure we build out a comprehensive MVP portfolio, we intend to identify additional MVP priority areas for development and include those within our guidance materials for the MVP candidate submission process: *https://qpp.cms.gov/mips/mips-value-pathways/submit-candidate.*

(d) MVP Reporting Requirements

(i) Overview

We have reviewed the existing reporting requirements under traditional MIPS and believe that by changing the reporting requirements for MVPs, we would reduce reporting burden. We believe MVP reporting would allow for measurement that is more meaningful by requiring clinicians to report on measures and activities that comprehensively reflect an episode of care or clinical condition. We have heard from stakeholders the importance of having a choice when reporting. In this section, we discuss our proposals for MVP reporting requirements and subgroup reporting limitations for the Quality performance category; Cost performance category; Improvement Activities performance category; and the foundational layer-, which consists of the Promoting Interoperability performance category, and the population health measures.

(ii) Quality Reporting Requirements in MVPs

As described in the CY 2022 PFS proposed rule (86 FR 39370), since MVPs would include cohesive and complementary subsets of measures and activities that are relevant and to a given specialty, we believe that MVP Participants would report on measures that provide more meaningful and actionable results. MVP Participants would have the opportunity to select from a subset of measures within an MVP. Furthermore, as discussed above, we believe it is important to continue to require the reporting of outcome and high priority measures in MIPS. Therefore, at § 414.1365(c)(1), we proposed that except as provided in paragraph § 414.1365(c)(1)(i), an MVP Participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure, included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii). We discuss in section IV.A.3.b.(4)(b)(i)(B) of this final rule, that there may be instances where MVPs are developed to include outcomes-based administrative claims measures within the quality component of an MVP, where those measures are not considered to be population-health based. In such instances, we believe it would be appropriate to allow MVP Participants to select to be calculated on the outcomes-based administrative claims measure, at the time of MVP registration, and to allow that measure to meet the outcome measure requirement of MVP quality reporting.

In addition, we have concerns about the ability of small practices to report all required measures in the MVP quality performance category when they select Medicare Part B claims measures as a collection type. In cases when an MVP includes fewer than 4 Medicare Part B claims measures, an MVP Participant in a small practice would need to report an additional collection type which would add reporting burden. We are concerned that small practices do not have the same resources to meet the quality reporting requirement of 4 measures if the MVP does not include 4 Medicare Part B claims measures. We want to establish policy that does not penalize a small practice for submitting an MVP. Therefore, we proposed at § 414.1365(c)(1)(i) that paragraph § 414.1365(c)(1), does not apply to a small practice that reports on an MVP that includes fewer than 4 Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable. We solicited comments on these proposals and refer readers to section IV.A.3.b.(5)(b)(i) of this final rule for details on the MVP quality scoring proposals.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported a reduction in the number of quality measures within the MVP reporting option as compared with traditional MIPS because commenters believe that this would lead to a reduced burden for clinicians.

Response: We thank the commenters for their support.

Comment: One commenter supports the use of administrative claims measures to meet outcome-based measure requirements.

Response: We thank the commenter for their support.

Comment: One commenter urged CMS to develop MVPs that can be reported using only one collection type in order to reduce burden and maximize the number of MIPS eligible clinicians that can report MVPs.

Response: We disagree. We believe that limiting the number of collection types that are available for reporting an MVP would not be beneficial. If we were to only utilize one collection type in the reporting, fewer clinicians may be able to report the MVP if they are not using the collection type reflected in the MVP. Since MVPs include a focused selection of quality measures, MVP participants may select four measures to report on utilizing the collection types in which the measure is available, one of the four measures must be an outcome measure, or a high priority measure if an outcome is not available. We currently utilize measures that are implemented through one of the following collection types: MIPS CQMs; eCQMs; Medicare Part B Claims; and QCDR measures. As described above, we have concerns about the ability of small practices to report all required measures in the MVP quality performance category when they select Medicare Part B claims measures as a collection type. In cases when an MVP includes fewer than 4 Medicare Part B claims measures, an MVP Participant in a small practice will need to report an additional collection type which will add reporting burden. We are concerned that small practices do not have the same resources to meet the quality reporting requirement of 4 measures if the MVP does not include 4 Medicare Part B claims measures. We proposed to establish policy that does not penalize a small practice for submitting an MVP. As described in CY 2022 PFS proposed rule (86 FR 39370 through 39371). we proposed at § 414.1365(c)(1)(i) that paragraph (c)(1), does not apply to a small practice that reports on an MVP that includes fewer than 4 Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

Comment: One commenter expressed concern that MIPS eligible clinicians will be required to participate in a registry in order to report an MVP because the commenter believes this would be a significant cost burden.

Response: To clarify, MVP participants are not required to participate in a registry in order to report an MVP. All the MVPs are reportable without the use of a third party intermediary, it is to the MVP participant's discretion whether or not they would like to use a registry to report. The only instance where an MVP participant would be required to report through a QCDR however, would be if they'd like to report on a QCDR measure that is available in the MVP. We note

that QCDR measures are only reportable via a QCDR that is approved to support said QCDR measures.

Comment: One commenter recommended CMS ensure that MVPs across specialties are equitable.

Response: We agree with the commenter. We have established MVP development requirements to ensure that all MVPs are developed utilizing the same criteria. In addition, we believe Interoperability and population health are important areas that should apply across all MVPs through the foundational layer. In addition, as described in section IV.A.3.b.(4)(d) of this final rule, all MVP participants are held to the same reporting requirements (with the exception of small practices if they have fewer Part B Claims measures to report on) to support that MVPs amongst MVP participants are fair and equitable.

Comment: A few commenters expressed concern for the lack of choice within the quality performance category under MVPs. One commenter expressed the belief that it should be up to the MIPS eligible clinician to select appropriate measures, rather than having a limited set of measures. One commenter recommends adding as many eCQMs into each MVP as possible since eCQMs have been encouraged and incentivized by CMS in the past. Another commenter urged CMS to allow MIPS eligible clinicians to submit additional outcome or high priority measures and receive bonus points.

Response: We disagree with the commenters who believe there is a lack of choice within the quality performance category under MVPs. A focused selection of quality measures have been curated based on consideration of clinical relevance and feedback from stakeholders. Over the past 5 years of traditional MIPS, as well as in precursor programs such as Physician Quality Reporting System (PQRS), we have found that clinicians, groups, practice administrators tend to select measures they believe they will perform the best on and not necessarily measures that would lead to improvements in the care provided. That has led to many measures that have topped out status, providing little to no value to clinicians, nor leading to improved patient outcomes. While we believe it is important that MVP participants have choice in the measures they report, we believe the level of choice should be narrowed to focus in on measures that are directly and clinically relevant to the topic being measured, and intend on identifying such measures through groupings within MVPs. We agree that eCQMs should be included in MVPs where feasible, dependent on whether the eCQM is clinically relevant to the topic being measured. We encourage stakeholders to submit more than the required number of outcome or high priority measures if they can. As described in section IV.A.3.b.(5), when MVP participants submit more than the required number of measures, only the highest scored measures will count towards the quality final score. We are currently not offering bonus points for the reporting of additional measures, however as discussed in section IV.A.3.b.(5) of this final rule, we are open to exploring additional incentives to report MVPs through future rulemaking.

After consideration of public comments, we are finalizing our policies as proposed.

(iii) Cost Reporting Requirements in MVPs

As described in the CY 2022 PFS proposed rule (86 FR 39371), as MVPs are implemented and available for reporting, each MVP would only include cost measures that are relevant and applicable to the MVP topic. Therefore, the number of cost measures in a given MVP may vary depending on the clinical topic of the MVP. An MVP may include the episode-based cost measures that are relevant to the topic, total per capita cost measure (TPCC), and/or Medicare Spending Per Beneficiary Clinician (MSPB Clinician) measure. As such, we proposed at § 414.1365(c)(2) that an MVP Participant is scored on the cost measures included in the MVP they select and report. To be clear, MVP Participants would not submit data for the cost measures; they would be calculated by CMS using administrative claims data, as in traditional MIPS. We solicited comments on this proposal. We did not receive any comments and are finalizing the proposal as proposed. In addition, we refer readers to section IV.A.3.b.(5)(b)(ii) of this final rule for details of the MVP cost scoring policies and Appendix 3: MVP Inventory for a summary of the comments we received and our responses related to individual cost measures.

(iv) Improvement Activity Requirements in MVPs

Similar to the quality performance category within MVPs, we also believe the improvement activities performance category should provide clinicians with an opportunity to select from a subset of improvement activities within an MVP that are relevant to the clinical topic being measured. Therefore, in the CY 2022 PFS proposed rule (86 FR 39371), we proposed at § 414.1365(c)(3), that MVP Participant who reports an MVP, must report one of the following: Two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice as described at (82 FR 53652) and at § 414.1380(b)(3)(ii). We note that these proposed MVP improvement activity requirements are reduced in comparison to what is required in traditional MIPS (82 FR 53652) under which we generally require two high-weighted activities, one high-weighted and two medium-weighted activities, four medium-weighted activities, or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice. We believe reduced reporting requirements are necessary to support adoption of and reduce burden for implementation of MVPs. We solicited comments on this proposal and refer readers to section IV.A.3.b.(5)(b)(iii) of this final rule for proposals related to MVP improvement activities scoring and discussion of why improvement activities are double-weighted under MVP reporting.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported double weighted improvement activities for MVP reporters. One commenter believes that this would allow for a more cohesive participation experience.

Response: We thank the commenters for their support.

Comment: A few commenters requested that CMS provide more flexibility in MVP reporting requirements, including providing automatic credit for the Improvement Activities performance category. One commenter believes that a commitment to improvement is inherent in many of the measures in MIPS.

Response: We disagree that additional flexibilities are needed within the reporting requirements. We do not believe there is value in offering automatic credit for the improvement activities performance category. Improvement activities are meant to have a complimentary relationship to the quality measures and cost measures included in an MVP. We do not believe automatic credit will lead to improved patient outcomes or improvements in the care provided to patients. Lastly, as described in section 1848(q)(2) of the Act, we are required to have four performance categories: Quality,

improvement activities, cost, and promoting interoperability. We believe there are other ways to incentivize clinicians and groups to report MVPs, and refer readers to section IV.A.3.b.(5) of this final rule for further discussion of future considerations of incentives.

After consideration of public comments, we are finalizing our policies as proposed

(v) Reporting Requirements for the Foundational Layer

(A) Promoting Interoperability

(aa) Reporting Requirements

As described in the CY 2021 PFS final rule (85 FR 84849 through 84853), all MVPs should include the entire set of Promoting Interoperability measures, as a part of the foundational layer. We do not intend to establish different reporting requirements for Promoting Interoperability for MVPs from what is established under traditional MIPS. Therefore, in the CY 2022 PFS proposed rule (86 FR 39371), we proposed at § 414.1365(c)(4)(i) that an MVP Participant, is required to meet the Promoting Interoperability performance category reporting requirements described at § 414.1375(b). We solicited comments on this proposal and refer readers to section IV.A.3.b.(5)(b)(iv) of this final rule for details of the policies for MVP Promoting Interoperability scoring and reweighting.

The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS adopt different requirements for the Promoting Interoperability performance category within MVPs. One commenter urged CMS to use the MVP framework as an opportunity to provide clinicians with flexibility to demonstrate meaningful use in more innovative ways that account for differences in practices. One commenter requested that CMS include a menu of yes/no measures similar to the improvement activities performance category. Another commenter recommended that MVPs support meeting national standards that enable the bidirectional movement of health data across the digital environment through the Promoting Interoperability performance category.

Response: While we did not propose different reporting requirements for the Promoting Interoperability performance category in the first wave of MVPs, we are continuing to refine the composition of MVPs and may incorporate these suggestions in future rulemaking. In addition, we disagree that solely relying on measures that require a ''yes/no'' response would be sufficient for the Promoting Interoperability performance category. In the CY 2019 PFS final rule (83 FR 59785 through 59796) we finalized a performance-based scoring methodology for the Promoting Interoperability performance category that recognizes MIPS eligible clinicians who push themselves on measures that are most applicable to how they deliver patient care and increase health information exchange through interoperability. While we do have several yes/no measures in the Promoting Interoperability performance category, we do not believe using only ''yes/no'' measures would enable us to distinguish varying performance levels among MIPS eligible clinicians.

Comment: One commenter requested that CMS provide flexibilities for certain types of clinicians, such as non-patient facing clinicians, for the Promoting Interoperability performance category in general within MIPS because the commenter believes these clinicians often have difficulties meeting the requirements of the Promoting Interoperability performance category.

Response: Our current policy under § 414.1380(c)(2)(i)(C) is to reweight the Promoting Interoperability performance category for non-patient facing MIPS eligible clinicians as defined under § 414.1305, which includes groups and virtual groups that have more than 75 percent of clinicians as non-patient facing. This policy will apply under MVPs, as discussed in section IV.A.3.b.(5)(c)(i)(B)(aa) of this final rule.

Comment: One commenter suggested that in MVPs, the Promoting Interoperability performance category measures shift to yes/no attestation rather than percentages because some measures may not be applicable to a clinician's practice or different thresholds may be more appropriate.

Response: We disagree. Beginning with the CY 2019 performance period/CY 2021 MIPS payment year (83 FR 59785 through 59796) we implemented a performance-based scoring methodology to encourage clinicians to push themselves on measures that are the most applicable to how they deliver care to patients. We believe that having Promoting Interoperability performance category measures that require a numerator/denominator response allows clinicians to differentiate themselves from other clinicians by recognizing higher achievement on these measures. Our goal has been to enable clinicians to focus more on patient care and health data exchange through interoperability.

Many measures have exclusions available for instances where a measure is not applicable to the clinician's practice.

After consideration of public comments, we are finalizing our policies as proposed.

(bb) Subgroup Limitations

As described in the CY 2022 PFS proposed rule (86 FR 39371 through 39372), we believe that subgroups should be assessed using subgroup level data to the extent that it is operationally feasible. However, through the MVP Town Hall (85 FR 84846), we heard from stakeholders that some clinicians would need additional time to resolve operational challenges, including challenges related to configuration of EHR systems. Given these operational challenges, as well as other considerations specific to the Promoting Interoperability performance category, we believe that each subgroup should submit their affiliated group's data for the Promoting Interoperability performance category and receive a score based on that data. We acknowledge that requiring each subgroup to submit their affiliated group's data could result in duplicative reporting of the same data if their affiliated group also reports as a group for the Promoting Interoperability performance category. However, we believe that this approach is the most appropriate way to address the operational challenges identified by stakeholders and other issues specific to the Promoting Interoperability performance category. For instance, requiring clinicians to report Promoting Interoperability by subgroup may initially disincentivize clinicians from choosing to report MVPs as it may exacerbate the reporting burden and use of resources by a smaller cohort of clinicians. Furthermore, the Promoting Interoperability measures are applicable to many clinician types and are not designed to be specialty specific like the quality measures, therefore, it is unclear whether an advantage of assessing Promoting Interoperability performance on a subgroup of clinicians exists. Other performance categories include specialty specific measures, where assessment of performance at the subgroup level may be more meaningful. Therefore, we proposed at § 414.1365(c)(4)(i)(A) that for the CY 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years, to require an MVP Participant that is a subgroup to submit its affiliated group's data for the Promoting Interoperability performance category. The submission of the affiliated group's data will be on the subgroup's behalf. If the affiliated group chooses to report as

a group for the Promoting Interoperability performance category, the group still will be required to submit its own data separately and in accordance to the reporting rules for groups.

We refer readers to the CY 2022 PFS proposed rule (86 FR 39371 through 39372) for the discussion of subgroup limitations.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the reporting of Promoting Interoperability data for the affiliate group for subgroups.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing the policy as proposed.

(B) Population Health Measures

As described in the CY 2017 Quality Payment Program final rule (81 FR 77130 through 77136) we had received public comment that not all population health measures are applicable or attributable to all specialties. In order to mitigate this concern, we discuss our proposal in the CY 2022 PFS proposed rule (86 FR 39372), at § 414.1365(c)(4)(ii), that an MVP Participant is scored on 1 population health measure in accordance with paragraph § 414.1365(d)(1). To be clear, the population health measure calculation does not contribute to the required reporting of four quality measures, as described at § 414.1365(c)(1) and in section IV.A.3.b.(4)(d)(ii) of this final rule. Since the aforementioned population health measures are administrative claims based, they do not require data submission from clinicians. Therefore, it is important that an election period is established in which MIPS eligible clinicians, groups, subgroups, and APM entities would identify which MVP and population health measure they intend to report. We refer readers to the proposed registration process below and intend to provide additional guidance through subregulatory means.

In crafting our proposal, we also considered the alternative where we would note require MVP participants to select which population health measure to be calculated on. Under this alternative considered, we would require and calculate both population health measures and apply the higher score to the quality score. While we thought this approach would reduce some of the burden associated with requiring this selection at the time of MVP registration, we ultimately decided to proposed to allow MVP participants to select which population health measure to be calculated on. As discussed above, this selection process is being proposed in an effort to mitigate some of the previously stated concerns stakeholders had with these measures.

We solicited comments on our proposal as discussed above and refer readers to section IV.A.3.b.(5)(b)(i)(B) of this final rule for details on the scoring of population health measures.

We received public comments on the reporting requirements of the population health measures. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the use of cross-cutting, claims-based, population-level measures in the foundational layer of MVPs and recommended that CMS prioritize use of outcome measures with an evidence-based and tested risk adjustment methodology to ensure meaningful comparisons between clinicians and groups.

Response: We thank the commenter for their support and will take their recommendations into consideration.

After consideration of public comments, we are finalizing our policies as proposed.

(vi) Subgroup Reporting

(A) Subgroup Reporting Overview

As discussed in the CY 2022 PFS proposed rule (86 FR 39372 through 39373) and section IV.A.3.b.(3)(a) of this final rule, subgroup reporting would provide an avenue for clinician teams within a larger group to be able to submit MVPs that are clinically relevant to them and would be a first step in allowing more granular clinician information to be made available to patients. To generate more clinically relevant and granular information about clinician performance, we believe that subgroups should be assessed using subgroup level data to the extent that it is operationally feasible. We anticipate more granular data would be available for patients, clinicians, and other stakeholders through a three-pronged approach of mandatory subgroup reporting, broad use of standards-based APIs that leverage the FHIR standard and the creation and use of dQMs as discussed in section IV.A.1.c. of this final rule. We believe that subgroups should report data for the quality and improvement activities performance categories as a subgroup. The cost performance category does not require data submission; however, as described in section IV.A.3.b.(5)(b)(ii) of this final rule, we believe cost data should be assessed at the subgroup level as well.

(B) Subgroup Reporting Limits

As described in section IV.A.3.b.(2)(c)(i) of this final rule, we proposed voluntary reporting of MVPs as a gradual approach to prepare stakeholders through the transition plan for MIPS before eventually requiring reporting through an MVP or the APP. As a part of the transition, we discuss our intention to continue to offer reporting through traditional MIPS at the group level, as discussed in section IV.A.3.b.(2)(c)(i) of this final rule, to allow clinicians and groups additional time to continue reporting in traditional MIPS while we work expand the inventory of MVPs over the next few years.

While we intend to allow for this flexibility through the transition, we believe that groups should only form subgroups if they are reporting through an MVP or the APP and not through traditional MIPS. As such, we proposed at § 414.1318(c)(2) that individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all of the MIPS performance categories based on an MVP in accordance with § 414.1365, and on the APP in accordance with § 414.1367, as applicable. Subgroups that are MVP Participants must adhere to an election process described in § 414.1365(b). This includes MIPS eligible clinicians who are APM participants that choose to report on an MVP as a subgroup. We believe encouraging the subgroup reporting in MVPs is an important step to help MVP Participants transition to MVP reporting in the future.

As stated in the CY 2021 PFS final rule (85 FR 84846), we envisioned subgroup reporting would be implemented for multispecialty groups reporting MVPs. A subset of a TIN could form a subgroup if they are part of the same TIN, but could not form a subgroup if they are part of different TINs. For example, a group consisting of a single billing TIN that contains a number of participants in the same APM Entity, could form a subgroup to report an MVP or the APP. However, an APM Entity could not select eligible clinicians who are part of different TINs, based on their specialty, and report as a single subgroup. Due to operational and technical issues described above, we do not believe it is feasible to permit MIPS eligible clinicians in multiple TINs to form a subgroup to report MVPs or the APP. We solicited public comment on whether there are strategies we should consider to enable formation of

subgroups comprised of MIPS eligible clinicians from multiple billing TINS to report MVPs or the APP.

We did not receive public comments on this proposal, and are finalizing it as proposed.

(vii) MVP Reporting Requirements Summary

Table 47 summarizes the finalized MVP reporting requirements:

TABLE 47: MVP Reporting Requirements

Quality Performance Category*	Improvement Activities Performance Category*	Cost Performance Category
An MVP Participant selects 4 quality measures, 1 must be an outcome measure (or a high priority measure if an outcome is not available or applicable). *As applicable, an administrative claims measure, that is outcome-based, may be selected at the time of MVP registration to meet the outcome measure requirement.*	MVP Participant selects: Two medium weighted improvement activities **OR** One high weighted improvement activity. **OR** Participates in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at (82 FR 53652) and at § 414.1380(b)(3)(ii)	An MVP Participant, is scored on the cost measures that are included in the MVP that they select and report.
Foundational Layer (MVP agnostic) **Population Health Measures*** An MVP Participant selects 1 population health measure, at the time of MVP registration, to be scored on. The results are added to the quality performance category score. **Promoting Interoperability (PI) Performance Category** An MVP Participant is required to meet the Promoting Interoperability performance category requirements at § 414.1375(b).		

*Indicates MVP Participant may select measures and/or improvement activities.

(e) Third Party Intermediaries Reporting MVPs

We believe it is also important to ensure that third party intermediaries have the capabilities to support MVPs. We refer readers to section IV.A.3.h.(2)(b) of this final rule for proposals related to requiring third party intermediaries to support MVP and subgroup reporting.

(f) MVP Participant Registration

As described in our proposals in the CY 2022 PFS proposed rule (86 FR 39373 through 39376), we strive to limit administrative burden and offer as much flexibility as possible. With this principle in mind, we proposed steps that an MVP Participant must take to inform CMS of their participation and submission options, with certain exceptions for when the method of collection requires the information in advance of the performance period or we do not have any discretion (such as in virtual groups). We believe that a registration process will be easiest and the most efficient option for MVP Participants and CMS to accurately capture: (1) MVP selection; (2) population health measure selection; (3) administrative claim-based quality measure selection; and (4) subgroup participation.

(i) Registration Timeline

(A) General Timeline

We refer readers to the CY 2022 PFS proposed rule (86 FR 39373 through 39374) for discussion of the considerations that went into development of the registration timeline. We proposed at § 414.1365(b)(1), that to report an MVP, an MVP Participant must register for the MVP, and if applicable, as a subgroup during a period that begins on April 1 and ends on November 30 of the applicable CY performance period or a later date specified by CMS. Under this proposal, to report the CAHPS for MIPS survey associated with an MVP, a group, subgroup, or APM entity must complete their registration by June 30 of such performance period or a later date specified by CMS.

We believe the benefits of aligning MVP registration, MVP population health measure selection, and subgroup registration during the performance period, outweigh the limitations of performance period registration. Through the MVP town hall, we have heard stakeholders indicate that a registration period that is held during the performance period is limiting because it provides clinicians with less time to decide which MVP they would like to report or make changes to their selection. However, we believe that this would encourage clinicians to identify important MVP topics early on in the performance period, in which they can focus their quality improvement efforts on. Also, this would allow us sufficient time to identify clinician participation in subgroups and provide more granular and meaningful subgroup performance feedback to inform quality improvement and patient choice resulting in clinician assessment on more information relevant to their subgroups, such as targeted administrative claims quality measures and cost measures.

In addition, we believe that the proposed registration period would allow more flexibility in the creation of subgroups that represent clinical alignment and to add or remove clinicians from the subgroup, or

otherwise, make changes to their participation status in subgroups, before the end of the registration period.

We solicited public comments on our proposals as discussed above.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the registration timeline for MVPs, including the CAHPS for MIPS registration timeline. One commenter shared their belief that CMS proposed a large enrollment window that should give MVP participants the opportunity to determine the most appropriate MVP for their practice.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS open the MVP registration period on January 1 of the performance period instead in April to allow for more flexibility, especially for MVP participants who would like to register for more than one MVP and be able to assess which MVP may be the most appropriate.

Response: We considered beginning the registration period on January 1st of the performance period, but we believe that doing so would cause stakeholders undue burden considering in January stakeholders may be in the midst of data submission for the prior performance period. We understand that the data submission period may be a busy time for organizations and practices. Therefore, we proposed for the registration period to begin in April, once the data submission period is over. While the registration period will not open until April 1st, MVP participants may start to evaluate and determine which MVP they would like to report much earlier, once the final rule is published. We plan to continue to assess this registration timeline, along with all other MVP policies, and make any necessary changes, as needed through future rulemaking.

We note that, as described in the CY 2022 PFS proposed rule (86 FR 39374), MVP participants may select one MVP at the time of MVP registration, and may not make changes to their registration after the close of the registration period. Through the CY 2022 PFS proposed rule (86 FR 39374), we had solicited public comment on, if MVP participants would be interested in selecting multiple MVPs at the time of registration and the value in this allowance. We will consider any feedback received under consideration for future rulemaking.

Comment: A few commenters did not support the proposed registration timeline of April to November and recommended that CMS allow MVP participants to register at the time of data submission for the given year they report the MVP. One commenter believed that clinicians and subgroups will need additional flexibility as they shift from traditional MIPS reporting to MVP reporting.

Response: We disagree. We believe MVP participants should register prior to the data submission period in order to give our systems a sufficient amount of time to track the MVP for which participants would be eligible for the purposes of providing enhanced feedback. That is why we proposed the MVP registration window to encompass eight months of the performance period, to allow MVP participants sufficient time to identify and register for an MVP that is relevant to their practice. In addition, On January 7, 2021, we held the MVP Town Hall (85 FR 74729) (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1290/MIPS%20Value%20Pathways%20Town%20Hall%20Slide%20Deck.pdf*) in which stakeholders overwhelmingly voiced their preference for an earlier registration period. We believe participants who are ready to transition to MVP reporting will take the time to select a relevant MVP and understand the reporting requirements expected under MVPs before reporting.

Comment: One commenter requested CMS to consider the opportunity for MVP participants to change their registration status and switch from MVP reporting to traditional MIPS after the MVP registration deadline for the 2023 and 2024 MIPS performance periods. The commenter believes that such flexibility may be necessary in instances where a practice discovers that the MVP measures are not supported by its EHR vendor.

Response: We agree. As described in section IV.A.3.b.(5)(c)(i) of this final rule, MVP participants may register for an MVP then decide to report traditional MIPS instead; or may report the MVP and also choose to report measures and activities through traditional MIPS. We have finalized in section IV.A.3.f.(5) of this final rule, a scoring hierarchy that would account for MIPS eligible clinicians and groups reporting both traditional MIPS and an MVP. We believe this flexibility is important while MVP reporting is initially voluntary, to give stakeholders time to adjust their workflows and prepare for an eventual transition to mandatory MVP reporting when traditional MIPS sunsets. We refer readers to section IV.A.3.f.(5) of this final rule for additional discussion of the scoring hierarchy policies.

Comment: One commenter recommended that CMS offer clear guidance on the expectations for MVP participants, specifically requesting targeted communications to the clinicians that qualify for a given MVP and detailed information on how the registration process will work.

Response: We agree. As technically feasible, we intend on providing additional information and resources regarding the registration process after the final rule is published and prior to the beginning of the registration period to allow stakeholders sufficient time to prepare.

After consideration of public comments, we are finalizing our policies as proposed.

(B) Exception for MVP Participants That Want to Report the CAHPS for MIPS Survey Measure

Currently, as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77072), groups that register to administer the CAHPS for MIPS survey measure prior to the registration deadline could cancel their registration or change their CAHPS for MIPS survey selection before the close of registration on June 30th. In the CY 2022 PFS proposed rule (86 FR 39374), we proposed at § 414.1365(b)(1) that in order for an MVP Participant to report the CAHPS for MIPS survey measure associated with an MVP, a group, subgroup, or APM entity will need to register by the same deadline as the CAHPS for MIPS registration, which is June 30 of the applicable 12-month performance period (81 FR 77072).

Under this proposal, clinicians participating in subgroups or groups reporting on the CAHPS for MIPS survey measure within an MVP would be unable to make any changes to their participation in the CAHPS for MIPS survey beginning July 1 of the applicable performance period. We note that clinicians in subgroups who do not intend to report the CAHPS for MIPS measure would still be able to make changes to their participation status in subgroups before the registration period ends on November 30th. We solicited public comments on these proposals.

We did not receive public comments on these proposals and are finalizing them as proposed.

(ii) MVP Participant Registration Requirements

We believe there are certain elements of information that are important to include at the time of MVP registration. Specifically, we proposed at § 414.1365(b)(2)(i) and (ii), that at the time of registration, an MVP Participant

must submit the following information, as applicable: (1) Each MVP Participant must select an MVP, 1 population health measure included in the MVP, and if applicable, any outcomes-based administrative claims measure on which the MVP Participant intends to be scored; (2) Each subgroup must submit a list of each TIN/NPI associated with the subgroup which identifies each individual eligible clinician NPI in the applicable subgroup for the group TIN and a plain language name for the subgroup. The following subsections discuss each of these elements.

(A) MVP Selection

To accurately capture who is participating in MVP reporting, it is important to establish the use of identifiers to identify what is intended to be reported, and by whom. We intend to publish a list of MVPs that have been finalized in rulemaking in the prior year, with identifiers available for a given performance period on the QPP Resource Library, prior to the start of the registration period, along with registration guidance. Therefore, we proposed that the MVP Participants must select a specific MVP, at the time of registration, as described at proposed § 414.1365(b)(2)(i). Under this proposal, MVP Participants would not be able to submit or make changes to the MVPs they select after the close of the registration period, and therefore, would not be allowed to report on an MVP they did not register for. We solicited comments on this proposal.

We did not receive public comments on our proposal, and are finalizing it as proposed. We have solicited public comment on whether MVP participants would be interested in the ability to select multiple MVPs at the time of registration. We thank commenters for the feedback received. We may consider this information to inform future rulemaking.

(B) Population Health Measure Selection

Similarly, we plan to publish a list of the population health measures that have been finalized for a given performance period on the QPP Resource Library. We plan for this to occur prior to the start of the registration period, along with posting registration guidance. As discussed in section IV.A.3.b.(4)(d)(v)(B) of this final rule, we proposed that MVP Participants who report an MVP, must submit one population health measure of their choice from the list of finalized population health measures within the foundational layer of the MVPs. The two proposed and previously finalized population health measures are both administrative claims based, and do not require physical data submission by clinicians. Therefore, in order for this selection to be tracked, we proposed at § 414.1365(b)(4)(i) that MVP Participants would be required to select this population health measure at the time of registration. Under this proposal, MVP Participants would not be able to submit or make changes to the selected population health measure after the close of the registration period. In addition, MVP Participants would not be able to successfully register to report an MVP if they do not select a population health measure, as the registration would be considered incomplete. We solicited comments on this proposal.

We did not receive public comments on this proposal, and are finalizing it as proposed.

(C) Outcomes-Based Administrative Claims Measure Selection

Within the MIPS quality performance category quality measure portfolio, there are some MIPS quality measures that are outcomes-based and utilize the administrative claims-based collection type. There are instances in which these measures are not identified as population health measures. For example, because the measure related to a specific procedure such as hip and knee arthroplasty we do not define this as population health since it does not necessarily impact the health of a population. While these measures may not be population health measures, they still reflect important clinical concepts and practices that are important to clinicians and lead to improved patient outcomes. Therefore, we believe it is important to not exclude these measures from MVPs. Depending on the MVP topic, these quality measures may be applicable and relevant to the topic being measured. In addition, administrative claims-based measures reduce reporting burden placed on clinicians because CMS calculates these measures utilizing administrative claims data. As such, we proposed at § 414.1365(b)(2)(i) that the MVP Participant must select any outcomes-based administrative claims measures on which the MVP Participant intends to be scored. As discussed in section IV.A.3.b.(4)(d)(ii) in this final rule, we proposed at § 414.1365(c)(1) that an MVP Participant must select and report 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP. As applicable, an outcomes-based administrative claims measure, may be selected at the time of MVP registration to meet the outcome measure requirement (excluding the population health measures required under § 414.1365(c)(4)(ii)). We solicited comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the inclusion of administrative claims measures but expressed concern about the availability of these measures to anesthesiologists.

Response: We appreciate the commenter's support. We understand that the availability of administrative claims-based measures is currently limited. We will continue to assess the feasibility of developing additional administrative claims-based measures, and can evaluate the feasibility of developing such measures for specialties such as anesthesia.

After consideration of public comments, we are finalizing our policies as proposed.

(D) Subgroup Participants

As part of the registration process, to accurately capture all the clinicians participating in a subgroup, we proposed at § 414.1365(b)(2)(ii) that each subgroup must submit: (1) A list of each TIN/NPI associated with the subgroup, which should identify each individual eligible clinician NPI in the applicable subgroup for the group TIN; and (2) the subgroup's name in a plain language manner.

We believe that the subgroup names would help communicate the specialty, location, or other relevant information which would be displayed on the Compare Tools, helping stakeholders differentiate between subgroups. We plan to provide additional guidance for the template in subregulatory guidance for the nomenclature of subgroups and intend to provide a template and guidance to clinicians and practices on the use of plain language for naming subgroups. For example, a subgroup which consists of oncologists in the Mayberry location of one overall group TIN who chooses to report the Oncology MVP could be called Mayberry Oncology.

Upon successful registration submission, we would assign a unique subgroup identifier. This subgroup identifier would be separate from the individual NPI identifier, the group TIN identifier, and the MVP identifier, discussed in this final rule. We would maintain the same identifier year over year, as applicable. In scenarios where a subgroup's makeup changes, which will be identified at the time of registration, we will issue the subgroup

a new identifier. We believe this identifier is also needed to allow third-party intermediaries to capture and submit performance data for clinicians participating in subgroup reporting as discussed in section IV.A.3.b.(4)(f)(ii)(D) of this final rule.

We solicited public comments on these proposals. Additionally, we solicited feedback on if there are any additional operational considerations or recommendations for the implementation of this policy for future consideration.

The following is a summary of the comments we received and our responses.

Comment: One commenter requested that CMS offer clear and detailed guidance on subgroup registration and reporting requirements. Another commenter expressed concerns about identifying clinicians in the appropriate subgroup and recommended a process to rectify unintentional mistakes in the subgroup registration process.

Response: We intend on offering clear guidance regarding the registration process, including the process of subgroup registration. As described above in section IV.A.3.b.(4)(d)(v)(A)(bb) of this final rule, and at § 414.1365(c)(4)(i)(A) that for the CY 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years, an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category. Through the registration process, subgroups may make changes to their elections and rectify any unintentional mistakes before the close of the registration period. We thank the commenter for their recommendation that we should establish a process to rectify unintentional mistakes, that perhaps are identified after the registration period closes. We will take it into consideration as we plan for the establishment of the registration process.

After consideration of public comments, we are finalizing our policies as proposed.

(iii) Summary of the Overall Registration Process

Table 48 presents a comprehensive perspective of the overall finalized registration timeline:

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TABLE 48: Registration Process for MVP and Subgroup Elections Beginning with the CY 2023 MIPS Performance Period

April 1st of the applicable performance period, or a later date specified by CMS	MVP Participants may begin to register for MVP reporting.
June 30th of the applicable performance period, or a later date specified by CMS	Groups, subgroups, APM entities, who intend to report the CAHPS for MIPS Survey Measure through an MVP, must submit: • MVP selection and population health measure selection • As applicable, select an outcomes-based administrative claims measure that is associated with an MVP. • As applicable, each subgroup must submit a list of each TIN/NPI associated with the subgroup. • As applicable, each subgroup must submit a plain language name for the subgroup. • Separately register through the MIPS registration system by June 30th to participate in the CAHPS for MIPS Survey.
November 30th of the applicable performance period, or a later date specified by CMS	The registration period closes. New registrations or changes to registration will not be accepted after November 30th. MVP Participants cannot make any changes to registration of: • MVP selection • Population health measure selection • As applicable, the selection of an outcomes-based administrative claims measure associated with the MVP • As applicable, the list of each TIN/NPI associated with the subgroup. • As applicable, subgroup participation (including the subgroup's plan language name).

Table 49 presents a crosswalk of the various clinician types, the information expected at the time of registration, and a reminder of the finalized MVP reporting requirements.

TABLE 49: How MVP Reporting Will Work

Who Reports	Information Required at the time of MVP Registration	MVP Reporting Requirements
Years 1-3 (2023, 2024, and 2025)		
Individual Clinicians	MVP selection, Population Health Measure selection, and (as applicable) outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.
Groups	MVP selection, Population Health Measure selection, and (as applicable) administrative-claims based measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1. Members of the group will be required to report on the same measures and activities within an MVP.
Subgroups	MVP selection, Population Health Measure selection, (as applicable) the outcomes-based administrative claims measure selection, and the subgroup participant information described at § 414.1365(b)(2). *Subgroups will also receive a subgroup identifier from CMS at the time of registration.*	Requirements in table 1. Members of the subgroup will be required to report on the same measures and activities within an MVP.
APM Entities	MVP selection, Population Health Measure selection, and as applicable outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.
Year 4 and Future Years (2026 and beyond)		
Individual Clinicians	MVP selection, Population Health Measure selection, and (as applicable) outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.
Single Specialty Groups[+]	MVP selection, Population Health Measure selection, and (as applicable) outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1. Members of the group will be required to report on the same measures and activities within an MVP.
Subgroups[+]	MVP selection, Population Health Measure selection, (as applicable) outcomes-based administrative claims measure selection, and the subgroup participant information described at § 414.1365(b)(2). *Subgroups will also receive a subgroup identifier from CMS at the time of registration.*	Requirements in table 1. Members of the subgroup will be required to report on the same measures and activities within an MVP.
APM Entities	MVP selection, Population Health Measure selection, and as applicable outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.

[+] *Multispecialty Groups will be required to form subgroups in order to report an MVP.* We refer readers to § 414.1305 for the definitions of MVP Participant and subgroup.

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(5) Scoring MVP Performance

(a) Overview of MVP Scoring

In the CY 2022 PFS proposed rule (86 FR 39377 and 39378), we described previous feedback we received on the CY 2020 PFS proposed rule and during the MVP Town Hall on January 7, 2021 related to how we should address scoring policies as we transition to MVPs (86 FR 39377). In general, we proposed policies to score MVPs similar to policies established for traditional MIPS, including, without limitation, the methodology to score MVP Participants based on their performance on measures and activities in the four performance categories; the use of performance standards for each of the performance categories; policies for calculation of achievement and improvement scores; and calculation of the final score. We stated that we aimed to ensure our methodology to convert the scores of measures and activities into a final score balanced the statutory requirements and goals of the program with ease of use, stability, and meaningfulness to MIPS eligible clinicians. We also stated that our proposed scoring methodology would allow for accountability and alignment across the performance categories and minimize burden on MIPS eligible clinicians. We also noted that we believed these proposed scoring policies would ensure the meaningful evaluation of performance of MVP Participants based on measures and activities in the MVP, and that several of the proposed MVP specific scoring policies would support our identified goal to simplify the program by offering MVPs that link clinically relevant measures and activities, which are meaningful to clinicians, patients, and the program (86 FR 39378).

We proposed at § 414.1365(d)(1) that an MVP Participant that is not an APM Entity is scored on measures and activities included in the MVP in

accordance with paragraphs § 414.1365(d)(1) through § 414.1365(d)(3) (86 FR 39378). We also proposed at § 414.1365(d)(1) that an MVP Participant that is an APM Entity is scored on measures and activities included in the MVP in accordance with § 414.1317(b) (86 FR 39378). Additionally, we proposed at § 414.1365(d)(2) that unless otherwise indicated in § 414.1365(d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 39378). Lastly, we proposed at § 414.1365(d)(3) that an MVP Participant is scored under MIPS in four performance categories (86 FR 39378).

We solicited public comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed the belief that, given the complexity of the program and multiple participation options, alignment of scoring policies with traditional MIPS will be essential to reducing burden on clinicians, especially small practices, as they familiarize themselves with MVPs and prepare for their eventual mandatory participation.

Response: We thank the commenters for their support.

Comment: A few commenters did not support our proposal to align MVP scoring with traditional MIPS. One commenter recommended a wholesale departure from traditional MIPS that offers a true onramp for clinicians to Alternative Payment Models (APMs). Another commenter recommended that CMS should develop a scoring methodology for MVPs that is more team-based, holding teams accountable for patient event rates, Patient Reported Outcomes Measures, and meeting patients' goals and expectations. The commenter supported attestation for quality measures, rather than measuring performance against a benchmark.

Response: We believe it is important, whenever possible, to build on the scoring that is familiar to clinicians to reduce confusion and complexity as we transition into MVPs. We are interested in supporting clinicians in the transition to APMs and believe that MVPs are an important step in gaining experience with submitting and scoring a cohesive set of measures and activities. We evaluated all traditional MIPS scoring policies and maintained those that are required under section 1848(q)(2) of the Act such as requirements to measure achievement and improvement of the quality and cost of care, and those policies that supported the goals of transitioning to MVPs. We believe that it is appropriate to adopt policies that are different from traditional MIPS policies in cases where different policies support the goals of our transition to MVPs. We have signaled the importance of incorporating the patient voice in MVPs; specifically, in the CY 2021 PFS final rule (85 FR 84850), we finalized MVP development and selection criteria that considers the inclusion of (to the extent feasible), patient-reported outcome measures, patient experience measures, and/or patient satisfaction measures. Furthermore, as measures for patient voice and Patient Reported Outcome Measures are added to MVPs we believe that no special scoring policies are needed. Our inventory of cost measures, which continues to expand, includes episode-based measures that can be used in MVPs when linked with meaningful quality outcome measures and improvement activities. We are required under section 1848(q)(3)(B) of the Act to use performance standards for measures and activities, and we have identified benchmarks to measure achievement of quality and cost measures, rather than relying on attestation. Additionally, when measures are compared to a benchmark, we can provide performance information to patients seeking care, as well as to clinicians to improve care. We are not aware of any scoring policies necessary for certain types of clinicians, including clinicians who are part of team-based risk bearing entities. We believe our MVP scoring policies hold clinicians accountable by scoring them against performance standards using relevant measures for the four performance categories. We look forward to hearing stakeholder feedback on scoring policies to determine if different approaches are needed in the future.

Comment: A few commenters recommended incentives for clinicians to report MVPs, including scoring policies that allow for MVPs to be reported during an informational period without scoring or scoring that will 'hold harmless' or ensure that no negative payment adjustments will be applied for any clinician reporting an MVP.

Response: The MIPS statute requires us to measure performance for purposes of determining a payment adjustment, using data from four performance categories, in a budget neutral manner. We believe that MVPs offer incentives in terms of requiring fewer measures and activities tied to a specialty or medical condition that can offer clinicians a more cohesive experience. In the CY 2022 PFS proposed rule, we discussed the delay in the implementation timeline to allow for a gradual process that provides MVP participants and third-party intermediaries with time to adapt to the changes in policy, requirements, and programming updates that would need to occur in technological systems (86 FR 39355 through 39356). We believe the delayed timeline should allow clinicians to change clinical workflows and be able to submit and be assessed on MVPs. We do not have discretion to have a ''hold harmless'' approach for clinicians reporting an MVP, and furthermore do not believe this approach would be appropriate. We do not intend for the MVP reporting option to be a mechanism to avoid a negative payment adjustment; but instead as an approach to improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to facilitate the movement into APMs. We also do not want to introduce bonuses for reporting MVPs or other incentives that may mask performance and artificially inflate final scores. However, we are evaluating additional incentives that align with our scoring policies and the goals of MVPs. We anticipate addressing any incentives through future notice and comment rulemaking.

Comment: Several commenters indicated that scoring policies should break down the silos between the four performance categories and that a single measure or activity should be scored in multiple performance categories. One commenter recommended that if a measure submitted by a QCDR encompasses actions for more than one performance category, scoring policies should provide automatic credit in the quality, Promoting Interoperability, and improvement activities categories. Commenters expressed the belief that this would allow better cohesion within the program, rather than having four separate categories. Commenters also believed that this would serve as an incentive to report an MVP and result in a reduction of reporting burden.

Response: We note that the MIPS statute requires the use of four performance categories (which we refer to as the quality, cost, improvement activities, and Promoting Interoperability performance categories) in determining the composite performance score (which we refer to as the final score). We refer readers to our discussion of the intent of MVPs (85 FR 84844) to make MIPS more meaningful by allowing a more cohesive participation experience by connecting

activities and measures from the four MIPS performance categories relevant to a patient population, standardizing performance measurement of a specialty or a medical condition, and reducing the siloed nature of the traditional MIPS participation experience. We also refer commenters to the CY 2021 PFS final rule, where we finalized MVP development criteria, including a criterion that assesses the extent to which the measures and activities in the MVP link to one another, as well as another criterion that assesses the extent to which improvement activities complement and/or supplement the quality action rather than duplicating it (85 FR 84849 through 84853). We believe that it is important that MVPs include measures and activities from the four performance categories that are complementary, and note that we do currently have improvement activities and measures that include related concepts. However, in addition to being required by statute, we believe each of the four performance categories offers value, and therefore, we do not at this time believe automatic credit for a performance category or assigning points to multiple performance categories for the submission of a single measure or activity would be appropriate. We invite further feedback from stakeholders on how offering multi-category credit will increase the information available to patients and improve patient outcomes. Our goals include providing comparative data to patients and caregivers who are evaluating clinician performance and making choices about their care (86 FR 39353) and we believe this is best achieved through the use of the four performance categories.

We did not receive any comments on proposals to score an MVP Participant that is an APM Entity.

After consideration of public comments, we are finalizing these policies as proposed.

(b) Performance Category Scores

(i) Scoring the Quality Performance Category in MVPs

(A) Scoring Based on Achievement

In the CY 2022 PFS proposed rule (86 FR 39378 through 86 FR 39379), we proposed to maintain scoring policies finalized in traditional MIPS for MVPs to leverage meaningful scoring policies and retain stable scoring for MVP Participants. We refer readers to § 414.1380(b)(1)(i) for details on our policies for scoring performance on quality measures for traditional MIPS (81 FR 77276 through 77307, 82 FR 53694 through 53701, 83 FR 59841 through 59856, 84 FR 63011 through 63019, and 85 FR 84904 through 84906). Our proposed policies for scoring quality in traditional MIPS are described in further detail in the CY 2022 PFS proposed rule (86 FR 39439 through 39437). We refer readers to the CY 2022 PFS proposed rule (86 FR 39432 through 39434) for our proposals to remove the 3-point floor for Class 1 and Class 2 measures for the CY 2022 performance year/2024 MIPS payment year for traditional MIPS, and to provide a score from 5 to 10 points in the first two performance periods a measure is used in MIPS for Class 4 measures (new measures). We proposed to align with these policies as well to maintain consistency between MVPs and traditional MIPS (86 FR 39378).

We proposed at § 414.1365(d)(3)(i) that, except as provided in paragraphs (d)(3)(i)(A)(*1*) and (B), the quality performance category score for MVP Participants is calculated in accordance with § 414.1380(b)(1) based on measures included in the MVP.

We did not receive any comments on our proposal, and we are finalizing it as proposed.

(B) Population Health Measures

In the CY 2022 PFS proposed rule, we proposed that we would score the selected measure according to § 414.1365(d)(3)(i) (86 FR 39378). Since we proposed to adopt our scoring policies used in traditional MIPS for MVPs, we also proposed that we would exclude the selected measure from the total achievement points and the total available points if the measure does not have a benchmark or meet the case minimum requirement in accordance with § 414.1380(b)(1)(i)(A)(2)(*ii*) (86 FR 39378). We proposed at § 414.1365(d)(3)(i)(A) that, except as provided in paragraph (d)(3)(i)(A)(*1*), each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP Participant's total measure achievement points and total available measure achievement points (86 FR 39378).

We also proposed at § 414.1365(d)(3)(i)(A)(*1*) that subgroups are scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score, if available (86 FR 39378). We stated that we believed this is appropriate because we believe it is important for subgroups to be scored on population health measures, and we believe that the groups score will be reflective of the subgroup's performance on population health measures. We are concerned about the ability of subgroups to meet the case minimum for an administrative claims measure and are interested in including population health measures in the subgroup's score for the MVP. Therefore, we also proposed at § 414.1365(d)(3)(i)(A)(*1*) that, if the subgroup's affiliated group score is not available, each population health measure is excluded from the subgroup's total measure achievement points and total available measure achievement points (86 FR 39378).

In the CY 2022 PFS proposed rule, we also noted our concern about scoring individual clinicians on population health measures (86 FR 39378 through 39379). Because population health measures have measured the quality of a population or cohort's overall health and well-being, we historically have required a minimum reliability standard of 0.4 which for most measures equates to a high case minimum in order to be scored. We believe it will be common that a solo practitioner, or an individual clinician that is part of a group but chooses to be scored as an individual clinician will not be scored on population health measures. In these scenarios, we proposed that each population health measure would be excluded from the subgroup's total measure achievement points and total available measure achievement points in accordance with § 414.1380(b)(1)(i)(A)(2)(*ii*). Historically, we have not combined performance for the individual clinician with performance from the group, and therefore, have concerns with using the group score for individual clinicians who cannot be scored for population health measures. We understand there may be concerns from stakeholders on scoring individual clinicians on broad population health measures. However, we solicited comment on approaches to scoring individual clinicians on population health measures given the importance of these measures.

We solicited comments on our proposals for scoring population health measures in MVPs. The following is a summary of the comments we received and our response:

Comment: One commenter did not support the use of population health measures for clinicians and stated they should be used as measures for APMs or facility-level quality measurement. The commenter recommended that if population health measures are used that they should not be scored and that the resulting data should be used only to provide clinicians with confidential feedback.

Response: We believe that we should score population health measures, when there is a sufficient case volume and a benchmark, for all MVP Participants, which includes MIPS eligible clinicians, groups, and APM entities (see section IV.A.3.b.(2)(c)(i) of this final rule). In the CY 2020 PFS final rule (84 FR 62947 through 62948), we established the implementation of a foundational population health core measure set that can be broadly applied to communities or populations and can result in MVPs that provide more uniformity in how the program measures population health, reduces clinician burden, focuses on important public health priorities, and increases the value of MIPS performance data. We believe that it is important to score population health measures as part of the foundational layer of the MVP when clinicians submitting an MVP can be scored on the selected population health measure.

Comment: A few commenters recommended that CMS not score individual clinicians on population health measures because individual clinicians may not have the infrastructure and resources required to positively influence population health measure outcomes. One commenter recommended that scoring for population health measures should not be implemented in a way that would penalize MVP Participants' quality performance category scores if the case minimum was not met.

Response: As discussed in section IV.A.3.b.(4)(b)(i)(C)(aa)(AA) of this final rule, we are finalizing our proposal to define a population health measure at § 414.1305 as a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as access to care, clinical outcome, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services. MVPs include a cohesive set of measures and activities, including a foundational layer of population health measures. We believe that clinicians will select an MVP with an understanding that performance on all of the measures and activities will be used to determine a final score. We also believe that MVP Participants that meet the case minimum for the selected population health measure will have the infrastructure and resources to influence the population health measure.

We believe it is appropriate to score all MVP Participants, including individual clinicians, on population health measures using scoring policies for MVPs that align with our finalized policies for traditional MIPS and note that population health measures will be scored only if there is a benchmark or the case minimum is met. We have proposed that we exclude the selected measure from the total achievement points and total available points if the measure does not meet the case minimum or have a benchmark. We believe this approach to scoring which focuses on performance of measures that meet the standards for case minimum does not penalize MVP Participants, including individual clinicians, who have insufficient case volume to allow measurement.

After consideration of public comments, we are finalizing our policies as proposed.

We did not receive public comments on our proposal that subgroups are scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score, if available. We are finalizing this policy as proposed.

(C) Outcomes-based Administrative Claims Measures

In the CY 2022 PFS proposed rule (86 FR 39479), we proposed at § 414.1365(d)(3)(i)(B) that MVP Participants receive zero measure achievement points for each selected outcomes-based administrative claims measure that does not have a benchmark or meet the case minimum requirement (86 FR 39379). This aligns with our proposal to score Class 2 measures in traditional MIPS (86 FR 39432). If the clinician selects the outcomes-based administrative claims measure, which can be calculated and submits more than three measures including an additional outcome or high priority measure, scores from the highest four measures including one outcome or high priority measure would be used to determine the quality performance category score. Please see the CY 2022 PFS proposed rule (86 FR 39379 through 39380) for an example of scoring for outcomes-based administrative claims measures under this proposal. We solicited public comments on this proposal.

We did not receive any public comments on this proposal and are finalizing it as proposed.

(D) Scoring for MVP Participants That Do Not Meet the Quality Performance Category Requirements

In the CY 2022 PFS proposed rule (86 FR 39379), we described our rationale for why we do not believe we need a validation process to determine the availability and applicability of measures for MVP Participants because MVPs will focus on a condition or specialty, and we believe MVPs will be selected and reported because of the MVP applicability to their practice and patients. We refer readers to the CY 2022 PFS proposed rule (86 FR 393870 through 39380) for an example of scoring the quality performance category for an MVP.

(ii) Scoring the Cost Performance Category in MVPs

In the CY 2022 PFS proposed rule (86 FR 39380), we proposed to use the methodology established for traditional MIPS to score the cost performance category for MVPs, including the proposed revisions to that methodology described in the CY 2022 PFS proposed rule (86 FR 39437). We refer readers to § 414.1380(b)(2)(i) through (v) for our previously finalized policies to score the cost performance category for traditional MIPS based on achievement and improvement when the case minimum specified under § 414.1350(c) is met or exceeded and CMS has determined a benchmark. We proposed at § 414.1365(d)(3)(ii) that the cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report. We also noted that we intend to monitor for reporting of MVPs to ensure MVPs reflect the clinical nature of the MVP Participants that report (86 FR 39380). We solicited public comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: One commenter voiced concern that multispecialty groups may take advantage of the option to report for the entire group at the subgroup level and select an MVP for which the group does not meet the case minimum for the cost measures to avoid being scored on the cost performance category.

Response: We understand the potential gaming concern voiced by the commenter and will monitor how multispecialty groups report and are scored on MVPs. Although an entire multispecialty group cannot report as a single subgroup, we acknowledge that, initially, multispecialty groups will have the option to either participate in traditional MIPS as a group, to report a specific MVP as a group, or to form subgroups to report MVPs that are more meaningful to their scope of practice. As finalized in section IV.A.3.b.(2)(c)(ii) of this final rule, multispecialty groups will have to form subgroups in order to report an MVP beginning with the CY

2026 performance period/2028 MIPS payment year. We plan to monitor how often the cost performance category is reweighted for MVP participants in order to assess whether it may be possible that large multispecialty groups are reporting MVPs as subgroups in order to avoid being scored on the cost performance category.

After consideration of public comments, we are finalizing at § 414.1365(d)(3)(ii) that the cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report.

(iii) Scoring the Improvement Activities Performance Category in MVPs

Under traditional MIPS, we score improvement activities by assigning each improvement activity a weight, either high-weight or medium-weight, and by assigning 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity. We refer readers to § 414.1380(b)(3) for details on scoring the improvement activities performance category for traditional MIPS. Additionally, we refer the reader to §§ 414.1317(b)(3) and 414.1380(b)(3)(i), which provide that a MIPS eligible clinician participating in an APM receives a score of at least 50 percent in the improvement activities performance category. As a result, an APM entity that reports an MVP will receive an improvement activities performance category score of at least 50 percent.

In the CY 2022 PFS proposed rule (86 FR 39380), we proposed at § 414.1365(d)(3)(iii) that the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. We also proposed that MVP Participants would receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Therefore, to receive a score of 40 points, or full credit, an MVP Participant would be required to submit one high-weighted improvement activity or two medium-weighted improvement activities included in the MVP.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal for scoring improvement activities in MVPs.

Response: We thank the commenter for their support.

Comment: A few commenters did not support the proposal to assign 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity. One commenter believed that different scoring policies for traditional MIPS and MVPs will add complexity to the program.

Response: We acknowledge the commenter's concern about complexity in the program and note that we are still scoring high-weighted and medium-weighted activities and the approach is not unfamiliar to clinicians. We believe the reduced requirements for the improvement activities performance category will incentivize clinicians to report MVPs by reducing burden, since fewer improvement activities are required to receive a full score for the category.

Comment: One commenter recommended that MVP developers identify improvement activities associated with using clinical data relevant to the MVP and recommended a scoring approach for improvement activities, including a graduated scale based on the MVP's potential impact on PROMs or care complications.

Response: We believe that a standardized approach to scoring is needed to provide consistency and to reduce complexity. We also have concerns and believe that a graduated scoring approach would introduce additional and unnecessary complexity to attestation, which would be confusing for clinicians accustomed to being scored by attestation on medium-weighted and high-weighted improvement activities. We believe that it is important, whenever possible, to build on the scoring approach is familiar to clinicians to reduce confusion and complexity as we transition into MVPs. We evaluated all traditional MIPS scoring policies and maintained those that are required by statute. Additionally, we believe that it is appropriate to adopt policies that are different from MIPS policies in cases where different policies support the goals of our transition to MVPs.

Comment: A few commenters recommended that CMS should award automatic credit for the improvement activities performance category, and potentially other performance categories, to reduce burden, simplify requirements and scoring for MVPs, and potentially serve as an incentive to submit MVPs.

Response: We do not believe it would be appropriate to provide automatic credit for any of the performance categories. Instead, we have finalized our proposal to provide full credit for MVP participants who report one high-weighted or two medium-weighted improvement activities or who participate in a certified or recognized patient-centered medical home or comparable specialty practice (please see section IV.A.3.b.(4)(d)(iv) of this final rule for more details). We are concerned about whether providing automatic credit would further our goals of improving patient outcomes, as this approach limits the data and information available and would reduce the impact of a performance category, all four of which we believe provide value. MVPs are complementary sets of measures and activities that are meaningful to clinicians. We have previously stated our belief in the importance of the clinician experience with MVPs, including through an aligned measurement of quality and cost, continuous improvement/innovation within the practice, and efficient management and transfer of information that will help remove barriers to APM participation (85 FR 84844 and 84845).

We believe each of the four performance categories offers value, and therefore, we do not at this time believe automatic credit for any category would be appropriate. We are concerned and would invite further feedback from stakeholders on how offering multi-category credit will increase the information available to patients and improve patient outcomes. Our goals include providing comparative data to patients and caregivers in evaluating clinician performance and making choices about their care (86 FR 39352 and 39353) and we believe this is best achieved through the use of the four performance categories. The improvement activities performance category is an important component of the MVP. We believe we should use the improvement activities performance category scoring established in traditional MIPS and continue scoring high-weighted and medium weighted improvement activities that support the linked activities and measures specified within the MVP.

We believe that incentives already exist in MVPs, including reduced reporting requirements, as described in section IV.A.3.b.(4)(d) of this final rule, which allow MVP Participants to report on a smaller, more cohesive subset of

measures and activities that are relevant to a given clinical topic, condition, or episode of care, as well as enhanced performance feedback, as described in section IV.A.3.b.(5)(d) of this final rule.

Comment: One commenter recommended we provide improvement activity credit for clinicians involved in testing QCDR measures that are undergoing testing for inclusion in MVPs.

Response: We appreciate suggestions for improvement activities that might be meaningful for MVP and recommend that the improvement activity be nominated during the Annual Call for Activities.

After consideration of public comments, we are finalizing this proposal as proposed.

(iv) Scoring the Promoting Interoperability Performance Category in MVPs

In the CY 2022 PFS proposed rule (86 FR 39380 through 39381), we proposed to use the scoring methodology established for the Promoting Interoperability performance category in traditional MIPS, as proposed to be revised in of the CY 2022 PFS proposed rule (86 FR 39409 through 39428), for MVP Participants, with the exception that subgroups would be scored based on their affiliated group's Promoting Interoperability performance category data. The Promoting Interoperability performance category is a foundational layer of MVPs that uses limited, connected complementary sets of measures that are meaningful to clinicians. The scoring methodology for the Promoting Interoperability performance category recognizes the importance of promoting adoption and use of CEHRT to support quality improvement, interoperability, and patient engagement and provides an important approach to scoring that we proposed to use for MVPs. Therefore, we proposed at § 414.1365(d)(3)(iv) to calculate the Promoting Interoperability performance category score for an MVP Participant using the methodology at § 414.1380(b)(4), except as provided at § 414.1365(d)(3)(iv)(A).

We solicited public comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed scoring for the Promoting Interoperability performance category and efforts to keep approaches as consistent as possible across MVPs and traditional MIPS.

Response: We thank the commenter for their support.

Comment: A few commenters recommended different scoring flexibilities for the Promoting Interoperability performance category for MVP Participants. Examples recommended include assigning all available points to any clinician who achieves 50 points or more, providing credit to clinicians who demonstrate meaningful use of EHRs in more innovative ways specific to the clinician's group composition, assigning points for infrastructure and experience with health information technology, allowing clinicians to attest to using 2015 Edition CEHRT, and providing full credit for the Promoting Interoperability performance category for PCMH recognition.

Response: As we established in the CY 2021 PFS final rule (85 FR 84849 through 84853), we believe all MVPs should include the entire set of Promoting Interoperability measures, as part of the foundational layer of MVPs. We do not believe that MVPs should introduce complexity through special scoring rules such as assigning full points to any MVP Participant who achieves 50 or more points in the Promoting Interoperability performance category, and that scoring should be based on the methodology established for traditional MIPS. As stated previously (86 FR 39381) we believe that the current scoring methodology recognizes the importance of promoting adoption and use of CEHRT to support quality improvement, interoperability, health information exchange and patient engagement. In regard to reducing the requirements of the Promoting Interoperability performance category to an attestation to the use of 2015 Edition CEHRT or achieving PCMH recognition, we refer readers to our earlier discussion of establishing interoperability as a foundational element of MVPs and the importance of using a uniform set of measures that would apply to all clinicians, regardless of MVP, for whom the Promoting Interoperability performance category is required (84 FR 62948). We believe that merely requiring an attestation regarding the use of 2015 Edition CEHRT would not align with our desire to recognize differences in performance on Promoting Interoperability performance category measures.

After consideration of public comments, we are finalizing at § 414.1365(d)(3)(iv) to calculate the Promoting Interoperability performance category score for an MVP Participant using the methodology at § 414.1380(b)(4), except as provided at § 414.1365(d)(3)(iv)(A).

We proposed at § 414.1365(c)(4)(i)(A) to require subgroups to submit their affiliated group's data for the Promoting Interoperability performance category. We proposed at § 414.1365(d)(3)(iv)(A) that if a subgroup does not submit its affiliated group's data for the Promoting Interoperability performance category, the subgroup will receive a score of zero for the Promoting Interoperability performance category.

We solicited public comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposed scoring for Promoting Interoperability for MVP participants. One commenter recommended that CMS carry over numerous other scoring policies that keep approaches as consistent as possible across MVPs and traditional MIPS as we introduce subgroups.

Response: We thank the commenters for their support. We will continue to review opportunities to align scoring between MVPs and MIPS.

Comment: A few commenters did not support our proposal to require subgroups to submit their affiliated group's Promoting Interoperability data. One commenter indicated that groups may use multiple EHRs, and that if subgroups using a single EHR could report their own Promoting Interoperability performance category data, it would increase flexibilities in subgroup requirements. One commenter voiced concerns that non-patient facing clinicians would need to submit their affiliated group's Promoting Interoperability performance data, rather than have the Promoting Interoperability performance category reweighted. The commenter stated their preference to have the Promoting Interoperability performance category reweighted for non-patient-facing clinicians.

Response: As described in the CY 2022 PFS proposed rule (86 FR 39371), for MVPs, we proposed to require that each subgroup submit their affiliated group's data for the Promoting Interoperability performance category and receive a score based on that data because we heard from stakeholders that some clinicians would need additional time to resolve operational challenges to submit subgroup level data for the Promoting Interoperability performance category. We believe that, until MIPS eligible clinicians are able to resolve these operational challenges, the benefit of requiring subgroups to submit their affiliated group's data outweighs the benefit of any flexibility that can be

afforded from subgroups submitting their own Promoting Interoperability data, such as commenter's concern that groups may use multiple EHRs and subgroups using a single EHR could report their own Promoting Interoperability performance category data. In section IV.A.3.b.(5)(c)(i)(B) of this final rule, we finalized that a subgroup may receive reweighting independent of the affiliated group in certain circumstances, but non-patient facing status is not one of those circumstances. In section IV.A.3.b.(3)(c)(ii) of this final rule, we finalized that we determine special status (such as non-patient facing status) for a subgroup at the group level, not at the subgroup level.

After consideration of public comments, we are finalizing at § 414.1365(c)(4)(i)(A) to require subgroups to submit their affiliated group's data for the Promoting Interoperability performance category and are also finalizing at § 414.1365(d)(3)(iv)(A) that if a subgroup does not submit its affiliated group's data for the Promoting Interoperability performance category, the subgroup will receive a score of zero for the Promoting Interoperability performance category.

(v) Facility-Based Scoring

We believe facility-based MIPS eligible clinicians and groups should have the same opportunities to submit MVPs as other MIPS eligible clinicians and groups. In the CY 2022 PFS proposed rule (86 FR 39381), we proposed at § 414.1365(e)(3) that if an MVP Participant that is not an APM Entity is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). In this case, we would use the highest final score according to our policies at § 414.1380(e)(6)(vi).

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the policy to allow facility-based scoring for MVP Participants, because the policy aligns with traditional MIPS policies and accommodates the complex nature of physicians' contracting and business agreements.

Response: We appreciate the commenters' support.

After consideration of public comments, we are finalizing the policy as proposed.

(c) Calculating the Final Score in MVPs

(i) Final Score Calculation

In the CY 2022 PFS proposed rule (86 FR 39381), we proposed at § 414.1365(e) that the final score is calculated for an MVP Participant using the same scoring methodology at § 414.1380(c) unless otherwise indicated in § 414.1365(e).

We solicited public comment on the proposal.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported our approach to calculate the final score for an MVP Participant who is not an APM entity using the same methodology established for traditional MIPS.

Response: We thank the commenter for their support.

Comment: One commenter voiced concerns that scoring for subgroups might be confusing for some clinicians, in terms of understanding when the subgroup performance is scored versus when the affiliated group performance is scored for population health and Promoting Interoperability measures.

Response: We have tried to use the same scoring methodology established in traditional MIPS where appropriate, with few differences. To ensure that subgroups can be scored on the foundational layers of the MVP, data from the affiliated group will be used for population health and Promoting Interoperability measures. We believe data from the group will be reflective of subgroup performance for the foundational layers of MVPs. The subgroup will be scored on the subgroup data for the cost performance category, improvement activities performance category and the quality performance category (except for the population health measure which will be assessed on the affiliated group data since that is part of the foundational layer). We will continue to provide future communication on how subgroups can participate in MVPs through routine communication channels, including but not limited to issuing emails and notices on the QPP website, *qpp.cms.gov.*

After consideration of public comments, we are finalizing the proposal as proposed.

(A) General Performance Category Weights

In the CY 2022 PFS proposed rule (86 FR 39381), we proposed at § 414.1365(e)(1) to use the performance category weights established for traditional MIPS and described at § 414.1380(c)(1) to calculate the final score for an MVP Participant that is not an APM Entity. We also proposed at § 414.1365(e)(1) to use the performance category weights established for APM Entities and described at § 414.1317(b) to calculate the final score for an MVP Participant that is an APM Entity.

We solicited public comments on these proposals and did not receive any.

We are finalizing as proposed at § 414.1365(e)(1) to use the performance category weights established for traditional MIPS and described at § 414.1380(c)(1) to calculate the final score for an MVP Participant that is not an APM Entity. We are also finalizing as proposed at § 414.1365(e)(1) to use the performance category weights established for APM Entities and described at § 414.1317(b) to calculate the final score for an MVP Participant that is an APM Entity.

(B) Flexibility for Weighting Performance Categories

(aa) Reweighting Performance Categories for MVPs

For MVP Participants, we proposed reweighting policies that generally align with our current policies for traditional MIPS with a few minor modifications (86 FR 39381). We proposed at § 414.1365(e)(2)(i) that for an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in the circumstances described at §§ 414.1380(c)(2)(i)(A)(*2*) through (*9*), and 414.1380(c)(2)(i)(C). As discussed in the CY 2022 PFS proposed rule, for MVP Participants, we do not believe there will be cases where no measures in the quality performance category are available and applicable and can be scored (86 FR 39381). Therefore, we stated that we do not believe the traditional MIPS policy for reweighting the quality performance category when no quality measures can be scored as specified at § 414.1380(c)(2)(i)(A)(1) should be applicable to MVP Participants. We also proposed at § 414.1365(e)(2)(i) that for an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b).

We proposed at § 414.1365(e)(2)(ii) that for an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, we proposed at § 414.1365(e)(2)(ii) that if reweighting is not applied to the affiliated group, the subgroup may receive reweighting

independent of the affiliated group in the following circumstances, for the reasons discussed in the CY 2022 PFS proposed rule (86 FR 39381). We proposed at § 414.1365(e)(2)(ii)(A) that a subgroup may submit an application to CMS demonstrating that it was subject to extreme and uncontrollable circumstances and receive reweighting in accordance with § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*). Under this proposal, we proposed that in the event that a subgroup submits data for a performance category, the scoring weight described at § 414.1380(c)(1) would be applied and its weight would not be redistributed. We also proposed at § 414.1365(e)(2)(ii)(B) that a subgroup would receive reweighting if CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for the subgroup are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the subgroup and its agents, in accordance with § 414.1380(c)(2)(i)(A)(*9*) and (c)(2)(i)(C)(*10*).

We requested public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the use of the reweighting policies established in traditional MIPS for MVPs that are submitted by an MVP Participant that is not an APM Entity, including reweighting of the Promoting Interoperability performance category when applicable. One commenter recommended that CMS evaluate if automatic reweighting of performance categories unnecessarily and unfairly excludes clinicians, such as physical therapists from participating in MVPs.

Response: We believe the reweighting policies allow all MVP Participants that have sufficient measures and activities applicable and available to be scored fairly on their performance. We do not believe that our reweighting policies exclude clinicians from participating in MVPs. Rather, the reweighting policies allow clinicians to receive reweighting if they are impacted by a qualifying extreme and uncontrollable event and do not submit data.

Comment: One commenter supported the reweighting policy to not reweight the quality performance category in MVPs because no quality measures can be scored.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing these proposals and the regulation text at § 414.1365(e)(2) as proposed.

(C) Redistributing Performance Category Weights

In the CY 2022 PFS proposed rule (39381 through 39382), we proposed to redistribute the performance category weights for MVPs in accordance with the redistribution policies we proposed for traditional MIPS in the CY 2022 PFS proposed rule (86 FR 39448). We proposed at § 414.1365(e)(2)(iii) that for an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in accordance with § 414.1380(c)(2)(ii). We also proposed at § 414.1365(e)(2)(iii) that for an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b).

We solicited public comments on these proposals.

We did not receive public comments on these proposals. We are finalizing these proposals and the regulation text at § 414.1365(e)(2)(iii) as proposed.

(D) Complex Patient Bonus

We refer the reader to § 414.1380(c)(3) and to the proposed rule (86 FR 39439 through 39446) for our previously established and proposed policies on applying a complex patient bonus. In the CY 2022 PFS proposed rule (86 FR 39382), we proposed at § 414.1365(e)(4) to add a complex patient bonus to the final score for an MVP Participant in accordance with § 414.1380(c)(3).

We solicited public comments on this proposal.

Comment: One commenter supported the use of the traditional MIPS complex patient bonus scoring policies for MVPs.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing as proposed at § 414.1365(e)(4) to add a complex patient bonus to the final score for an MVP Participant in accordance with § 414.1380(c)(3).

We refer readers to the CY 2022 PFS proposed rule (86 FR 39382) for an example of the final score calculation for MVPs.

(d) Enhanced Performance Feedback in MVPs

(i) Background

In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that under section 1848(q)(12)(A)(i) of the Act, on an annual basis, we will provide confidential feedback to MIPS eligible clinicians and groups on their performance. Currently, in traditional MIPS, clinicians are not required to submit data throughout the performance period. Instead, data is submitted through the submission period that follows the performance period, as described at § 414.1325(e). In addition, current performance feedback includes measure-level performance data and scores, activity-level scores, and category comparison.

In the CY 2020 PFS final rule, we indicated a commitment to the transformation of MIPS to allow for streamlined, cohesive reporting through MVPs that would result in enhanced and timely feedback (84 FR 62945). Through previous rulemaking cycles, we have heard from stakeholders that clinicians are interested in receiving feedback reports from CMS throughout the year rather than annually to allow clinicians to review and make improvements where appropriate. Other stakeholders have expressed interest in receiving feedback which includes comparative data to other practices of similar size, location, and specialty. Stakeholders have indicated this is also key to put performance in perspective, particularly if performance evaluation and payment adjustments are contingent on the performance of other clinicians (84 FR 63057 through 63058).

(ii) Enhanced Performance Feedback in MVPs

In the CY 2022 PFS proposed rule, we explained that we considered two options for providing enhanced performance feedback (86 FR 39383). The first option is to provide comparative performance feedback, comparing the performance of like clinicians who report on the same MVP, which provides more granular comparison than is currently available. The second option is to provide performance feedback during the performance period to provide more timely and actionable feedback, but require clinicians to submit earlier. This option may require a significant investment of resources, including both time and money for CMS, third party intermediaries, and clinicians.

Therefore, beginning with the CY 2023 performance period/CY 2025 MIPS payment year, we proposed the first option described—to include comparative performance feedback within the annual performance feedback we provide for MVP Participants, comparing the performance of similar clinicians who report on the same MVP.

The comparative feedback would only be available to those who report on MVPs and will be incorporated into the annual performance feedback that we currently provide in traditional MIPS.

We solicited public comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to provide comparative feedback to clinicians who submit MVPs.

Response: We thank commenters for the support.

Comment: A few commenters had concerns that it is premature to offer feedback to clinicians on performance on MVPs, because MVPs are still under development, clinicians are still gaining experience with the use of population and cost measures and may not benefit from enhanced feedback. Commenters indicated that clinicians also have the burden of transitioning to digital quality measures (dQMs) and will not have resources to receive and understand enhanced performance feedback.

Response: We believe that MVPs provide an opportunity for enhanced feedback for MVP Participants, because MVPs allow for comparison to other MVP Participants who submitted the same MVP. We plan to provide enhanced feedback to MVP Participants beginning with the first performance period the MVP participation option is available (CY 2023 performance period/CY 2025 MIPS payment year). We do not believe it is premature to offer feedback after an MVP is submitted, particularly as the information is provided to the MVP participant only and is not publicly reported. As clinicians begin to adopt MVPs we will provide feedback in as timely a manner as possible and we anticipate that feedback reports will help clinicians become familiar with population health and cost measure data, as well as the other elements of the MVP. We acknowledge the concern that clinicians will be transitioning to dQMs, and while it is not required that clinicians review and use the feedback on MVPs, we continue to believe that feedback on MVPs will be a valuable source of information regarding performance. The comparative performance data from MVPs on connected measures and activities may help MVP Participants target potential gaps in care related to the MVP and focus needed changes in clinical workflow to address care gaps.

Comment: A few commenters wanted clarification on whether all clinicians that participate in the MVP would be compared to all clinicians who submitted the MVP, or if neurologists who participate in a stroke care MVP would be compared to other neurologists in the MVP.

Response: We will provide comparative feedback on performance of clinicians within a group or subgroup submitting an MVP to all other clinicians who reported the same MVP, which provides more granular comparison than is currently available under traditional MIPS. However, we do not plan to provide comparative feedback that is specialty specific for MVP Participants.

After consideration of public comments, we are finalizing our policy that beginning with the CY 2023 performance period/CY 2025 MIPS payment year, we will include comparative performance feedback within the annual performance feedback we provide for MVP Participants, comparing the performance of similar clinicians who report on the same MVP. The comparative feedback will only be available to those who report on MVPs and will be incorporated into the annual performance feedback that we currently provide in traditional MIPS.

(iii) Request for Information for Future Consideration

As described in the CY 2020 PFS proposed rule (84 FFR 40733 through 40734), stakeholders have requested that they be provided with actionable feedback. To gain a better understanding, we solicited comments from stakeholders to elaborate on what they consider to be ''actionable''. Would this include CMS identifying in the annual performance feedback areas of improvement based on how a clinician scores on a measure? Is there unintended burden to stakeholders such as third party intermediaries and EHR vendors associated with receiving ''actionable'' feedback? For example, this could include financial burden from system changes or operational burden on changes to workflows.

We thank commenters for the feedback received through this request for information. We may consider this information to inform future rulemaking.

b. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859), we finalized the APM Performance Pathway (APP), which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation. The APP is available for reporting by any submitter type, with the exception of Virtual Groups.

(2) MIPS Performance Category Scoring

(a) Quality Performance Category

In the CY 2021 PFS final rule, we finalized our proposal to use the measures listed in Table 50 for purposes of quality performance category scoring for the APP.

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TABLE 50: Measures included in the 2021 Final APM Performance Pathway Measure Set+

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

+ We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) do not have benchmarks and are therefore not scored; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2021 MIPS Performance year only.

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In the CY 2021 PFS final rule, we finalized the inclusion of the CMS Web Interface as an option for Shared Savings Program ACOs to report quality for the 2021 performance period only, and this quality reporting option would no longer be available beginning with the CY 2022 performance period. However, as we explained in the CY 2022 PFS proposed rule (86 FR 39384), since the CY 2021 PFS final rule, we have received stakeholder feedback that the transition away from reporting the CMS Web Interface measures to the reporting of eCQMs/MIPS CQMs is more technologically difficult for some ACOs than originally anticipated, particularly under the extraordinary circumstances of the PHE for COVID–19. In light of this feedback, we proposed to extend the CMS Web Interface as a means of reporting quality under the APP for Shared Savings Program ACOs for performance years 2022 and 2023.

Under this proposal, for performance year 2022, Web Interface reporting would work in the same manner as for performance year 2021, where ACOs would have the option of reporting either the CMS Web Interface, the APP eCQM/MIPS CQM measure set, or both.

In addition, we proposed that for the 2023 performance year, we would score

Web Interface submissions only for ACOs that have also submitted at least one eCQM/MIPS CQM measure from the APP measure set. While we stated in the proposed rule that we understand that there may be barriers to ACOs transitioning away from the CMS Web Interface along the timeline originally contemplated, we further explained that we believe it is important to continue to encourage and incent that transition. By extending the CMS Web Interface for the 2022 and 2023 performance years, as proposed, we would give ACOs additional time to familiarize themselves with the eCQM/MIPS CQM measures and the data aggregation and submission processes. However, we also stated our belief that by proposing to limit the continued use of the CMS Web Interface in the 2023 performance year only to those ACOs that also attempt an eCQM/MIPS CQM submission, we would continue to move these ACOs and their ACO participants towards CMS' goal of more complete and uniform reporting requirements for all MIPS participants.

In the proposed rule, we noted that for both performance year 2022 and performance year 2023, ACOs would continue to have the opportunity to report on both the eCQMs/MIPS CQMs and the CMS Web Interface measures, and to have their MIPS quality performance category score based on the submission that receives a higher score. We stated our belief that these proposed policies would help to encourage ACOs to move towards eCQM/MIPS CQM reporting in a low-risk environment where they will have the opportunity to continue to rely on measures reported through the CMS Web Interface for purposes of quality performance scoring as they become familiar with the eCQM/MIPS CQM submission and scoring process.

We solicited comments on these proposals.

Comment: Many commenters supported our proposal to extend the CMS Web Interface reporting option for Shared Savings Program ACOs during the 2022 and 2023 performance years.

Response: We thank commenters for their support. We agree that given the complexity of the shift from the selective beneficiary sampling method of the CMS Web Interface to the use of all-patient data for reporting eCQM/MIPS CQMs, it is prudent to ensure that ACOs, their ACO participants, and vendors have sufficient time to implement the technology and workflows necessary to make this transition a success.

Comment: Some commenters supported the extension of the use of the Web Interface for Shared Savings Program ACOs, but believed that requiring reporting on at least one eCQM/MIPS CQM in 2023 as a prerequisite to scoring those Web Interface measures created the same level of burden as fully transitioning to eCQM/MIPS CQMs in that year. They recommended that the proposed requirement that ACOs report a minimum of one eCQM/MIPS CQM in 2023 should not be implemented.

Response: We understand commenters to mean that they believe that the majority of the burden is in developing the technical capabilities to report on these measures, and not in the data collection and reporting itself. Therefore, by including this requirement in performance year 2023, we would be imposing a deadline to have completed the transition to the new reporting framework before stakeholders believe they would be ready.

In light of these concerns, we are not finalizing our proposal to require a single eCQM measure to be reported in 2023 in order to be eligible for Web Interface scoring. Instead, we are finalizing at policy to continue the 2021 policy including use of the CMS Web Interface for Shared Savings Program ACOs into MIPS performance years 2022 and 2023. In addition, in response to comments received on our comment solicitation in the CY 2022 PFS proposed rule (86 FR 39269), we are also extending the use of the CMS Web Interface as a reporting option under the APP into MIPS performance year 2024.

For the CY 2021 MIPS performance period, we limited the use of the Risk-standardized, All-cause Unplanned Admissions for Multiple Chronic Conditions for ACOs (MCC for ACOs) measure to ACOs because, at that time, we were still investigating the question of whether it would be appropriate to include the Risk-standardized, All-cause Unplanned Admissions of Multiple Chronic Conditions for MIPS (MCC for MIPS) measure in the generally applicable MIPS quality measure set. However, in the CY 2022 PFS proposed rule (86 FR 39385), we proposed to add the MCC for MIPS measure into the MIPS quality measure set beginning with the CY 2022 MIPS performance period, as discussed in Appendix 1 of this final rule.

We also proposed to replace the MCC for ACOs measure with the MCC for MIPS measure within the APP beginning with the 2022 MIPS performance period. We explained that this change would continue our transition towards alignment of quality measure data reported by MIPS eligible clinicians who are not participants in APMs and those who are, as discussed in the CY 2021 PFS final rule (85 FR 84859). We stated our belief that the MCC for MIPS measure is a valuable tool in assessing quality performance, with no additional reporting burden, and is therefore an asset to the APP measure set as well. By replacing the MCC for ACOs measure with the MCC for MIPS measure, we would have the opportunity to capture performance on this measure for additional MIPS eligible clinicians who are not participants in ACO-based APMs.

We also stated our belief that it is important to remove the MCC for ACOs measure from the APP in order to reduce the potential for confusion around performance scores and feedback for MIPS eligible clinicians who might otherwise have been scored on both measures with differing results.

We solicited comments on our proposal to include the measures listed in Table 40 of the proposed rule (86 FR 39386) in the quality measure set for the APP for the 2022 MIPS performance period.

The following is a summary of the comments we received on the proposed APP quality measure set and our responses.

Comment: One commenter noted that it is also important to consider smaller groups and individual MIPS eligible clinicians who may not meet the case minimums or who are unfamiliar with the measures in early years and stressed that flexibility for these providers will be important.

Response: We recognize that smaller groups may not meet case minimums to report on this measure, but reiterate that in such a case, the group would have the measure excluded from its total measure achievement points and total available measure achievement points in accordance with § 414.1367(c)(1)(i), and would not be negatively affected by the inability to score this measure. We also reiterate that APM participants are no longer required to be scored for purposes of MIPS as part of their APM, but may report using any MIPS measures or pathways that would otherwise be available to them. It is our intention that these policies will provide all MIPS eligible clinicians with flexibility to report on the measures that are most relevant to their specific practice.

Comment: A few commenters raised questions about the proposed change from the MCC for ACOs measure to the MCC for MIPS measure. Commenters noted the difference in patient population between the MCC for ACOs measure, which relies on data for

Medicare beneficiaries assigned to the ACO, to the MCC for MIPS measure, which uses all Medicare beneficiary data and requested that CMS reconsider the use of the MCC for MIPS measure in scoring ACOs.

Response: We recognize that there is a difference in the patient population used to calculate the MCC for MIPS measure relative to the patient population for the MCC for ACOs measure. Like all other quality measures in the MIPS program (with the exception of the CMS Web Interface, claims, and administrative claims measures), the MCC for MIPS is a measure intended to capture reporting on all patients seen by the eligible clinicians being scored. The goal of this transition towards all-beneficiary and all-payer data is to produce a more comprehensive picture of the care being provided by the eligible clinicians participating in ACOs to all Medicare beneficiaries and patients within their care. This way, beneficiaries will be better positioned to compare performance of various clinicians and empowered to make better choices for their own health care.

Therefore, we are finalizing our proposal to add the MCC for MIPS measure to the APP measure set, and to remove the MCC for ACOs measure.

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TABLE 51: Measures included in the 2022-2024 APM Performance Pathway Measure Set+

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

+ We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) do not have benchmarks and are therefore not scored for PY 2022; they are, however, required to be reported in order to complete the Web Interface dataset.
* ACOs will have the option to report via Web Interface for the 2022, 2023, & 2024 MIPS performance periods only.

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d. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

We refer readers to §§ 414.1330 through 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

In the proposed rule, we proposed to:

- Maintain the data completeness criteria threshold of at least 70 percent for CY 2021 and CY 2022 performance periods/2023 and 2024 MIPS payment years, and increase the data completeness criteria threshold to at least 80 percent for the CY 2023 performance period/2025 MIPS payment year.
- Extend the availability of the CMS Web Interface as a collection and submission type for the CY 2022 performance period/2024 MIPS payment year.
- Make changes to the MIPS quality measure set as described in Appendix 1 of this final rule, including addition of new measures, updates to specialty sets,

removal of existing measures, and substantive changes to existing measures.

- Establish criteria for determining whether a measure change is considered substantive starting with the CY 2022 performance period.
- Beginning with the CY 2021 performance period/2023 MIPS payment year CAHPS for MIPS survey, Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) are required to administer the CAHPS for MIPS Survey and report via the Alternative Payment Model (APM) Performance Pathway (APP). We proposed refinements to our policies for administration of the CAHPS for MIPS survey to align with certain policies that previously applied to the CAHPS for ACOs survey.

(b) Data Submission Criteria

(i) Submission Criteria for Quality Measures Excluding the CMS Web Interface and CAHPS for MIPS

In the CY 2017 Quality Payment Program final rule, we established the submission criteria for quality measures (excluding the CMS Web Interface measures and the CAHPS for MIPS survey measure) at § 414.1335, which requires a MIPS eligible clinician, group, or virtual group that is reporting on Qualified Clinical Data Registry (QCDR) measures, MIPS clinical quality measures (MIPS CQMs), electronic CQMs (eCQMs), or Medicare Part B claims measures to submit data on at least 6 measures, including at least 1 outcome measure (81 FR 77100 through 77114). If an applicable outcome measure is not available, then a MIPS individual eligible clinician, group, or virtual group will report on 1 other high priority measure. If there are fewer than 6 measures that apply to a MIPS eligible clinician, group, or virtual group, then reporting on each applicable measure is required. For MIPS eligible clinicians, groups, and virtual groups that report on a specialty or subspecialty measure set (as designated in the MIPS final list of quality measures established by CMS through rulemaking), they are required to submit data on at least 6 measures within the set, including at least 1 outcome measure. If an applicable outcome measure is not available, then a MIPS individual eligible clinician, group, or virtual group will report on 1 other high priority measure. If a specialty or subspecialty measure set contains fewer than 6 measures or if fewer than 6 measures within the measure set apply to a MIPS eligible clinician, group, or virtual group, then reporting on each applicable measure is required. In addition to the assessment of performance based on submitted data for at least 6 measures (all measures if there are fewer than 6 measures that are applicable), performance is also assessed on administrative claims measures. CMS automatically evaluates and calculates administrative claims measures for individual MIPS eligible clinicians, groups, and virtual groups if the case minimum requirement of the measure is met.

We noted in the CY 2022 PFS proposed rule that, with each year of program implementation, we continue to assess means for creating a more cohesive and meaningful participation experience in MIPS that improves value and reduces clinician burden. As the program evolves, we want to enable a seamless transition from participation in traditional MIPS to the preliminary onset of voluntary participation in MVPs to the required participation in MVPs. Transitioning from traditional MIPS to MVPs improves the participation experience of MIPS by having the program be more relevant to a clinician's scope of practice and meaningful to patient care. One element that we assessed in preparation for the transition from traditional MIPS to MVPs regards the utilization of outcomes-based administrative claims measures to reduce the reporting burden under MIPS, particularly the allowance of outcome-based administrative claims measures to be applied as the required outcome measure requirement under traditional MIPS (in general, 6 measures, including 1 outcome measure) and MVPs (in general, 4 measures as outlined in section IV.A.3.b.(4)(d)(ii) of this final rule).

In the CY 2022 PFS proposed rule, we noted that since the inception of MIPS under the Quality Payment Program, we established administrative claims measures that are automatically evaluated and calculated for individual MIPS eligible clinicians, groups, and virtual groups if the case minimum requirement of the measure is met (81 FR 77130 through 77136). The reporting burden is reduced for individual MIPS eligible clinicians, groups, and virtual groups when CMS conducts the assessment and calculations of administrative claims measures (81 FR 77134). A subset of the administrative claims measures are outcome-based measures (and in some cases, are also population health measures), which focus on the improvement of patient health outcomes. We want to further reduce the reporting burden by allowing outcome-based measures (not applicable to administrative claims measures that are considered population health measures) to fulfill the outcome measure requirement as more of such measures are implemented in MIPS, when applicable. For the CY 2022 performance period/2024 MIPS payment year, we proposed the following outcome-based administrative claims measure under MIPS: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (see Table Group A of Appendix 1 of this final rule).

In the CY 2022 PFS proposed rule, we proposed at § 414.1365(c)(1) to allow an administrative claims measure that is outcome-based (not applicable to administrative claims measures that are population health measures), if applicable, to be selected at the time of MVP registration as a measure to meet the outcome measure requirement starting with the CY 2023 performance period/2025 MIPS payment year. The outcomes-based administrative claims measure would be applicable and relevant to the specific MVP, and as a result, included as 1 of the measures available within an MVP. If an outcomes-based administrative claims measure was selected during the MVP registration process, the measure will meet the outcome-based measure reporting requirement and count as 1 of the 4 minimum required measures if the MVP Participant meet the case minimum requirement for the administrative claims measure; otherwise, the administrative claims measure would receive a score of zero points and the MVP Participant would not meet the minimum reporting requirement of 4 measures. However, if the MVP Participant selects an outcomes-based administrative claims measure available within the MVP and report on 4 measures, the MVP Participant would meet the minimum reporting requirement of 4 measures if it was determined that the case minimum requirement for the outcomes-based administrative claims measure was not met. We believe that such approach reduces reporting burden and allows for a more cohesive and meaningful participation experience that focuses on measures that are more relevant to a clinician's scope of practice while preventing gaming/misuse of selecting an outcomes-based administrative claims measures to be assessed and scored on for purposes of MVP participation.

As stated in the CY 2022 PFS proposed rule, we analyzed the allowance and utilization of outcome-based administrative claims measures

(not applicable to administrative claims measures that are population health measures) to be applied to fulfill the outcome measure requirement within traditional MIPS, it became apparent that the implementation of such a policy would pose challenges and obstacles. We assessed 3 options. For the first option, we assessed the potential implementation of outcomes-based administrative claims measures to fulfill the outcome requirement utilizing a registration system, similar to the proposal for MVPs. For traditional MIPS, a registration process would require the individual MIPS eligible clinicians, groups, and virtual groups to elect to have an outcomes-based administrative claims measure be calculated and scored to fulfill the outcome measure requirement as part of the 6 minimum required measures. Prior to an individual MIPS eligible clinician, group, or virtual group making such an election via a registration process, it would be imperative for a registration process to only permit an individual MIPS eligible clinician, group, or virtual group to register if eligible (meets case minimum requirement) for an outcome-based administrative claims measure (not applicable to administrative claims measures that are population health measures) to be calculated and scored. Such registration process would need to be able to identify which individual MIPS eligible clinicians, groups, and virtual groups would be eligible for an outcome-based administrative claims measure to fulfill the outcome measure requirement as part of the required minimum of 6 measures, which would prevent the potential for gaming and enable individual MIPS eligible clinicians, groups, and virtual groups to know in advance of the submission period if they would need to report on a minimum of 5 measures instead of a minimum of 6 measures; we believe that this approach would reduce burden.

In addition, for cases in which the case minimum of the outcomes-based administrative claims measure would not be met, and therefore, could not be calculated, we have considered whether the denominator should be reduced and performance assessment and scoring would be based on 5 measures instead of 6 measures (or less measures if, initially, there were fewer than 6 applicable measures or fewer than 6 measures available within a measure set), which would reduce the reporting burden under traditional MIPS. However, we recognize that if our policy—an election process, via a registration system, to have an outcome-based administrative claims measure as 1 of the required minimum of 6 measures—includes an element for a denominator reduction, we believe that our policy would pose the potential risk for gaming. We would want to prevent the potential for gaming—knowingly selecting an outcome-based administrative claims measures during registration that is not applicable to a practice or specialty, which would result in not meeting the case minimum requirement to be calculated and scored on such measure, and thus, having performance assessed on 5 measures instead of 6 measures (or less measures if, initially, there were fewer than 6 applicable measures or fewer than 6 measures available within a measure set).

As we assessed such approach, we believed that there would not be sufficient parameters/safeguards to ensure that only individual MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure calculation would be able to register. We would seek to prevent the potential for gaming by minimizing the number of individual MIPS eligible clinicians, groups, and virtual groups not eligible for an outcome-based administrative claims measure calculation to make such election. However, as we conducted our assessment, we determined that it would not be technically possible to develop a registration system based on applicable outcomes based administrative claims measure data for the applicable performance period to identify if a MIPS eligible clinician, group, or virtual group is eligible for an outcome-based administrative claims measure calculation given that such data would not be readily available until several months after the end of an applicable MIPS performance period. Without having an ability to identify MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure calculation for registration purposes based on data from the applicable performance period in order to prevent gaming, we believed that the implementation of a policy to allow for an outcome-based administrative claims measure to be applied as 1 of the minimum required 6 measures would pose risk to the integrity of the program. For the second option, we assessed the potential for automatically calculating an outcome-based administrative claims measure, if applicable, for individual MIPS eligible clinicians, groups, and virtual groups participating in traditional MIPS. For the implementation of such a policy, we would use the status quo of requiring the submission of the minimum of 6 measures (or less measures if fewer than 6 measures were applicable or fewer than 6 measures were available within a measure set) (81 FR 77100 through 77114) in addition to automatically calculating an applicable outcome-based administrative claims measure. We would calculate a score for a total of 7 measures (6 required measures and outcome-based administrative claims measure), but performance for the quality performance category would be based on 6 measures with the highest score, which would include an outcome-based measure.

For option 2, we would not be reducing the reporting burden given that the reporting requirements would remain as status quo, but instead of us applying all administrative claims to all MIPS eligible clinicians as an addition to their quality performance category denominator, we would be replacing the outcome measure requirement, with an available outcomes-based administrative claims measure, if it can be applied. Under this approach, we would not be able to objectively decipher the intent of a MIPS eligible clinician, group, or virtual group (without a formal process to signify an election) as to whether or not they would want to have the outcome-based administrative claims measure automatically calculated and applied as 1 of the 6 minimum required measures. To not objectively know the intension of a MIPS eligible clinician, group, or virtual group, the following scenario could arise under option 2. For example, a MIPS eligible clinician, group, or virtual group submitted 5 measures, it is unclear if it was intentional to only submit 5 measures with the expectation that the MIPS eligible clinician, group, or virtual group sought to be evaluated on the outcomes-based administrative claims measure or if the submission of 5 measures was a result of a MIPS eligible clinician, group, or virtual group of not meeting the minimum of 6 required measures and thus, receive zero points for 1 of the 6 required measures.

After assessing the first 2 aforementioned options, we assessed a third option that would address concerns regarding the first 2 options. For option 3, we assessed the utilization of historical data (for example, previous MIPS performance period data) given that applicable performance period data would not be readily available to be included as part of a registration process. The use of historical data for an outcome-based administrative claims measure as the means for eligibility

determinations within a registration system would only permit individual MIPS eligible clinicians, groups, and virtual groups identified as eligible for the calculation of an outcome-based administrative claims measure. Such option would allow an individual MIPS eligible clinician, group, or virtual group to select the application of an outcome-based administrative claims measure during a registration process, which would allow CMS to identify the individual MIPS eligible clinicians, groups, and virtual groups electing to have such measure applied as 1 of the minimum-required 6 measures that meets the outcome-based measure requirement. We believe that historical data would be able to adequately and reliably identify individual MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure calculation, which we anticipate could be available during the applicable MIPS performance period, as technically feasible. We believe that by providing this historical information to individual MIPS eligible clinicians, groups, and virtual groups would provide pertinent information to make a determine if they would be selecting an outcome-based administrative claims measure during a registration process to be applied as 1 of the minimum-required 6 measures. We believe this approach could minimize gaming and individual MIPS eligible clinicians, groups, and virtual groups would know that they would need to select a minimum of 5 (instead of 6) other measures to meet the reporting requirements for the quality performance category. The potential drawback to this option is it would only be available for individual MIPS eligible clinicians, groups, and virtual groups who participated in MIPS for a prior performance period, so not all clinicians would benefit under this option. However, if technically feasible, the utilization of historical data from the outcome-based administrative claims measure would be able to reduce the reporting burden and would align with the similar proposed process for MVPs. Although we did not make a proposal for the implementation of such policy, we requested feedback from stakeholders regarding how the automatic calculation of an outcome-based administrative claims measure and have it applied as 1 of the minimum 6 required measures, particularly the outcome-based measure requirement, and if such option is a policy that would be advantage for them as they participate in traditional MIPS. We actively seek the engagement of our stakeholders as we assess means for reducing the reporting burden and enhance the experience of participating in traditional MIPS.

Thus, we solicited public comment on the means for being able to implement such a policy. Are there other options that we should consider in determining how to implement such a policy? Are there other ways we would be able to identify which individual MIPS eligible clinicians, groups, and virtual groups are eligible for an outcomes-based administrative measure calculation to ensure that only those that are eligible are able make such an election? Should we consider the use of historical data that would allow the predetermination and identification of MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure? How would we be able to determine if a MIPS eligible clinician, group, or virtual group would like to have an automatic calculation of an outcome-based administrative claims measure conducted on their behalf outside of a registration process? Are there other challenges that we should be aware of as we continue to assess a means for developing and implementing such a policy?

We thank commenters for the feedback received. The information provided may inform future rulemaking.

(c) Data Completeness Criteria

(i) CY 2021 Performance Period (2023 MIPS Payment Year)

In the CY 2020 PFS final rule, we established the data completeness criteria at § 414.1340(a)(3) and (b)(3) for the CY 2020 performance period/2022 MIPS payment year, which determined that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, eCQMs, or Medicare Part B claims measures must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer. In regard to the data completeness criteria established for Medicare Part B claims measures for the CY 2020 performance period/2022 MIPS payment year, we found that the policy established at § 414.1340(b)(3) erroneously reflected the data completeness criteria only applicable to QCDR measures, MIPS CQMs, and eCQMs, which requires data submission to pertain to patients that meet the measure's denominator criteria, regardless of payer (all-payer). It is not possible for Medicare Part B claims data to include all-payer patients; the submission of data for Medicare Part B claims measures can only account for Medicare Part B patients. Since the implementation of MIPS, the data completeness criteria for Medicare Part B claims measures has pertained to the applicable Medicare Part B patients seen during an applicable MIPS performance period. The issue with the policy established at § 414.1340(b)(3) in the CY 2020 PFS final rule for Medicare Part B claims measures only pertains to the type of patient population for data submission purposes and not the threshold established for data completeness of at least 70 percent. Thus, we proposed to modify the data completeness threshold criteria established at § 414.1340(b)(3) for the CY 2020 performance period/2022 MIPS payment year retroactively, effective January 1, 2020, in accordance with section 1871(e)(1)(A)(ii) of the Act. We believe that failure to apply the change retroactively will be contrary to the public interest because it will require individual eligible clinicians, groups, and virtual groups to meet data completeness criteria (the submission of patient data for all-payers) for Medicare Part B claims measures that is not possible. We believe that it is imperative for individual eligible clinicians, groups, and virtual groups to be certain as to the true criteria used to measure data completeness for Medicare Part B claims measures. For the CY 2021 performance period/2023 MIPS payment year, we proposed to modify the data completeness criteria established at § 414.1340(b)(3) to be as follows: MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2022.

In the CY 2021 PFS proposed and final rules, we inadvertently omitted a proposal that would have otherwise extended our existing policy to determine the data completeness criteria for the CY 2021 performance period/2023 MIPS payment year; we only included a reference to the data completeness criteria of at least 70 percent for the CY 2021 performance period/2023 MIPS payment year as it relates to the scoring policies for class 1 measures as outlined in Table 49 of the CY 2021 PFS proposed and final rules (85 FR 50309 and 85 FR 84906). Thus, in the CY 2022 PFS proposed rule, we proposed to establish the data completeness criteria for the CY 2021 performance period/2023 MIPS

payment year retroactively, effective January 1, 2021, in accordance with section 1871(e)(1)(A)(ii) of the Act (86 FR 39390). We noted our belief that failure to apply the change retroactively will be contrary to the public interest because it could be construed as permitting the submission of incomplete, inaccurate, or otherwise comprised data, which would have a detrimental effect on the performance data used for calculating MIPS payment adjustments and public reporting. For the CY 2021 performance period/2023 MIPS payment year, we proposed at § 414.1340(a)(3) to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs will need to submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer; and at § 414.1340(b)(3) to establish the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the CY 2021 performance period to which the measure applies for MIPS payment year 2023.

We stated our belief that it is imperative to establish the data completeness criteria for the CY 2023 MIPS payment year in this final rule and any failure to apply the updated data completeness criteria retroactively would be contrary to the public interest as such omission presents ambiguity and a potential notion for an array of interpretations. We believe that it is in the public interest to retroactively apply the updated data completeness threshold as it would ensure that all MIPS eligible clinicians participating in MIPS for the CY 2021 performance period/2023 MIPS payment year, whether at the individual, group, or virtual group levels, would be aware that there is a definitive data completeness criteria for the CY 2021 performance period and any data submitted for the quality performance category would need to meet the data completeness criteria. We noted that such approach would: Establish the data completeness criteria prior to the timeframe in which data submission will occur (first 3 months of CY 2022), which would enable MIPS eligible clinicians participating in MIPS at the individual, group, or virtual group levels to prepare their data submission to meet the updated data completeness criteria; and ensure that all data submitted for the quality performance category would meet the same criteria (that is, specific data completeness threshold of at least 70 percent of a MIPS eligible clinician or group's patient population that meets the measure's denominator criteria for QCDR measures, MIPS CQMs, and eCQMs; or specific data completeness threshold of at least 70 percent of the applicable Medicare Part B patients seen during the CY 2021 performance period for Medicare Part B claims measures) versus an unspecified, interpretive data completeness threshold that could result in various threshold ranges and inconsistent reported patient populations such as portion of submitted data be a representative of all patient (all-payer) data while the remaining portion of submitted data be a representative of only Medicare patient data, which would provide data integrity, usability, and reliability to assess the performance of MIPS eligible clinicians at the individual, group, or virtual group level in a manner that is consistent and enable performance data to be comparable to the applicable historical benchmarks that have been established for the various measures.

We solicited public comment on our proposal to maintain the data completeness criteria threshold of at least 70 percent for the CY 2021 performance period/2023 MIPS payment year. We received public comments regarding the proposal. The following is a summary of the public comments received.

Comment: Most commenters supported the proposal to maintain the data completeness criteria threshold of at least 70 percent for the CY 2021 performance period/2023 MIPS payment year.

Response: We appreciate the support from commenters.

Comment: A few commenters did not support the proposal to maintain the data completeness criteria threshold of at least 70 percent for the CY 2021 performance period/2023 MIPS payment year and indicated that it is difficult for some clinicians to meet the data completeness criteria. The commenters recommended that the data completeness threshold be decreased to 60 percent for the CY 2021 performance period/2023 MIPS payment year.

Response: Due to the retroactive effect of our proposal, we believe it would be most appropriate to maintain the 70 percent data completeness criteria that had been adopted for the prior year. Interested parties that reviewed our data completeness standards for prior years and our statements in the CY 2021 PFS proposed rule and final rule regarding the completeness standard for class 1 measures during the CY 2021 performance period could most reasonably have expected that we would maintain a 70 percent data completeness criteria threshold. We do not agree with commenters that the data completeness criteria threshold for the CY 2021 performance period/2023 MIPS payment year should be decreased to a threshold established for the CY 2019 performance period/2021 MIPS payment year. When the data completeness criteria threshold increased from at least 60 percent to at least 70 percent for the CY 2020 performance period/2022 MIPS payment year (84 FR 62952), it was based on an analysis of data completeness rates from the submission of data from the CY 2017 performance period (84 FR 62951), in which the data analyzed demonstrated that it would be generally feasible for MIPS eligible clinicians and groups to achieve a higher data completeness threshold of at least 70 percent. Absent further analysis, we believe it is most appropriate to maintain the standard of at least 70 percent for the data completeness threshold.

After consideration of the public comments, we are finalizing our proposal as proposed at § 414.1340(a)(3) and 414.1340(b)(3) to maintain the data completeness criteria threshold of at least 70 percent for the CY 2021 performance period/2023 MIPS payment year.

(ii) CY 2022 MIPS Performance Period (2024 MIPS Payment Year)

In the CY 2017 and CY 2018 Quality Payment Program final rules, we note that we would increase the data completeness criteria threshold over time (81 FR 77121 and 82 FR 53632). Starting with the CY 2020 performance period/2022 MIPS payment year, we increased the data completeness criteria from at least 60 percent to at least 70 percent and as noted above, we proposed to maintain the data completeness criteria threshold of at least 70 percent for the CY 2021 performance period/2023 MIPS payment year. We continue to believe that it is important to incrementally increase the data completeness criteria as MIPS eligible clinicians, groups, and virtual groups gain experience with MIPS. However, with the COVID–19 PHE that started during the CY 2020 performance period/2022 MIPS payment year and continued into the CY 2021 performance period/2023 MIPS payment year, we believe that it will be

appropriate to continue to maintain the data completeness criteria of at least 70 percent for the CY 2022 performance period/2024 MIPS payment year as healthcare systems across the country have been overwhelmed and strained by the COVID–19 PHE.

In order to not place further undue burden as MIPS eligible clinicians, groups, and virtual groups navigate through the COVID–19 pandemic, we proposed for the CY 2020 performance period/2022 MIPS payment year:

- At § 414.1340(a)(3) to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs will need to submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer, for the CY 2022 performance period/2024 MIPS payment year; and
- At § 414.1340(b)(3) to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the CY 2022 performance period to which the measure applies for MIPS payment year 2024.

We solicited public comment on our proposals to maintain the data completeness criteria threshold of at least 70 percent for the CY 2022 performance period/2024 MIPS payment year. We received public comments regarding the proposal. The following is a summary of the public comments received.

Comment: Most commenters supported the proposal to maintain the data completeness criteria threshold of at least 70 percent for the CY 2022 performance period/2024 MIPS payment year.

Response: We appreciate the support from commenters.

Comment: A few commenters did not support the proposal to maintain the data completeness criteria threshold of at least 70 percent for the CY 2022 performance period/2024 MIPS payment year and indicated that it is difficult for some clinicians to meet the data completeness criteria. The commenters recommended that the data completeness threshold be decreased to 60 percent for the CY 2022 performance period/2024 MIPS payment year.

Response: We do not agree with commenters that the data completeness criteria threshold for the CY 2022 performance period/2024 MIPS payment year should be decreased to a threshold established for the CY 2019 performance period/2021 MIPS payment year. When the data completeness criteria threshold increased from at least 60 percent to at least 70 percent for the CY 2020 performance period/2022 MIPS payment year (84 FR 62952), it was based on an analysis of data completeness rates from the submission of data from the CY 2017 performance period (84 FR 62951), in which the data analyzed demonstrated that it would be generally feasible for MIPS eligible clinicians and groups to achieve a higher data completeness threshold of at least 70 percent. Absent further analysis and further information from the commenters explaining why it would be difficult to meet a data completeness criteria threshold of at least 70 percent, we believe it is most appropriate to maintain the standard of at least 70 percent for the data completeness threshold; we believe that maintaining the current standard provides MIPS eligible clinicians, groups, and virtual groups with additional time to obtain more experience in meeting this standard and prepare for a future incremental increase in the data completeness criteria threshold.

After consideration of the public comments, we are finalizing our proposal as proposed at § 414.1340(a)(3) and (b)(3) to maintain the data completeness criteria threshold of at least 70 percent for the CY 2022 performance period/2024 MIPS payment year.

(iii) CY 2023 Performance Period (2025 MIPS Payment Year)

We believe that the incorporation of higher data completeness thresholds in future years ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures and avoid any selection bias. We have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients. The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. The data completeness threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program.

Since the inception of the program, we have provided notice to MIPS eligible clinicians, groups, and virtual groups in order for them to take the necessary steps to prepare for higher data completeness thresholds in future years. In a similar manner, we are providing advance notice that we intend to increase the data completeness criteria threshold for the CY 2023 performance period/2025 MIPS payment year. We proposed: At § 414.1340(a)(4) to increase the data completeness criteria threshold from at least 70 percent to at least 80 percent, in which MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, eCQMs, or Medicare Part B claims measures will need to submit data on at least a 80 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer, for the CY 2023 performance period/2025 MIPS payment year; and at § 414.1340(b)(4) to increase the data completeness criteria threshold from at least 70 percent to at least 80 percent, in which MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 80 percent of the applicable Medicare Part B patients seen during the CY 2023 performance period to which the measure applies for MIPS payment year 2025. We believe that MIPS eligible clinicians, groups, and virtual groups will be provided with adequate time to prepare for the data completeness criteria threshold to increase.

We solicited public comment on our proposal to increase the data completeness criteria threshold from at least 70 percent to at least 80 percent for the CY 2023 performance period/2025 MIPS payment year. We received public comments regarding the proposal. The following is a summary of the public comments received.

Comment: A few commenters supported the proposal to increase the data completeness criteria threshold from at least 70 percent to at least 80 percent for the CY 2023 performance period/2025 MIPS payment year.

Response: We appreciate the support from commenters.

Comment: Most commenters did not support the proposal to increase the data completeness criteria threshold to at least 80 percent for the CY 2023 performance period/2025 MIPS payment year. Some commenters requested that CMS implement a more gradual increase of the data completeness criteria threshold, with one commenter urging CMS to not increase the data completeness threshold above 80 percent. A few commenters expressed concerns that the data completeness criteria threshold should not be increased amidst the COVID–19 PHE or as they prepare to

transition to MVPs and digital quality measures. A few commenters indicated that the increasing of the data completeness criteria threshold would make it more difficult for some MIPS eligible clinicians, groups, and virtual groups to meet the requirement, particularly small and rural practices. One commenter stated that it is difficult for some MIPS eligible clinicians to meet a data completion rate for patient reported outcome-based measures. Another commenter specified that other CMS quality programs have lower data completeness criteria thresholds and requested that the data completeness criteria threshold for MIPS reflect a lower threshold similar to other CMS quality programs.

Response: We acknowledge the concerns expressed from commenters regarding increasing the data completeness criteria threshold amidst the COVID–19 PHE that has healthcare systems across the country overwhelmed and strained, which may have continued implications that expand beyond the CY 2022 performance period/2024 MIPS payment year. Thus, we are not finalizing the proposal to increase the data completeness criteria threshold to at least 80 percent for the CY 2023 performance period/2025 MIPS payment year while individual MIPS eligible clinicians, groups, and virtual groups recover from the unexpected impact of the COVID–19 PHE; instead, we will be maintaining the data completeness criteria threshold of at least 70 percent for the CY 2023 performance period/2025 MIPS payment year.

We also believe that maintaining the data completeness criteria threshold of at least 70 percent for the CY 2023 performance period/2025 MIPS payment year is most responsive to stakeholder concerns regarding an increase to the data completeness criteria threshold amidst the COVID–19 PHE. For the segment of MIPS eligible clinicians, groups, and virtual groups experiencing challenges in meeting the established data completeness criteria threshold of at least 70 percent, we believe that the COVID–19 PHE may have the potential to exacerbate those challenges. Maintaining the data completeness criteria threshold for the CY 2023 performance period/2025 MIPS payment year also would reduce burden and provide additional time for MIPS eligible clinicians, groups, and virtual groups to adopt the final policy changes and recover fiscally from the pandemic, prepare to transition to MVPs, which will be available starting with the CY 2023 performance period/2025 MIPS payment year. We considered not establishing a data completeness criteria threshold policy for the CY 2023 performance period/2025 MIPS payment year in this final rule, but we believe that it is more beneficial to establish such policy in advance for MIPS eligible clinicians, groups, and virtual groups. In establishing data completeness criteria thresholds in advance of an applicable performance period, we believe it is advantageous to delineate the expectations for MIPS eligible clinicians, groups, and virtual groups in order for them prepare for a transition to higher data completeness criteria threshold when such threshold is increased in the future. We believe that by maintaining the data completeness criteria threshold of at least 70 percent for the CY 2023 performance period/2025 MIPS payment year, the number of MIPS eligible clinicians, groups, and virtual groups able to meet a higher data completeness criteria threshold in future years would increase. We intend to continuously consider feedback from stakeholders as we plan to incrementally increase the data completeness criteria threshold and determine which performance period to increase the data completeness criteria threshold given that the threshold of at least 70 percent will be implemented for 4 years as of the CY 2023 performance period/2025 MIPS payment year.

We recognize that the user experience under MIPS varies across a continuum and there may be some MIPS eligible clinicians, groups, and virtual groups that will experience more challenges than others in meeting the reporting requirements for the quality performance category under MIPS, particularly MIPS eligible clinicians, groups, and virtual groups considered to be small practices for purposes of MIPS (15 or fewer clinicians). We note that, in order to enhance the user experience for such small practices, we established the Medicare Part B Claims collection type. The assessment of performance for such measures is based on Medicare Part B claims data, not all-payer claims data. In addition, to support the participation of small practices in MIPS, we established the small practice bonus, in which 6 measure bonus points are applied to the numerator of the quality performance category for small practices that submit data on at least one quality measure (83 FR 59850). As we evolve the implementation of MIPS, we continue to assess means for reducing burden and improving user experience.

In regard to the comment pertaining to challenges meeting the data completion rate for patient-reported outcome-based measures, we recognize that the user experience varies across a continuum. We do not believe that data completeness criteria threshold for patient-reported outcome-based measures would pose additional challenges. Such measures narrow the patient population to those that would benefit in capturing the patient voice. For example, many of the patient-reported outcome-based measures capture functional assessments that would allow clinicians to adjust their treatment plan to improve the outcomes. In the instance that the assessments are not completed, data completeness would not be impacted, but rather the performance rate would be impacted.

Lastly, we recognize that other CMS quality programs may have different data completeness criteria thresholds. While the commenter did not specify a CMS quality program or outline specific reporting requirements regarding data completeness that differ from MIPS, we believe that reporting requirements for CMS quality programs such as data completeness criteria, data validation, patient population eligible for a measure, measure specification requirements, case minimum standards, or measure exclusions or exceptions are not directly comparable across CMS quality programs. We believe that it is not accurate to characterize one element of a reporting requirement such as data completeness criteria threshold with an assertion that an overarching reporting burden for a CMS quality program is reduced if a standard differed from the data completeness criteria threshold of at least 70 percent established under MIPS. We note that reporting requirements may not only differ across CMS quality programs, but reporting requirements may differ by measure within a program. Thus, we believe that the reporting requirements such as the data completeness criteria threshold under other CMS quality programs should not be a factor in determining the data completeness threshold for MIPS as reporting requirements for other CMS quality programs are not directly comparable to the reporting requirements established under MIPS.

Furthermore, we believe that it is critical to increase data completeness thresholds over time to more accurately assess a MIPS eligible clinician's performance on quality measures and prevent any selection bias. A data completeness criteria threshold of less than 100 percent reduces burden and accommodates operational issues that may arise during data collection within the initial years of the program. We have previously provided notice to MIPS eligible clinicians in order for them to

take the necessary steps to prepare for higher data completeness criteria thresholds in future years (82 FR 53632, 83 FR 59758, and 84 FR 62951). We want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS.

Comment: A few commenters that did not support the increase of the data completeness criteria threshold of at least 80 percent for the CY 2023 performance period/2025 MIPS payment year indicated that some groups, virtual groups, and APM Entities such as ACOs rely on multiple EHR systems or use a combination of EHR systems and registries for submitting data to MIPS and ACOs. One commenter requested that CMS consider an allowance for groups, TINs within virtual groups, and TINs within ACOs using multiple EHR systems to submit data from each EHR to CMS and for CMS to aggregate the data for such groups. The commenter indicated placing this responsibility on such groups increases the cost of such reporting.

Response: We interpret the comments received to address the technological challenges that some groups, virtual groups, and APM Entities such ACOs experience as they transition from the reporting requirements for the CMS Web Interface to meeting the reporting requirements for eCQMs and/or MIPS CQMs. These challenges include reporting all-payer data in lieu of reporting only Medicare patient data under the CMS Web Interface and meeting higher data completeness criteria.

We recognize that there are technical and operational dynamics that groups, virtual groups, and APM Entities such ACOs must address, particularly the transition of multiple EHR systems to code and capture all-payer data that meets the data completeness criteria for eCQMs and/or MIPS CQMs. To ease the burden of transitioning to using an alternative collection type and/or submission type, we are extending the 70 percent data completeness criteria threshold, as described above. We refer readers to section IV.A.3.d.(1)(d) of this final rule regarding the proposal to extend the CMS Web Interface.

Comment: A few commenters indicated that there may be special circumstances in which clinicians, groups, and virtual groups participating in MIPS should be able to apply for an exemption regarding the data completeness criteria, such as the transition from one EHR system to another EHR system, which makes it difficult to report 12 months of data and meet the data completeness requirement.

Response: We recognize that there are certain circumstances when a MIPS eligible clinician, group, virtual group, or APM Entity may be unable to complete reporting to MIPS due to, for example, extreme and uncontrollable circumstances, hardship, or the unavailability or inapplicability of measures due to practice size or other data limitations. Therefore, under the authority provided in section 1848(q)(5)(F) of the Act, it may be necessary to reweight one or more performance categories. We believe our previously established reweighting policies account for an array of circumstances that may impact the ability to meet reporting requirements for one or more performance categories.

After consideration of the public comments, we are not finalizing our proposals at § 414.1340(a)(4) and (b)(4) to increase the data completeness criteria threshold from at least 70 percent to at least 80 percent for the CY 2023 performance period/2025 MIPS payment year, but finalizing our proposals with modification at § 414.1340(a)(3) and (b)(3) to maintain the data completeness criteria threshold of at least 70 percent for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years. Specifically, we are finalizing the following proposals with modification:

- At § 414.1340(a)(3), to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs will need to submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer, for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years; and
- At § 414.1340(b)(3) to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the CY 2021, CY 2022, and CY 2023 performance periods to which the measure applies for 2023, 2024, and 2025 MIPS payment years.

(d) Groups and Virtual Groups Reporting via the CMS Web Interface

The CMS Web Interface is a collection type through which a group and virtual group with 25 or more eligible clinicians may report data on a set of pre-determined quality measures. For the CY 2021 performance period, the total number of CMS Web Interface measures required to complete reporting on is 10 CMS Web Interface measures (83 FR 59756). In the CY 2021 PFS final rule, the CMS Web Interface was removed as an available collection and submission type under MIPS starting with the CY 2022 performance period (85 FR 84870). In addition, starting with the CY 2022 performance period, we revised the terms collection type and submission type to no longer include the CMS Web Interface measures as an available option. It was our belief that the removal of the CMS Web Interface as a collection and submission type would reduce the potential burden experienced by groups and virtual groups during the COVID–19 PHE. Based on the public comments we received on this proposal in the CY 2021 PFS proposed rule, we believed that the 1-year delay to remove the CMS Web Interface as a collection and submission type would provide stakeholders utilizing the CMS Web Interface sufficient time to prepare and transition to an alternative collection and/or submission type starting with the CY 2022 performance period.

We noted in the CY 2022 PFS proposed rule that, following the close of the data submission period for the CY 2020 performance period (March 31, 2021), stakeholders utilizing the CMS Web Interface had contacted CMS to convey their concerns that technological challenges and resource limitations would prevent them from transitioning to an alternative collection and/or submission type by the CY 2022 performance period (86 FR 39391). Also, they emphasized that some practices continued to endure a negative fiscal impact resulting from the COVID–19 pandemic and need additional time to prepare for a transition to an alternative collection and/or submission type. Such CMS Web Interface users indicated that if CMS extended the availability of the CMS Web Interface for an additional year (the CY 2022 performance period), they would have sufficient time to address the technological challenges such as the implementation of processes to aggregate data within one EHR system or across multiple EHR systems to align with the reporting requirements of another collection type (that is, MIPS CQMs or eCQMs), build and integrate new health IT infrastructures and systems, implement workflows, and train staff on new health IT systems.

In the CY 2022 PFS proposed rule, we recognized that an adequate and sufficient timeframe is a critical factor

in the success of a group or virtual group transitioning to an alternative collection and/or submission type, particularly with such a transition occurring amidst the COVID–19 pandemic (86 FR 39391). We noted that, as CMS Web Interface users had begun to transition to a different collection and/or submission type, the timeframe identified by most CMS Web Interface users (starting with the CY 2022 performance period) in response to the proposal in the CY 2021 PFS proposed rule did not provide adequate time for CMS Web Interface users to fully transition to an alternative collection and/or submission type. We noted that we considered the concerns expressed by CMS Web Interface users such as the technological challenges that they needed to overcome, their inability to update systems and workflows in time for the CY 2022 performance period, and the cost they bear to mitigate and respond to the COVID–19 PHE.

Due to such concerns, we noted our belief that it is appropriate to reduce the burden of groups and virtual groups at this time by extending the availability of the CMS Web Interface as a collection and submission type for the CY 2022 performance period. We recognized that, while groups and virtual groups are on a continuum regarding their technological readiness to transition to a different collection type, we believed that the availability of the CMS Web Interface for the CY 2022 performance period would reduce burden by providing additional time, and would enable more groups and virtual groups to successfully transition to another collection type by the start of the CY 2023 performance period. Moreover, we wanted to ensure that groups utilizing the CMS Web Interface were prepared to participate in MIPS as it evolves from traditional MIPS to MVPs. We noted that such groups could begin voluntary participation in an MVP as MVPs become available starting with the CY 2023 performance period.

Thus, we proposed at § 414.1325(c)(1) to remove the CMS Web Interface measures as a collection type/submission type starting with the CY 2023 performance period. Additionally, we proposed at § 414.1305 to modify the definition of the terms collection type and submission type to remove the CMS Web Interface measures as an available option starting with the CY 2022 performance period/2024 MIPS payment year. We proposed to modify the definition of ''collection type'' to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS Survey; and administrative claims measures. We proposed to modify the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years, the CMS Web Interface.

For the CY 2022 performance period, the total number of CMS Web Interface measures required to complete reporting on will be 10 CMS Web Interface measures (83 FR 59713 through 79715 and 59756). In Table Group B of Appendix 1 of the CY 2022 PFS proposed rule, we proposed modifications to the CMS Web Interface measures and in Table Group D of Appendix 1 of the CY 2022 PFS proposed rule, we proposed substantive changes to the CMS Web Interface measures. We believe that it is necessary for the CMS Web Interface measures to be updated to reflect applicable substantive changes for the CY 2022 performance period given that the CMS Web Interface measures have remained the same for 3 consecutive (CY 2019, CY 2020, and CY 2021) performance periods.

We solicited public comment on our proposals: to extend the availability of the CMS Web Interface as a submission and collection type for the CY 2022 performance period, which would sunset and remove the collection and submission type under MIPS starting with the CY 2023 performance period; and update the CMS Web Interface measures with substantive changes for the CY 2022 performance period as outlined in Table Group D of Appendix 1 of the CY 2022 PFS proposed rule. The following is a summary of the public comments received regarding the proposal to extend availability of the CMS Web Interface as a collection and submission type for the CY 2022 performance period. For a summary of the comments received pertaining to the proposed substantive changes to the CMS Web Interface measures for the CY 2022 performance period, we refer readers to Table Group D of Appendix 1 of this final rule.

Comment: Most commenters supported the proposal to extend the CMS Web Interface for an additional year as a collection and submission type and thereby, to allow its use for the CY 2022 performance period. The commenters indicated that the additional year would provide them with the needed time to transition to a different collection and/or submission type.

Response: We appreciate the support from commenters.

Comment: Some commenters supported the eventual sunset of the CMS Web Interface as a collection and submission type, but recommended that CMS extend the availability of the CMS Web Interface by 2 additional years, not one. The commenters indicated that such an extension would provide groups and virtual groups with more time to transition to alternative collection and/or submission types.

A few commenters expressed concern that the sunset of the CMS Web Interface, starting with the CY 2023 performance period, would increase undue burden on groups and virtual groups as it would require them to invest in resources and staffing to prepare their EHR systems to collect and report quality data using a different collection and/or submission type such as eCQMs or MIPS CQMs amidst the COVID–19 pandemic and PHE. The commenters indicated that as groups and virtual groups navigate the COVID–19 pandemic, they are enduring resource and staffing (clinical and non-clinical staff) shortages, which exacerbates the difficulties of preparing to transition to using an alternative collection and/or submission type.

Response: In considering the concerns expressed by CMS Web Interface users such as the technological and staffing challenges that they would need to overcome and the fiscal implications they endure from mitigating and responding to the COVID–19 PHE, we believe that the extended availability of the CMS Web Interface as a collection and submission type for one additional year reduces burden and provides sufficient time for the transition to different collection and/or submission types for the CY 2023 performance period. In assessing a timeframe to transition to a new collection, based on an assumption that a group or virtual group is not prepared to collect and report data using EHR technology, we believe that it would be approximately 18 months for a group or virtual group to prepare and implement EHR technology to report data, which would enable a group or virtual group to use a collection/submission type for reporting on eCQMs or MIPS CQMs. With the extended availability of the CMS Web Interface, groups and virtual

groups would have more than 18 months to prepare and transition to using another collection and/or submission type.

Comment: One commenter did not support the sunset the CMS Web Interface as a collection and submission type. The commenter expressed concerns that the transition to utilizing a different collection and/or submission type would require the reporting of all-payer data, in which data would be pulled from an entire clinical patient population, including safety net clinics serving patients with high social determinants of health. Also, the commenter indicated that assessment of performance based on all-payer data may unfairly lower quality scores for some clinicians.

Response: We recognize that the user experience of meeting reporting requirements for the CMS Web Interface differs from the user experience of meeting reporting requirements using an alternative collection type such as eCQMs and/or MIPS CQMs. We believe that the assessment of performance based on all-payer data (compared to reporting Medicare patient data only under the CMS Web Interface) and data completeness criteria (compared to reporting on a sample of Medicare patients for each CMS Web Interface measure) requirements accurately assess the performance of a group or virtual group and avoid selection bias. We have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients. The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. We do not believe that the assessment of performance should exclude any segment of a patient population based on social determinants of health, but assess performance based on an accurate reflection of a patient population. In order to further account for the dynamics pertaining to social determinants of health, we are seeking to include health equity. As we implement and enhance the inventory of quality measures under MIPS, health equity is an element we are encouraging for inclusion in measure development and would be an item we assess as part of the submission process for the annual Call for Quality Measures.

Based on the information available to us, we do not believe that the assessment of all-payer data, including patients with varying levels of social determinants of health, will negatively skew performance. With measure being risk adjusted and the way in which benchmarks are developed, we believe that social determinants of health will not inadvertently skew performance. For each collection type, specific benchmarks are established using historical data when possible, which allows us to account for the differing means of implementation of a measure for each collection type. Historical benchmarks for QCDR measures, MIPS CQMs, eCQMs, and Medicare Part B claims measures are based on historical performance data. As a result, the performance of each MIPS eligible clinician, group, or virtual group will be assessed relative to their actual performance compared to a benchmark that includes all-payer data, when specified in the measure and collection type.

We recognize that some MIPS eligible clinicians, groups, and virtual groups will experience more challenges than others in meeting the reporting requirements for the quality performance category under MIPS, particularly MIPS eligible clinicians, groups, and virtual groups considered to be small practices for purposes of MIPS (15 or fewer clinicians). We note that, in order to enhance the user experience for such small practices, we established the Medicare Part B Claims collection type. The assessment of performance for such measures is based on Medicare Part B claims data, not all-payer claims data. As we evolve the implementation of MIPS, we continue to assess means for reducing burden and improving user experience.

After consideration of the public comments, we are finalizing our proposal to sunset the CMS Web Interface measures as a collection type/submission type. We note that the availability of the CMS Interface as a collection type/submission type differs for groups and virtual groups participating in MIPS than for APM Entities participating in the Shared Savings Program and meeting the APM Performance Pathway reporting requirements. While the availability of the CMS Web Interface as a collection type/submission type for groups and virtual groups participating in MIPS is through the CY 2022 performance period, the availability of the CMS Web Interface for APM Entities (specifically, Shared Savings Program ACOs meeting the APM Performance Pathway reporting requirements only) is through the CY 2024 performance period. In section III.J.1.c. of this final rule, we discuss the final policies regarding the reporting requirements for Shared Savings Program ACOs reporting under the APM Performance Pathway, which include the extended availability of the CMS Web Interface as a collection type/submission type to the CY 2024 performance period.

In accordance with our finalized policy, we are finalizing conforming amendments to §§ 414.1305 and 414.1325(c)(1). Specifically, we are finalizing § 414.1305 with modification to amend the definition of ''collection type'' to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS Survey; and administrative claims measures. Paragraph (1) of the amended definition of ''collection type'' provides that for the CY 2021 through CY 2024 performance periods/2023 through 2026 MIPS payment years, collection types include CMS Web Interface measures for APM Entities reporting through the APM Performance Pathway in accordance with § 414.1367. Similarly, we are finalizing to amend the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and the CMS Web Interface (except as provided in paragraph (5)(i) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years). Paragraph (5)(i) of the amended definition of ''submission type'' provides that for the CY 2021 through CY 2024 performance periods/2023 through 2026 MIPS payment years, submission types include the CMS Web Interface for APM Entities reporting through the APM Performance Pathway in accordance with § 414.1367. We note that our conforming amendments refer to APM Entities rather than Shared Savings Program ACOs to maintain consistency with existing regulatory terminology. However, no substantive distinction is intended as no APM Entities other than Shared Savings Program ACOs report via the CMS Web Interface for purposes of the APM Performance Pathway. Finally, we are finalizing § 414.1325(c)(1) with modification to remove the reference to the sunset of the CMS Web Interface measures as a collection type/submission type because § 414.1325(c)(1) is expressly listing data

''submission types'' for groups, and our sunsetting policies are now incorporated into the amended definitions of ''collection type'' and ''submission type''. Accordingly, it is unnecessary to restate them in § 414.1325(c)(1).

(e) Selection of MIPS Quality Measures

Previously finalized MIPS quality measures can be found in the CY 2021 PFS final rule (85 FR 85045 through 85377); CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). Proposed changes to the MIPS quality measure set, as described in Appendix 1 of the CY 2022 PFS proposed rule, include the following: the addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the CY 2022 performance period, we proposed a measure set of 195 MIPS quality measures.

The new MIPS quality measures we proposed for inclusion in MIPS for the CY 2022 performance period and future years can be found in Table Group A of Appendix 1 of the CY 2022 PFS proposed rule. For the CY 2022 performance period, we proposed five new MIPS quality measures, which includes 2 administrative claims measures. Also, in Table Group AA of Appendix 1, we outlined 1 potential new MIPS quality measure, the COVID–19 Vaccination by Clinicians measure, which we intended to propose in a future rulemaking cycle. We refer readers to the CY 2022 PFS proposed rule for our request for information pertaining to the COVID–19 Vaccination by Clinicians measure specifications (86 FR 39393 through 39394; and for reference, available in section IV.A.3.d.(1)(f) of this final rule).

In addition to the establishment of new individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. Our proposals for modifications to existing specialty sets and new specialty sets were outlined in Table Group B of Appendix 1 of the CY 2022 PFS proposed rule. We noted that specialty sets may include: new measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 7, 2021, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 6 of MIPS under the Quality Payment Program.[226] These recommendations were based on the MIPS quality measures finalized in the CY 2020 PFS final rule and the 2020 Measures Under Consideration List; they recommend to add or remove current MIPS quality measures from existing specialty sets, or to create new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with were proposed in the proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as outlined in Tables Group A and Group B of Appendix 1 of the CY 2022 PFS proposed rule, we refer readers to Table Group C of Appendix 1 of the CY 2022 PFS proposed rule for a list of quality measures and rationales for removal. For the CY 2022 performance period, we proposed to remove 19 MIPS quality measures: 1 MIPS quality measure that is duplicative to another current MIPS quality measure; 9 MIPS quality measures that do not align with the Meaningful Measure Initiative; 5 MIPS quality measures that are no longer stewarded or maintained; and 4 MIPS quality measures that are under the topped out lifecycle. We have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. We noted our belief that our proposal to remove the quality measures outlined in Table Group C of the CY 2022 PFS proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the quality measures to determine whether they meet our removal criteria.

Lastly, MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1 of the CY 2022 PFS proposed rule. We proposed substantive changes to 84 MIPS quality measures. On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive measure changes to be proposed and identified through notice-and-comment rulemaking. In the CY 2017 Quality Payment Program final rule (81 FR 77137), we determined that substantive changes to measures (that is, measure specifications, measure title, and domain modifications) will be identified during the rulemaking process while maintenance changes that do not substantively change the intent of the measure (that is, updated diagnosis and procedure codes, definitions, and changes to patient population exclusions) will not be included in the rulemaking process.

We did not propose any changes to our current approach of identifying substantive measure changes during the rulemaking process. However, in order to more precisely distinguish between substantive measure changes and non-substantive measure changes, we proposed to consider the following criteria for determining whether a measure change is substantive starting with CY 2022 performance period:

- Whether the change causes the measure to be more stringent;
- Whether the change modifies the collection and/or submission types applicable to the measure;
- Whether the change impacts the clinical action and/or outcome of the measure;
- Whether the change increases the burden of the measure;
- Whether the change modifies the premise and/or objective of the measure;
- Whether the change modifies the scope of the measure (such as patient population eligible for the measure or measurement period); and
- Other relevant criteria as may be identified by CMS on a case-by-case basis.

We noted that any substantive change made to a measure would be proposed and identified through notice-and-comment rulemaking. For a substantive change to a measure, we only intend to propose and identify the substantive change as applicable to the appropriate elements (that is, only include substantive changes if it is applicable to the measure specifications, collection type(s), measure description, measure title, etc.) of the measure through notice-and-comment rulemaking. For example, if there is a substantive change to a

[226] CMS, Quality Payment Program listserv, ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2022 Program Year of MIPS'' (January 7, 2021).

measure in the measure specifications that changes the premise/overarching objective (that is, a screening measure that is changed to include treatment and follow-up) and/or clinical action of the measure, such substantive change would be proposed and identified through notice-and-comment rulemaking. We do not believe that it is necessary to propose or identify through notice-and-comment rulemaking changes to a measure that do not meet any of the above substantive change criteria for measures (for example, a modification to the title or domain that do not change or impact any element of the measure). We generally consider such changes to be non-substantive and would be published in subregulatory guidance. We noted our belief that it is important to provide a clear delineation of substantive changes to be included in a rulemaking process versus our previous approach, which generally included any changes made to measure specifications, measure titles, and domain modifications (81 FR 77137). We found that many changes made to measures based on our previous approach were not substantive in nature and should not be classified as substantive changes. Thus, we believe that establishing the substantive change criteria for measures provides further clarity as to what we consider a substantive change, particularly as it relates to how a change affects and/or impacts a measure. We noted that measures identified as having a substantive change would generally have an update to their applicable benchmark. For measures that meet the data completeness criteria, but do not have a benchmark or meet a case minimum (class 2 measures), we noted that they would be scored in accordance to our proposed scoring policy as outlined in the CY 2022 PFS proposed rule (86 FR 39433 through 39434).

In addition, we intended to align the utilization of terminology across CMS programs when appropriate and applicable for consistency purposes. Since the implementation of MIPS, we have referenced the term patient reported outcome as a type of measure, which is similar, but not exact to a measure type categorization reference in the CMS Blueprint. In order to align the categorization reference of such measure type under MIPS with the CMS Blueprint terminology, we are modifying how the term is referenced as a measure type under MIPS and will reference such measure type as patient-reported outcome-based performance measure (PRO–PM) starting with the CY 2022 performance period. We believe that such modification does not have any substantive implications, but is merely a minor technical change of semantics that enables the utilization of consistent terminology across CMS programs when referencing such measure type.

We refer readers to Table Groups A through D of Appendix 1 of this final rule for a summary of public comments received regarding the proposed changes to the MIPS quality measure set for the CY 2022 performance period and our final decisions. For the CY 2022 performance period, we are finalizing with modification a measure set of 200 MIPS quality measures, which includes the following:

- Implementation of 4 new MIPS quality measures (includes one administrative claims measure);
- Removal of 13 MIPS quality measures: 1 MIPS quality measure that is duplicative to another current MIPS quality measure; 4 MIPS quality measures that do not align with the Meaningful Measure Initiative; 5 MIPS quality measures that are no longer stewarded or maintained; and 3 MIPS quality measures that are under the topped out lifecycle; and
- Substantive changes to 87 MIPS quality measures.

We solicited public comment on our proposal to establish measure substantive change criteria that would be utilized by CMS to identify such measures. The following is a summary of the public comment received.

Comment: One commenter supported the intent and criteria for determining whether a substantive change has been made to a quality measure and encouraged CMS to consider the definition of a substantive change to include any modification to a measure that impacts performance scores that may likely be due to the changes in the measure construct or coding and not clinician performance.

Response: We appreciate the support from the commenter. However, when we assess whether or not a change to a measure is substantive, the factors we consider assess how the measure is changed. We recognize that a substantive change may affect performance, but we do not believe that an impact to performance scores necessitates for a change to a measure to be classified as substantive. We do not believe that it is appropriate for the determination of whether or not a measure change is substantive to be based on whether performance scores would increase or decrease. Rather, we believe that the determination of whether a measure change is substantive should pertain to elements of the measure and not to the spectrum of performance on the measure. If a change to a measure is substantive such as causing the measure to be more stringent, we believe that such dynamic reflects a change to an element in the measure. If the performance scores increase or decrease due to changes in a measure, we believe that performance scores reflect how measure requirements are met. As we assess whether or not a change to a measure is substantive, the premise of our assessment and analysis stems from how a measure is changed such as the construct of a measure, coding updates, and if the measure is more stringent or increases burden; the premise of our assessment and analysis does not stem from whether or not the measure substantive change will impact performance because we believe that it is inherent for a measure substantive change to have a potential effect on performance. We assess performance based on whether or not measure requirements for a clinical quality action is met.

After consideration of the public comment, we are finalizing our proposal to establish measure substantive change criteria that will be utilized by CMS to identify such measures. CMS will consider the following criteria for determining whether a measure change is substantive starting with CY 2022 performance period:

- Whether the change causes the measure to be more stringent;
- Whether the change modifies the collection and/or submission types applicable to the measure;
- Whether the change impacts the clinical action and/or outcome of the measure;
- Whether the change increases the burden of the measure;
- Whether the change modifies the premise and/or objective of the measure;
- Whether the change modifies the scope of the measure (such as patient population eligible for the measure or measurement period); and
- Other relevant criteria as may be identified by CMS on a case-by-case basis.

(f) Request for Information Regarding the COVID–19 Vaccination by Clinicians Measure

As of July 7, 2021, the Centers for Disease Control and Prevention (CDC) reported that there are 33,582,352 cases of coronavirus disease 2019 (COVID–19) and 603,656 deaths [227] caused by COVID–19 at the time of publication of

[227] *https://covid.cdc.gov/covid-data-tracker/#cases_totalcases.*

the CY 2022 PFS proposed rule and subject to change. In 2020, COVID–19 was the third leading cause of death in the United States, exceeded only by cancer and heart disease.[228] Widespread vaccination to prevent COVID–19 will be critically important to stemming the morbidity and mortality caused by this disease. Three vaccines have received the FDA emergency use authorization (EUA) for the prevention of COVID–19 (Pfizer-BioNTech, Moderna, and Janssen) as of July 7, 2021 (86 FR 39393). As noted in the CY 2022 PFS proposed rule, the EUA allows the Pfizer-BioNTech, Moderna, and Janssen COVID–19 vaccines to be distributed in the United States.[229] As of July 7, 2021, 331,651,464 vaccine doses have been administered (86 FR 39393).[230] However, in this final rule, we note that on August 23, 2021, the FDA approved the first COVID–19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID–19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID–19 disease in individuals 16 years of age and older.[231]

To address this urgent PHE, CMS began the development of the COVID–19 Vaccination by Clinicians measure for MIPS, which would assess the percentage of patients aged 18 years and older seen for a visit during the measurement period who have ever completed or reported having ever completed a COVID–19 vaccination series. The measure would be reported by MIPS eligible clinicians as a MIPS CQM to determine the percentage of patients seen for a visit during the measurement period who have ever completed or reported having ever completed a COVID–19 vaccination series, either from the submitting MIPS eligible clinician or another MIPS eligible clinician. The measure as specified at the time of publication of the CY 2022 PFS proposed rule (see Table Group AA of Appendix 1 of the CY 2022 PFS proposed rule) would allow clinicians to determine a patient's vaccination status and deliver a vaccine dose, if possible and appropriate. The measure is intended to capture whether or not clinicians take an appropriate step to ensure that their patients are vaccinated. Patients receiving hospice care at any time during the measurement period would be excluded from the patient population of measure. The measure would allow for an exception if the COVID–19 vaccination series was not administered, as documented by a MIPS eligible clinician, due to patient contraindication, or vaccine availability.

Between November of 2020 and January of 2021, we solicited feedback on the measure from measure-specific multi-stakeholder expert workgroups, specifically the Measure Application Partnership (MAP) coordinated through the National Quality Forum.[232] While the MAP agreed that the COVID–19 Vaccination by Clinicians measure could be an important tool to: Support vaccine uptake by collecting valuable information from the field, provide feedback to clinicians, and help identify where to conduct targeted education and outreach to limit the spread of infections, the MAP expressed concerns regarding the following elements of the measure: The patient population that would be assessed to measure performance (the inclusion of assessing patients who received 1 dose of a COVID–19 vaccine versus only assessing patients who received a complete COVID–19 vaccination series), and lack of available evidence and clinical guidance for vaccine administration (the feasibility of implementing the measure given the limited vaccine supply and availability, and the potential inconsistencies and discrepancies derived from the novelty of data collection and reporting for COVID vaccinations). We seek to mitigate such issues by obtaining further information and feedback from additional stakeholders. We intend to utilize the obtained information and feedback to inform measure specification improvements that would be implemented for a future performance period.

We solicited public comment on the draft COVID–19 Vaccination by Clinicians measure specifications, which is available on the Quality Payment Program website in the Resource Library located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1471/Draft%20COVID-19%20Vaccine%20Specs.pdf.*

Specifically, we solicited feedback on the following questions. Should the measure assess whether or not patients completed a COVID–19 vaccination series to capture provision of effective clinical care and why? Given that there are differences in the age ranges for patients eligible to receive the various COVID–19 vaccinations (Moderna and Janssen COVID–19 vaccines are authorized for patients ages 18 years and older; Pfizer-BioNTech COVID–19 vaccine is authorized for patients ages 12 and older; and future COVID–19 vaccines may be approved for other age ranges that are implemented after the publication of the CY 2022 PFS proposed rule), is 18 years and older an appropriate initial age threshold for this measure? Given the current COVID–19 PHE and the intent of the measure, should this measure be mandatory for reporting in a future year? If this measure would be mandated as a required measure for reporting purposes under MIPS, what issues or concerns would need to be considered and/or mitigated regarding the implementation of the measure in a future year? What are the potential unintended consequences associated with the potential future implementation of the measure as specified in Table Group AA of Appendix 1 of the CY 2022 PFS proposed rule and applicable measure specifications? What are the feasibility challenges and barriers to implementing the measure? What are the potential options and/or recommendations that we should consider to address and/or mitigate the feasibility challenges and barriers to be experienced during the CY 2022 performance period/2024 MIPS payment year that could be improved upon for the CY 2023 performance period? If this measure would be mandated, how would the collection of the measure data be useful after the CY 2023 performance period/2025 MIPS payment year?

We thank commenters for the feedback that we received. We may consider such information to inform future rulemaking.

(g) Quality Data Submission Criteria

(i) CAHPS for MIPS Background

As part of the CY 2021 PFS final rule (85 FR 84718), we finalized a policy requiring Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). Beginning with the CY 2021 performance period/2023 MIPS payment year, Shared Savings Program ACOs are required to field the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey as part of the APP. We had previously established in the CY 2019 PFS final rule that MIPS quality benchmarks will be based on collection type, from all available sources,

[228] *https://www.scientificamerican.com/article/covid-19-is-now-the-third-leading-cause-of-death-in-the-u-s1/.*

[229] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.*

[230] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html.*

[231] FDA, News Release, ''FDA Approves First COVID–19 Vaccine'' (August 23, 2021) located at *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.*

[232] *http://www.qualityforum.org/map/.*

including MIPS eligible clinicians and APM Entities, to the extent feasible, during the applicable baseline or performance period (83 FR 59842). Given that Shared Savings Program ACOs will now be required to field the CAHPS for MIPS survey as part of the APP, we note that beginning with the CY 2022 performance period/2024 MIPS payment year CAHPS for MIPS survey, the CAHPS for MIPS benchmarks will be calculated based on summary survey measure (SSM) scores from MIPS groups and APM entities (including Shared Savings Program ACOs) that fielded the CAHPS for MIPS Survey in the applicable baseline or performance period. Furthermore, the CAHPS for MIPS SSM scores will be adjusted for patient case-mix using a single case-mix adjustment model that incorporates data from both MIPS groups and APM entities (including Shared Savings Program ACOs) that field the CAHPS for MIPS Survey.

Beginning with the CY 2022 performance period/2024 MIPS payment year for the CAHPS for MIPS survey, to further support the alignment of CAHPS for MIPS sampling and scoring procedures between Shared Savings Program ACOs and MIPS groups, we proposed in the CY 2022 PFS proposed rule to adopt certain policies that had been part of the CAHPS for ACOs survey administration process, but had not previously been a part of CAHPS for MIPS. These policies fell into 3 broad categories: Sampling, case mix adjustment, and scoring. Policies related to certified survey vendors rendering the CAHPS for MIPS survey for subgroups were discussed in the proposed rule in section IV.A.3.h. (86 FR 39462 through 39463). We solicited comments on the following proposals related to CAHPS for MIPS.

(ii) CAHPS for MIPS Sampling Specifications

The CAHPS for MIPS Survey is administered to a sample of eligible patients for all Shared Savings Program ACOs and for those MIPS groups that elect the measure. Prior to drawing the sample, patients are excluded from the pool of potential survey recipients (called the sampling frame) for a number of reasons, including if they are known to have died or are known to be institutionalized. Currently, patients are considered institutionalized if 100 percent of their primary care charges are associated with an institutionalized setting during the sampling period. Starting in performance year 2018 under the Shared Savings Program, the CAHPS for ACOs survey additionally flagged patients as institutionalized if their *last* primary care visit during the sampling period was associated with an institutional setting. This change (called the ''last primary care visit rule'') was made to better identify and exclude from the sample, patients likely to be institutionalized at the time the survey is fielded, and by extension, to improve response rates on the survey. This was of particular importance for a few Shared Savings Program ACOs for which large portions of their assigned beneficiaries are in nursing homes. Analysis of the CY 2020 performance period/2022 MIPS payment year CAHPS for MIPS sample found that among the 100 MIPS groups that fielded the survey, less than 1 percent of the survey sample would be lost, on average, due to the application of this additional criterion to identify institutionalized patients. Of the groups fielding the survey in the CY 2020 performance period/2022 MIPS payment year, only 1 would have been excluded from participating in the survey as a result of falling below the minimum sampling threshold due to the expanded definition of institutionalization. Given these findings, which suggest a minimal impact on MIPS group sample sizes and eligibility to field the survey, we proposed beginning with the CY 2022 performance period/2024 MIPS payment year for the CAHPS for MIPS survey to add the ''last primary care visit rule'' as an additional exclusion to sampling for the CAHPS for MIPS survey. We explained that we expected this change would better identify and exclude from the sample those patients likely to be institutionalized at the time the survey is fielded, and by extension, would improve response rates on the survey.

As we explained in the CY 2022 PFS proposed rule, other CMS programs use different CAHPS surveys to gather information on patient experience in a variety of health care settings. The In-Center Hemodialysis (ICH) CAHPS survey is fielded twice per year to patients receiving dialysis treatment at an ICH facility. Previously, patients sampled for the ICH CAHPS survey during the spring implementation were removed from the CAHPS for ACOs sampling frame in an effort to improve response rates to the ICH CAHPS Survey and to avoid burdening patients with multiple surveys. Analyses of the CY 2019 and 2020 performance periods/ 2021 and 2022 MIPS payment years CAHPS for MIPS sampling frames suggest that implementing ICH CAHPS deduplication in CAHPS for MIPS would have only minor impacts on most MIPS groups. Of the groups fielding the survey in the CY 2020 performance period/2022 MIPS payment year, only 1 would have been excluded from participating in the survey due to falling below the minimum sampling threshold following ICH CAHPS deduplication (the same group that would have been excluded due to the ''last primary care visit rule'', above). For the CY 2019 performance period/2021 MIPS payment year, no participating groups would have been excluded. Therefore, we proposed that, beginning with the CY 2022 performance period/2024 MIPS payment year for the CAHPS for MIPS survey, we would remove patients who were sampled for the Spring ICH CAHPS survey from the sampling frames for CAHPS for MIPS. We stated that we expected this change would have only a minor impact on the CAHPS for MIPS sampling frame, but would increase response rates to the ICH CAHPS Survey and would avoid burdening patients with multiple surveys.

We received public comments on the CAHPS for MIPS sampling specifications. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed their support for our proposed updates to the CAHPS for MIPS sampling specifications.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing the change to the CAHPS for MIPS sampling specifications as proposed, and beginning with the CY 2022 performance period/2024 MIPS payment year for the CAHPS for MIPS survey, we will remove patients who were sampled for the Spring ICH CAHPS survey from the sampling frames for CAHPS for MIPS.

(iii) CAHPS for MIPS Case-Mix Adjustment Model

Under CAHPS for MIPS, we adjust summary survey measure scores for case-mix to promote meaningful comparison of the performance of MIPS groups despite differences in their patient populations (81 FR 77120). The case-mix adjustment model for CAHPS for MIPS includes the following case-mix adjustors: Age; education; self-reported general health status; self-reported mental health status; proxy response; Medicaid dual eligibility; and eligibility for Medicare's low-income subsidy. The CAHPS for ACOs Survey included an additional adjustor, Asian language survey, following prior literature that recommended adjustment for Asian language surveys to account

for cultural differences that affect reporting. The CAHPS for MIPS case-mix adjustment model has historically not included this adjustor because no Asian language surveys have been administered. Because Shared Savings Program ACOs are fielding the CAHPS for MIPS survey as of the CY 2021 performance period/2023 MIPS payment year, we proposed beginning with the CY 2022 performance period/2024 MIPS payment year CAHPS for MIPS survey to add use of an Asian language survey as a case-mix adjustor to the CAHPS for MIPS case-mix adjustment model. As we explained in the CY 2022 PFS proposed rule (86 FR 39395), use of an Asian language survey has been shown to be significantly associated with specific response patterns to a number of survey items that contribute to summary survey measures. In particular, Asian language survey respondents are generally less likely to use responses at the extremes of the scales, which tends to result in lower overall scores compared to patients who respond to English-language surveys. Therefore, it is important to retain use of Asian language survey as a case-mix adjustor for Shared Savings Program ACOs, and also appropriate to include it in the case-mix adjustment model for MIPS groups should Asian language surveys be completed for these groups in the future. Analysis of CY 2019 performance period/2021 MIPS payment year CAHPS for MIPS data found that adding the Asian language survey case-mix adjustor and pooling data from MIPS groups and Shared Savings Program ACOs for the purposes of case-mix adjustment had only a minimal impact on mean scores for MIPS groups, with scores increasing slightly as a result.

We received public comments on the CAHPS for MIPS case-mix adjustment model. The following is a summary of the comments we received and our response.

Comment: A few commenters supported the proposal to include the Asian language survey adjustor in the CAHPS for MIPS case-mix adjustment model.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing our proposal to add use of an Asian language survey as a case-mix adjustor to the CAHPS for MIPS case-mix adjustment model beginning with the CY 2022 performance period/2024 MIPS payment year CAHPS for MIPS survey.

(iv) Scoring CAHPS for MIPS Summary Survey Measures

The CAHPS for MIPS survey contains 10 summary survey measures (SSMs). Of these, 8 are benchmarked and scored while the other 2 (Health Status and Functional Status and Access to Specialists) are unscored and included for informational purposes only. The latter 2 measures had previously been scored but were changed to unscored starting with the CY 2018 performance period/2020 MIPS payment year (82 FR 53720). While Health Status and Functional Status was changed to unscored because it assesses underlying characteristics of a group's patient population and is less of a reflection of patient experience of care with the group, the Access to Specialists SSM was changed to unscored due to historically low reliability and response rates. At the same time this change was made (CY 2018 performance period/2020 MIPS payment year), a shorter, streamlined version of the CAHPS for MIPS Survey was implemented (82 FR 53632). Since the implementation of the shortened survey, which included a reduction in the number of survey items that make up the Access to Specialists SSM, response rates and reliability for this SSM have improved dramatically, with over 80 percent of MIPS groups achieving acceptable reliability on this SSM in the CY 2018, 2019, and 2020 performance periods/2020, 2021, and 2022 MIPS payment years, compared to less than 20 percent in the CY 2017 performance period/2019 MIPS payment year. Therefore, because CMS no longer had analytic concerns about scoring the measure, we proposed in the CY 2022 PFS proposed rule that beginning with the CY 2022 performance period/2024 MIPS payment year for the CAHPS for MIPS survey, we would once again benchmark and score the Access to Specialists measure, which would mean there would be 9 SSMs included in the CAHPS for MIPS scoring process, with 1 SSM remaining unscored (86 FR 39395). We solicited comments on this proposed change to the CAHPS for MIPS scoring process.

We received public comments on the scoring of the CAHPS for MIPS summary survey measures. The following is a summary of the comments we received and our response.

Comment: A few commenters supported the proposed change to the CAHPS for MIPS scoring process to include the Access to Specialists Summary Survey Measure (SSM).

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposal that beginning with the CY 2022 performance period/2024 MIPS payment year for the CAHPS for MIPS survey, we will once again benchmark and score the Access to Specialists measure, which means there will be 9 SSMs included in the CAHPS for MIPS scoring process, with 1 SSM remaining unscored.

(2) Cost Performance Category

(a) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, and CY 2021 PFS final rules (81 FR 77162 through 77177, 82 FR 53641 through 53648, 83 FR 59765 through 59776, 84 FR 62959 through 62979, and 85 FR 84877 through 84881, respectively) for a description of the statutory basis and existing policies pertaining to the cost performance category.

In the CY 2022 PFS proposed rule (86 FR 39395 through 39406), we proposed to add 5 new episode-based measures to the cost performance category beginning with the MIPS CY 2022 performance period/2024 MIPS payment year, and to update the operational list of care episode and patient condition groups and codes. Additionally, we proposed a new process for stakeholders to develop cost measures for MIPS. Finally, we proposed to establish criteria for determining whether a cost measure change is considered substantive starting with the MIPS CY 2022 performance period/2024 MIPS payment year. These proposals are discussed in more detail in the following sections.

(b) Addition of Episode-Based Measures

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. We would continue to evaluate cost measures that are included in MIPS on an ongoing basis and anticipate that measures could be added, modified, or removed through rulemaking as measure development continues. Any substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking, following review by the Measure Applications Partnership (MAP). The MAP is a multi-stakeholder partnership that provides guidance to CMS on performance measures for use in Federal health programs—more information is available at *https://*

www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx. The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are applicable to clinicians and complement program-specific statutory and regulatory requirements. Through its Measure Selection Criteria, the MAP focuses on selecting high-quality measures that address the National Quality Strategy's (NQS) three aims of better care, healthy people/communities, and affordable care, as well as fill critical measure gaps and increase alignment among programs.

We will take all comments and feedback from both the public comment period and the MAP review process into consideration as part of the ongoing measure evaluation process. Some modifications to measures used in the cost performance category might incorporate changes that would not substantively change the measure. Examples of such non-substantive changes may include updated telehealth service codes, diagnosis or procedure codes or risk adjustors. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. However, as described in section 7 of the Blueprint for the CMS Measures Management System Version 16.0 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), if substantive changes to these measures become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the MAP.

In sections IV.A.3.d.(2)(b)(ii) through IV.A.3.d.(2)(b)(iii) of this final rule, we summarize the new measures that will be included in the cost performance category for the MIPS CY 2022 performance period and future performance periods. For the new chronic condition episode-based measures, we provide detail about the measure framework, which lets attributed clinicians or clinician groups know the cost of care that is clinically related to their management of a patient's chronic condition during an episode of care (''episode''). For more information regarding the measure development timeline for the new episode-based measures, we refer readers to the overview in the CY 2022 PFS proposed rule (86 FR 39396 through 39397).

(ii) New Episode-Based Measures for CY 2022 and Future Performance Periods

In this section of this final rule, we discuss the 5 new episode-based measures, including 2 new chronic condition measures, which we proposed to add for the MIPS CY 2022 and future performance periods. These measures are listed in Table 52. The acute inpatient medical condition and procedural measures are based on the previously established framework for episode-based measures, which we described in detail in the CY 2019 PFS final rule (83 FR 59767 through 59773).

Chronic condition episode-based measures expand on the previously established framework for episode-based measures to address unique factors inherent to the continuous nature of chronic disease care management. In section IV.A.3.d.(2)(b)(iii) of this final rule, we provide detail about the proposed episode definition and attribution methodology for chronic condition episode-based measures. After chronic condition episodes are defined and attributed to a clinician group and, or individual clinician, we include items and services furnished during the episode that are clinically related to the care and management of a patient's chronic condition. Items and services may include treatment and diagnostic services, ancillary items (such as medical nutrition therapy and refining and maintenance of a portable pump for diabetes), services directly related to treatment, and those furnished as a consequence of care. The two chronic condition measures specified in this final rule are calculated using claims data from Medicare Parts A, B, and D. Part D costs are included to account for the full range of treatment options used to manage chronic conditions. As with Part A and B payment standardization, Part D costs are standardized to facilitate meaningful comparisons of resource use within the market-based Medicare Part D program by accounting for non-clinical variation in costs. For more detail, the Part D payment standardization methodology is available at *https://resdac.org/articles/cms-price-payment-standardization-overview.* The Medicare Parts A and B payment standardization methodology is also available at *https://resdac.org/articles/cms-price-payment-standardization-overview.*

Similar to other episode-based measures, chronic condition measures include features intended to ensure a more accurate comparison of costs across clinicians. First, we stratify the patient population captured by the measure into smaller, clinically similar patient cohorts. For example, the Diabetes measure separates patients with type 1 and type 2 diabetes, and the risk adjustment model is assessed at the level of each stratification to ensure that only patients with similar case mixes are compared to each other. We note that the term ''stratification'' will be used to describe a portion of a group in relation to the cost performance category and that such term is synonymous with the term ''episode sub-group'' used in the cost measure specification documents and other documents related to the cost performance category. In general, unless otherwise indicated, the term ''episode sub-group'' used in the cost measure specification documents and other documents related to the cost performance category has a different meaning than the term ''subgroup'' that we define under § 414.1305 in this final rule. Second, we standardize episode costs to limit observed differences in costs to those that may result from health care delivery choices. Third, we exclude unique groups of patients from episodes where it may be unreasonable to compare the costs of these patients to the whole cohort. Last, the measures account for patient characteristics that can influence spending and are outside of a clinician's control using risk adjustment. For example, the risk adjustment model is run separately for patients with and without enrollment in a Part D drug plan to account for differences in costs that we might observe between patients enrolled in Part D and those who are not. In addition, the risk adjustment model for chronic condition episode-based measures specified in this rule account for a patient's status as a dual Medicare and Medicaid enrollee. This was based on testing demonstrating that dual status had a notable impact on performance for the two measures. For more information on the chronic condition episode-based measure framework, we refer readers to the Chronic Condition Cost Measure Framework located at *https://www.cms.gov/files/document/chronic-condition-cost-measure-framework-poster.pdf.*

The specifications for all 5 proposed episode-based measures are available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.* The specifications documents for each measure consist of a methods document

that describes the steps for constructing the measure and a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides details about components of episode-based measures: Identifying patients receiving care, defining an episode-based measure, attributing episodes to clinicians and clinician groups, assigning costs, defining exclusions, risk adjusting, and calculating measure score. For each measure component, the methods document provides detailed methodology describing each logic step involved in constructing the measure. For the chronic condition episode-based measures, the specifications also include an appendix to the methods document which provides additional detail on particular components of the measure construction framework, including the sub-grouping methodology, episode construction and calculation, and attribution to individual clinicians. Second, the measure codes list contains the codes used in the measure specifications, including the episode triggers, attribution, sub-groups, assigned items and services, exclusions, and risk adjustors.

More information about the 5 proposed episode-based measures is available in the measure justification forms, the national summary data report, and the national summary data report addendum with risk adjustment regression results. These documents are available through the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*).

In the CY 2022 PFS proposed rule (86 FR 39395 through 39406), we solicited public comments on the 5 proposed episode-based measures, which are listed in Table 52.

TABLE 52: Episode-Based Measures Beginning with CY 2022 Performance Period/2024 MIPS Payment Year

Measure Name	Episode Type
Melanoma Resection	Procedural
Colon and Rectal Resection	Procedural
Sepsis	Acute inpatient medical condition
Asthma/Chronic Obstructive Pulmonary Disease (COPD)	Chronic condition
Diabetes	Chronic condition

We summarize and respond to the public comments on the proposed episode-based measures, which are listed in Table 52, after the discussion of the attribution for the new episode-based measures (that is, in section IV.A.3.d.(2)(b)(iii) of this final rule).

(iii) Attribution

In this section of this final rule, we discuss the attribution methodology for the episode-based measures. In the CY 2020 PFS final rule (84 FR 62962), we established at § 414.1350(b)(8) that beginning with the CY 2020 performance period/2022 MIPS payment year, each cost measure is attributed according to the measure specifications for the applicable performance period. For the proposed acute inpatient medical condition and procedural episode-based measures outlined in Table 52, we refer readers to the measure specifications for the attribution methodology, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.* For the proposed chronic condition measures, we use a new attribution framework for identifying and confirming a clinician-patient relationship, which we discuss below. For further detail regarding the specific attribution methodology for the proposed Asthma/COPD and Diabetes measures, we refer readers to the measure specifications for each measure, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.*

For chronic condition episode-based measures, we would attribute episodes to the clinician group that renders the services that constitute a trigger event, which is identified by the occurrence of two claims billed in close proximity by the same clinician group. Both claims must have a diagnosis code indicating the chronic disease captured by the measure (for example, type 1 or type 2 diabetes for the Diabetes episode-based measure). In the CY 2022 PFS proposed rule (86 FR 39398), we stated that the first claim must have an E/M code for primary care services and the second claim must have either another E/M code for primary care services or a condition-related HCPCS/CPT code for procedure codes related to the treatment or management of the chronic condition. In this final rule, for the chronic condition episode-based measures (the Asthma/COPD measure and the Diabetes measure referenced in Table 52), we are replacing the term ''primary care services'' with the term ''outpatient services''. We are describing these trigger E/M services as ''outpatient'' rather than ''primary care'' in order to more accurately characterize the nature of the specific E/M codes by referencing the setting rather than a nature of care. We believe that the revised terminology will be more readily understandable. There are no changes to the codes themselves being used in the trigger methodology. We intend to use such revised terminology in the chronic condition episode-based measure specifications, and any other future measures that use the same set of E/M codes, as well as other documents related to the cost performance category starting with the CY 2022 performance period/2024 MIPS payment year. The trigger event opens a year-long attribution window from the date of the initial E/M outpatient service, during which the same clinician group could reasonably be considered responsible for managing the patient's chronic disease. The initiation of the attribution window at the onset of the trigger event ensures that costs are attributed only after the start of the clinician-patient relationship. We could extend the initial attribution window and the clinician group's responsibility by another year each time we see additional E/M codes for outpatient services or condition-related HCPCS/CPT codes for procedure codes related to the treatment or management of the chronic condition that indicate an ongoing clinician-patient relationship. Therefore, the resulting total attribution window could span multiple years and vary in length for different patients. Because the total attribution window could span multiple performance periods, we measure it

incrementally and periodically by dividing it into segments of episodes, which we assess in the performance period in which they conclude. Dividing the total attribution window into episodes allows us to assign costs during the time-period in which the clinician group is responsible for the patient's chronic condition care management.

After we identify the attributed clinician group as described in the previous paragraph, we would attribute the episode to individual clinician(s). For individual clinicians, we would attribute episodes to each MIPS eligible clinician within an attributed clinician group that renders at least 30 percent of qualifying services during the episode. Qualifying services include E/M codes for outpatient services or condition-related HCPCS/CPT codes with a relevant chronic condition diagnosis. We would employ two additional checks to confirm the qualifying clinician's role in the ongoing management of the patient's chronic condition. First, we would check to ensure that the qualifying clinician(s) have rendered at least one E/M code for outpatient services or condition-related HCPCS/CPT code with a relevant diagnosis within 1 year prior to or on the episode start date. This ensures that clinicians are not attributed an episode before they have their first encounter with the patient. Second, we would check whether the clinician(s) have written at least 2 condition-related prescriptions on different days to two different patients during the performance period plus a one-year lookback period. The use of these prescription billing patterns would ensure that we are capturing the clinicians actually involved in providing ongoing chronic care management, rather than clinicians who may have only refilled a patient's prescription once, as a courtesy. MIPS eligible clinicians within an attributed clinician group that render at least 30 percent of qualifying services and meet the two additional checks are considered for attribution. The individual clinician's performance is based on all of the episodes attributed to the individual clinician, whereas the clinician group's performance is based on all of the episodes attributed to the clinician group. If a single episode is attributed to multiple clinicians in a single clinician group, the episode is only counted once toward the clinician group's performance. Additional detail for this attribution methodology is available in the measures specifications for the Diabetes and Asthma/COPD measures located on the MACRA Feedback Page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.*

To illustrate the attribution rules for chronic condition episode-based measures, we provide an example of a clinical scenario where 3 MIPS eligible clinicians (A, B, and C) are part of the same clinician group. A patient with type 2 diabetes presents to the clinician group to receive services related to their condition. Clinician A bills an initial E/M code for outpatient services related to the patient's diabetes (for example, an office/outpatient visit related to the patient's diabetes). During a follow-up appointment two weeks later, Clinician A bills a HCPCS/CPT code for tests related to the patient's diabetes. We consider the occurrence of these two services to constitute a trigger event indicating the start of a clinician-patient relationship. This trigger event opens a 1-year attribution window from the date of the initial E/M service and the clinician group that rendered the trigger event services would be attributed the Diabetes episode. If in this example, there were a total of 10 clinically related services captured during the episode, and Clinician A rendered 5 of those services, Clinician B rendered 2, and Clinician C rendered 3 of those services, then Clinicians A and C would be considered for attribution since they would have rendered at least 30 percent of qualifying services for the patient. Clinician B would not be considered for attribution. Before attributing the episode to Clinicians A and C, we check (i) whether the clinicians billed at least 1 E/M code for outpatient services or condition-related HCPCS/CPT code with a relevant diabetes diagnosis within 1 year prior to or on the episode start date and (ii) whether they wrote 2 diabetes-related prescriptions on different days for 2 different patients during the performance period plus a one-year lookback period. Assuming Clinician A met these two checks and Clinician C did not, then only Clinician A would be attributed this Diabetes episode. This episode would count towards the Diabetes measure's case minimum for Clinician A, but not for Clinicians B or C. At the group reporting level, the episode will be included in the calculation of the clinician group's measure score and would count towards the measure's case minimum for the clinician group.

The MAP considered these new episode-based measures in detail. For a full discussion on the MAP's evaluation of the measures, please see the description in the CY 2022 PFS proposed rule (86 FR 39399 through 39401).

We received public comments on the 5 new episode-based measures proposed in the CY 2022 PFS proposed rule (86 FR 39395 through 39403), which are listed in Table 52. The following is a summary of the comments we received and our responses.

Comment: Many stakeholders supported our proposal to include the 5 new episode-based measures in the MIPS program starting with MIPS CY 2022 performance period/2024 MIPS payment year. One commenter expressed appreciation for the transparent and efficient measure development process that incorporated input from various stakeholders through several different committees. Another commenter supported the development of episode-based measures as these include only the costs within the reasonable influence of the clinician.

Response: We thank commenters for their support of the measures and the robust measure development process.

Comment: Several commenters stated that there are no episode-based measures applicable to their specialties and also expressed concern that the population-based measures are not well-suited to assess the care provided within their specialty. Commenters highlighted the following specialties as needing cost measures: Occupational therapists, rheumatologists, radiologists, emergency clinicians. Commenters also provided suggestions of potential measure concepts within each respective scope of care. These include breast cancer screening or incidental findings from imaging for diagnostic radiologists, and a measure for clinical screening, diagnostic testing, and stabilization in the emergency department. One commenter believes that additional cost measures are needed for retina specialists, and another commenter requested the development of a low back pain measure to support the Low Back Pain MVP. One commenter urged CMS to develop more episode-based cost measures as rapidly as possible to address gaps in measurement.

Response: We thank commenters for their input and will take these suggestions into consideration during future waves of measure development. One of the criteria that we consider in prioritizing measure development is to address measurement gaps. When identifying measurement gaps, we consider clinical areas where specialties are not captured by the current set of measures. We have started to work on addressing these gaps that the commenters have identified. We note

that while there is no MVP specific to low back pain proposed in the CY 2022 PFS proposed rule, there are measures under development that address the management of low back pain (including the care provided by therapists) and focus on emergency medicine care. We expect the measures to undergo field testing in early 2022 and encourage stakeholders to provide feedback on those measures during that period. Future waves of measure development will also consider measurement gaps and the needs of potential MVPs. We also take into account other factors in measure prioritization, such as the opportunities for improvement and the potential for impact by covering a large share of Medicare cost. Additionally, we disagree that the population-based measures are not well-suited to assess care. As broadly applicable cost measures, the total per capita cost and Medicare Spending Per Beneficiary Clinician measures encourage clinicians to coordinate with other clinicians while treating a patient to improve overall cost performance. We also note that stakeholders can engage in their own cost measure development to submit measures (please see more information on the cost measure development process by stakeholders in section IV.A.3.d.(2)(c) of this final rule. As part of this process, we would publish materials outlining measurement gaps. Stakeholders can find summary of feedback on specific cost measurement gaps in the Wave 4 Public Comment Summary Report (*https://www.cms.gov/files/document/wave-4-public-comment-summary.pdf*) available on the MACRA Feedback page, and in the July 2021 Physician Cost Measures and Patient Relationship Codes TEP Summary Report (*https://www.cms.gov/files/document/physician-cost-measures-and-patient-relationship-codes-pcmp-technical-expert-panel-summary-report.pdf*) available on the CMS' TEP Current Panels website.

Comment: One commenter stated that the current measure development process is structured in a way that requires clinical experts to follow a single framework that does not account for the clinical condition or patient population, so the commenter disagreed that physician cost, quality and value of care can be evaluated using this approach. One commenter appreciated that CMS is introducing MIPS Value Pathways to better align cost and quality measures.

Response: We disagree with the commenter that the framework used to develop episode-based measures does not take into account the condition or patient population of interest. Episodes span a wide range of clinician-patient relationships, including acute inpatient conditions (for example, pneumonia hospitalization), chronic diseases (for example, diabetes management), and procedures (for example, hip replacement surgery), and the corresponding cost measure frameworks account for the differences in these clinician-patient relationships. Additionally, clinical subcommittees provide detailed input on measure specifications, which often include the components of the measure framework. Currently, there are 5 types of episode groups that serve as the basis for cost measures: (i) Procedural; (ii) acute inpatient medical condition; (iii) chronic conditions; (iv) therapy; and (v) emergency medicine. Please note that the therapy and emergency medicine frameworks are currently in development, and will undergo field testing in early 2022.

Additionally, to account for heterogeneity for patients with different cost profiles, we use various methods, such as episode subgroups (to compare episodes only with other episodes within that same episode subgroup), measure-specific risk adjustors (to predict expected episode cost based on patient or other characteristics that are out of the clinicians' reasonable influence and that may have an effect on episode cost), and episode-level exclusions (to remove episodes due to events or characteristics observed prior to or during the episode). Additionally, episode-based cost measures focus on resource use related to the treatment of a specific condition or procedure, by only including costs related to the condition under evaluation and attribute to multiple clinicians involved in this care, promoting collaborative care.

Finally, we agree with the commenter that to assess value, one needs to determine both quality and costs of care, and we appreciate the commenter acknowledging that CMS is introducing MIPS Value Pathways that would align episode-based measures with related quality measures. We agree with the importance of the MVPs as this alignment between episode-based measures and related quality measures will help further incentivize the transition from FFS to value-based care. As part of the new cost measure development process (please see section IV.A.3.d.(2)(c) of this final rule for more information), we encourage cost measures to be developed in a way that links and aligns cost and quality together to drive value, particularly in consideration of MVP development, while maintaining CMS priorities and meeting the standards/criteria outlined for cost measure development. The episode-based cost measures provide a nuanced examination of resource use that can be used alongside quality metrics to identify opportunities to improve the value by capturing costs that are clinically related to the care being delivered within a given patient-clinician relationship of care delivered to patients.

Comment: Some commenters stated that the measures should include social risk factors in the risk adjustment model. A commenter suggested that CMS explore alternative risk adjustment methodologies that do not rely on the HCC scores, while another stated that they believed that the risk adjustment model has not been adequately developed by CMS for cost measures.

Response: Each measure's risk adjustment model employs a common starting point of the CMS–HCC model, but the measure-specific expert workgroups considered enhancements to the model through the addition of risk factors specifically adapted for each episode group. The measure development contractor provided empirical analyses stratifying patient (or episode) cohorts of interest to inform the workgroup members' considerations of how particular factors should be accounted for in each measure's risk adjustment model. Workgroup members also considered patient characteristics, factors outside of the influence of the attributed clinicians, or any other measure-specific factors that would help prevent unintended consequences. We will continue to consider incorporating additional data sources in risk adjustment and welcome feedback on potential alternatives.

We consider the inclusion of social risk factors in risk adjustment based on the testing results for each measure. The Asthma/COPD and Diabetes cost measures include a risk adjustor for dual eligibility. This is based on extensive testing during the measure development process where these two chronic condition measures showed a greater impact from social risk factors than other measures. The measure development contractor conducted analyses to assess the impact of the following social risk factors: Income, education, employment, race, sex, and dual-eligibility status. For the Sepsis, Melanoma Resection, and Colon and Rectal Resection measures, the inclusion of social risk factors had minimal impact on the measures. For the two chronic condition measures, dual eligibility had an impact on the

measures; the other social risk factors tested had minimal impact beyond dual eligibility. Based on these results, we believe that it is necessary and appropriate to adjust for dual eligibility for the Asthma/COPD and Diabetes cost measures. Discussion of these results can be found in the measure justification form for the 5 episode-based measure on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). We will continue to monitor the effect of social risk factors on the measures on an ongoing basis.

Comment: Two commenters stated that the attribution method has not been adequately developed by CMS for cost measures, but did not provide additional detail.

Response: We appreciate the concern, and note that the attribution methodology has been developed with extensive stakeholder input to ensure that it captures clinician-patient relationships for the specific type of care being assessed. For instance, the attribution methodology for the Diabetes and Asthma/COPD measures reflects input from a TEP on the overall methodology and from a specific workgroup for each of the measures to determine details such as the list of codes to identify the start of a care relationship for the condition of focus. We encourage stakeholders to review the measure specifications, testing materials, and meeting summaries if there are additional concerns about the development of the attribution methodology for the cost measures.

Comment: One commenter stated that the most appropriate level of attribution for the measures is at the group practice/clinical team level.

Response: Generally, clinicians participating in MIPS can choose whether to report at the individual clinician or clinician group level. Thus, we believe it is important to allow for cost assessment at both levels of reporting, so the cost measures contain both individual clinician and clinician group level attribution methodologies.

Comment: Several commenters agreed with the comments brought up by the MAP (that is, correlations with quality measures, NQF endorsement, impact of upstream/high quality care and downstream costs) for the Diabetes, Asthma/COPD, and Sepsis measures. One commenter indicated that those concerns from the MAP need to be carefully monitored. Another commenter urged CMS to make NQF endorsement mandatory prior to finalizing any measures in the MIPS program. One commenter expressed concern about the cost measures used in the MIPS cost performance category in general, and asked CMS to not finalize the 5 new episode-based measures at this time. Finally, another commenter requested additional analyses for all cost measures in development that would look into the relationship between the cost and related quality measures. The commenter also stated that the cost measures need to be more actionable, and that CMS did not directly address one of the MAP's concerns for the Asthma/COPD and Diabetes measures on the examples of the connection between upstream medical interventions and downstream costs, as CMS did not provide any supporting data.

Response: We believe we have addressed the concerns raised by the MAP (as discussed in detail at 86 FR 39399 through 39401 of the proposed rule). The MAP's mitigation factors focused largely on testing, the results of which are publicly available in the testing updates document available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). These results directly address the concerns raised by the MAP regarding the relationship between cost and quality metrics, coding variation for the Sepsis measure, and clarifying that the role of cost measures is not to dictate clinical practice but to accurately reflect it. To address the MAP's mitigation point of NQF endorsement, we plan to submit all 5 episode-based measures to a future endorsement cycle; however, NQF endorsement is not required for cost measures to be implemented in the program. We believe that the extensive testing (including national field testing), expert clinician input, feedback from individuals with lived experiences of the conditions in question, the NQF's review through the MAP pre-rulemaking process that focuses on the use of the measure within a program, and numerous opportunities for public comment ensure that the newly developed measures are ready for implementation in MIPS. Given this robust development, testing, and review processes, we do not believe it appropriate to delay implementation for further NQF review.

We consider the importance of care that is assessed by the Diabetes, Asthma/COPD, and Sepsis episode-based measures, the potential for these measures to be impactful given the number of episodes, and the need for more episode-based measures, and believe that these measures play an important role in expanding the MIPS cost measure inventory and in moving towards the statutory goal of covering 50 percent of Medicare Parts A and B spending. Finally, we thank the commenter for the suggestion to conduct more extensive analyses looking at the relationship between cost and quality measures, including examining the correlations for clinicians with low versus high cost or quality measure scores. Regarding actionability of the measures and providing supporting data to address the MAP's concern about the connection between upstream medical interventions and downstream costs, we would like to clarify that we gathered input from expert clinicians and available literature to outline the opportunities that clinician have to take action and improve their performance on the Asthma/COPD and Diabetes measures. For more information please see the Measure Justification Forms available on the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*). This document cites evidence for the measures' focus based in clinical guidance and current literature.

Comment: A few commenters stated that episode-based cost measures are more appropriate to measure clinician performance on cost than the population-based measures, specifically the total per capita cost measure. Specifically, some commenters have concerns over the attribution methodology for the population-based measures (total per capita cost and Medicare Spending Per Beneficiary Clinician) and the lack of control clinicians have over these measures. One commenter believes that clinicians could be unfairly penalized for successfully improving the utilization of recommended preventive services if total per capita costs are measures in the same year as those services are provided.

Response: We continue to believe that the total per capita cost and Medicare Spending Per Beneficiary Clinician measures provide an important measurement of clinician cost performance (82 FR 53644) and that the measures intent to capture broad, overall care plays a significant role in MIPS to complement the more granular information captured by episode-based measures. By including both episode- and population-based measures in the cost performance category, we are able

to capture more aspects of care and ensure that there is continuity in clinician incentives throughout a patient's care trajectory. Both the total per capita cost and Medicare Spending Per Beneficiary Clinician measures have an important place in cost measurement given that the episode-based measures will only apply to a subset of clinicians at this time. As broadly applicable cost measures, the total per capita cost and Medicare Spending Per Beneficiary Clinician measures encourage clinicians to coordinate with other clinicians while treating a patient to improve overall cost performance. By holding multiple clinicians accountable under the total per capita cost measure, this promotes shared responsibility for a patient's care across primary care and specialties who tend to provide ongoing care. It also includes a specialty adjustment to account for the different scope of care provided by primary care clinicians and specialists. We disagree that the total per capita cost measure would unfairly penalize a clinician for improving the use of preventive services. The total per capita cost measure assesses clinicians' performance for one year following an attribution event, so these longer attribution windows allow the measure to capture the long-term benefits of ongoing primary care management that might not be fully realized within a short period. Using the example from the comment, preventive care services could increase costs when initially provided but could lower costs when measured over a sufficiently long time as downstream costs that usually result from lack of preventive care may be avoided. Additionally, to address stakeholder concerns about clinicians being held accountable for care that is outside their control, the Medicare Spending Per Beneficiary Clinician measure implemented a set of service exclusions. For example, the measure excludes the cost of all hospice services occurring at any time during the episode window. There are also a set of service exclusions specific to each Major Diagnostic Category (MDC) to remove the cost of some unrelated services. The measure also has a revised attribution methodology that involves separate attribution methods for medical and surgical episodes to identify the clinicians who are providing inpatient care. For medical episodes, the measure requires that the TIN bill at least 30 percent of inpatient E&Ms to focus on clinician groups that play a substantial role in inpatient care. For surgical episodes, the measure attribution is based on the clinician billing the procedure code. This attribution methodology appropriately identifies the clinicians who are providing care and reflects the team-based nature of hospital care. Internal medicine clinicians have the largest share of episodes (46 percent), followed by hospitalists (19 percent).

Comment: One commenter urged CMS to recognize that the episode-based measures used in MIPS are valid only for a certain period of time, when they are developed, and that these measures do not account for the changes in treatments that happen over time.

Response: We disagree with the comment that cost measures are only valid when they are newly developed. All cost measures undergo a measure maintenance process (including annual updates and comprehensive re-evaluation) that ensures that measures continue to meet program goals and priorities. This process balances the need to ensure that cost measures continue to meet the measure intent with the priority of providing certainty to stakeholders of what a cost measure entails by avoiding making unnecessary changes, such as those that are not substantiated by evidence. During annual measure updates, we identify potential updates and assess the nature of these updates to determine the appropriate process for implementing substantive and non-substantive changes. These updates take into consideration any changes in payment policies or clinical practices and treatments based on environmental scans, literature searches, stakeholder feedback, and empirical testing. The comprehensive re-evaluation process occurs on a 3-year cycle that is in line with the NQF endorsement maintenance processes and aligns with the CMS Blueprint for measure development.

Comment: One commenter urged CMS to consider a triggering method under which chronic condition episodes would not be triggered by an inpatient stay, so that costs could be included even when an inpatient stay does not occur.

Response: We appreciate this comment on the newly developed chronic condition framework. To clarify, the chronic condition episode-based measure framework does not require an inpatient stay to identify the start of a clinician-patient relationship. Instead, since chronic condition are by definition ongoing, we require two services specific to the care of the condition to occur within a certain period of time (that is, 180 days). One must be a clinician visit, and the other can be either another visit or a service for the treatment of the condition. For example, for the Diabetes measure, these codes could be (i) an office/outpatient visit where the clinician group confirms the patient's type 1 diabetes diagnosis, and (ii) a diabetes self-management training for the patient's' type 1 diabetes. Please find more information on what codes are used to identify the start or continuation of a clinician-patient relationship in the measure-specific codes list files available on the MACRA Feedback page (*https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*).

Comment: A few commenters opposed the inclusion of Medicare Part D prescription drug costs in the cost measures, as they stated they believe that including those costs would hold attributed physicians accountable for factors that are outside of their control, given that clinicians are not involved in the negotiations of formularies, coverage, and prices. One commenter also opposed the inclusion of Medicare Part B prescription drug costs in the cost measures, noting that inclusion of those costs would penalize physicians for costs over which they have no control.

Response: During the measure development process, our technical expert panel and measure-specific workgroup members recommended the inclusion of Part D costs in measures where Part D prescription drugs are a primary component of care for the relevant condition (for example, the Asthma/COPD, Diabetes, and Sepsis measures). For example, our analyses showed this was the case for the Diabetes measure, with results showing that 71 example of episodes contained Part D services in the episode window and more than 48 percent of episodes including Part D services were billed by an attributed clinician. Furthermore, analyses showed that approximately 62 percent of clinicians observe a change in measure score decile when Part D costs are added to the measure. Similarly, measure-specific workgroups have advised on including Medicare Part B prescription drugs in measures when clinically appropriate.

Importantly, the measures include Part B and Part D costs that have been standardized to remove price variation from non-clinical factors. For Part D costs specifically, by removing this variation, the measures (and the underlying standardization methodology) address concerns expressed by stakeholders during measure field testing that clinicians could be penalized during performance measurement for lacking control or awareness of drug pricing details set by plan and manufacturer negotiations. For

more detail, the Parts A and B payment standardization methodology and the Part D payment standardization methodology are available at *https://resdac.org/articles/cms-price-payment-standardization-overview.*

Comment: One commenter supported the inclusion of the Melanoma Resection measure in the MIPS program, as this measure would provide dermatologists an opportunity to fully participate in the MIPS program.

Response: We thank the commenter for their support.

Comment: A few highlighted the need to ensure that episode-based measures do not penalize clinicians for prescribing new and innovative medicines. Some commenters specifically stated this concern for the Melanoma Resection measure. One stakeholder recommended the removal of Lifileucel, a tumor-infiltrating lymphocyte (TIL) cell therapy from the measure as it could discourage clinicians from using this drug.

Response: Lifileucel is not included in the Melanoma Resection measure. The measure's focus is on resectable melanoma, not for treatment of advanced metastatic disease. For instance, the measure does not include any costs of chemotherapy or immunotherapy services.

More generally, as innovative drugs and treatments become available, we consider them on a case-by-case basis for each measure and whether they are clinically related to the condition in question and whether they are needed to help the measures accurately capture an episode of care. As cost measures include other types of care beyond direct treatment such as downstream complications, they are able to capture improvements that might result from the use of the innovative treatments. As with all other aspects of measure development, we consider unintended consequences and monitor for these through the maintenance processes. Finally, clinician and clinician group performance on cost measures is balanced with their performance on quality measures at the MIPS score level to capture the overall value of care provided to their patients.

Comment: One commenter supported the inclusion of the Sepsis episode-based measure in the MIPS program, as sepsis is an appropriate area of focus given the high impact on the patient population and Medicare costs.

Response: We appreciated the commenter's support for the measure.

Comment: One commenter noted optimism about the Asthma/COPD and Diabetes episode-based measures and was looking forward to potential endorsement of the measures by NQF.

Response: We intend to submit the episode-based measures for NQF endorsement in a future endorsement cycle.

Comment: One commenter did not support the inclusion of the Asthma/COPD measure, and stated they believe it needed additional testing, and was complex and difficult to use; therefore, the commenter urged CMS to postpone the measure's implementation until 2023. The commenter urged CMS to consider the impact of the U.S. West Coast wildfires that placed additional burden on physicians caring for beneficiaries with asthma and COPD, given that those patients required more intensive resource use.

Response: We believe that the measure is ready for implementation as it has undergone a rigorous development, testing, and review process. The Asthma/COPD measure was developed over a period of 18 months involving over 80 technical experts during 4 in-person and virtual meetings, input from a panel of patients and caregivers, and a national field testing. We continue to welcome feedback on how the field-testing period and the development process can be further refined to increase clinician familiarity with this and other cost measures. We also appreciate the commenter's concerns about the Asthma/COPD measure, particularly the increased burden on caring for patients with asthma and COPD due to the west coast wildfires. Under the regulations at § 414.1380(c)(2)(i)(A), clinicians who are subject to extreme and uncontrollable circumstances may submit an application to reweight the cost performance category. In the CY 2018 PFS final rule (82 FR 53780 through 53781), we define ''extreme and uncontrollable circumstance'' as '' rare (that is highly unlikely to occur in a given year) events entirely outside the control of the clinician and of the facility in which the clinicians practices that cause the MIPS eligible clinician to not be able to collect information that the clinician would submit for a performance category or to submit information that the clinician would submit for a performance category for an extended period of time.'' Natural disasters, including wildfires, are examples of such rare events. For more information, please reference the CMS QPP web page (*https://qpp.cms.gov/mips/exception-applications#extremeCircumstancesException-2021*).

After consideration of public comments, we are finalizing the 5 proposed episode-based measures listed in Table 52 as proposed.

(iv) Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other stakeholders.

In December 2016, we published the Episode-Based Measure Development for the Quality Payment Program (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Draft-list-of-episode-groups-and-trigger-codes-December-2016.zip*) and solicited input on a draft list of care episode and patient condition groups and codes as required by sections 1848(r)(2)(E) and (F) of the Act. In accordance with section 1848(r)(2)(G) of the Act, in January 2018, we posted an operational list of 8 care episode groups and patient condition groups, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-Operational-List-of-Care-Episode-and-Patient-Condition-Codes.zip.* Under section 1848(r)(5)(A)(iii) of the Act, to evaluate the resources used to treat patients with respect to care episode and patient condition groups, the Secretary shall, as the Secretary

determines appropriate, conduct an analysis of resource use with respect to care episode and patient condition groups. In accordance with this section, we used the 8 care episode groups and patient condition groups included in the operational list as the basis for the 8 episode-based measures that were finalized for use in MIPS in the CY 2019 PFS final rule (83 FR 59767 through 59773). In the CY 2020 PFS final rule (84 FR 62968 through 62969), in accordance with section 1848(r)(2)(H) of the Act, we revised the operational list beginning with CY 2020 to include 10 additional care episode and patient condition groups, which served as the basis for the 10 additional episode-based measures that were refined based on extensive stakeholder input and finalized for use in MIPS in that same final rule (84 FR 62979). The operational list as revised in the CY 2020 PFS final rule is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.*

Under section 1848(r)(2)(H) of the Act, we proposed to revise the operational list beginning with CY 2022 to include 5 new care episode and patient condition groups, based on input from clinician specialty societies and other stakeholders. These 5 care episode and patient condition groups were included in the draft list that we posted in December 2016 and refined based on extensive stakeholder input as described in the CY 2022 PFS proposed rule (86 FR 39396 through 39397). The codes and logic used to define these episode groups are available on our MACRA Feedback Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.* These care episode and patient condition groups serve as the basis for the 5 new episode-based measures that we proposed in the CY 2022 PFS proposed rule (86 FR 39397 through 39398) and finalized for the cost performance category in section IV.A.3.d.(2)(b) of this rule. We solicited comments on our proposal to revise the operational list to include these 5 new care episode and patient condition groups.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal to revise the operational list to add 5 new care episode and patient condition groups that served as the basis for the 5 new episode-based measure that we proposed for the cost performance category in the CY 2022 PFS proposed rule.

Response: We appreciate the commenter's support for this proposal.

After consideration of public comments, we are finalizing these revisions to the operational list as proposed.

(v) Reliability and Case Minimum

In this section of the rule, we discuss the case minima for the 5 proposed cost measures, weighing up considerations of reliability standards, the tradeoffs between accuracy and reliability, and the implications of increasing case minima on the extent to which the measure can apply to clinicians participating in MIPS. Reliability is a metric that evaluates the extent that variation in a measure comes from clinician performance (''signal'') rather than random variation (''noise''). Higher reliability suggests that a measure is effectively capturing differences between the clinician and their peer cohort.

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77171), we identified reliability levels between 0.4 to 0.7 as moderate and reliability levels above 0.7 as high. In the CY 2017 Quality Payment Program final rule, we also identified a threshold of 0.4 for mean reliability to be applied for measures in the cost performance category to ensure moderate reliability. This aligned with the reliability threshold applied to measures under the Value Modifier program and previous analyses of reliability.[233] We appreciate the concerns commenters had raised that this may be too low and as we stated in the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77171), we continue to work on developing measures with the highest level of reliability that is feasible within the MIPS program and have since continued to monitor the overall scientific evidence on reliability. There are many different interpretations of reliability and what these values represent. Studies have pointed to various standards to indicate sufficient, adequate, moderate, or good reliability across healthcare and other disciplines with performance measures and different methods of estimating reliability.[234] [235] [236] [237] [238] [239] [240] We also monitor the evaluation and standards applied throughout the measure endorsement processes, and note that the endorsement standards state there is no minimum threshold for reliability.[241] As such, we believe that the 0.4 threshold for mean reliability continues to be appropriate for moderate reliability.

Under section 1848(r)(5)(A) of the Act, to evaluate the resources used to treat patients (with respect to care episode and patient condition groups), the Secretary shall, as the Secretary determines appropriate, conduct an analysis of resource use (with respect to care episodes and patient condition groups of such patients) using codes reported on claims. Our approach to cost measurement focuses on defining clinically homogenous patient conditions and care episodes. This ensures that these measures accurately compare clinician performance without the results being solely driven by clinical differences across episodes.

[233] Mathematica, Inc., ''Memorandum: Reporting Period and Reliability of AHRQ, CMS 30-Day and HAC Quality Measures—Revised,'' *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.*

[234] Portney, L.G. and Watkins, M.P. (2000) Foundations of clinical research: Applications to practice. 2nd Edition, Prentice Hall Health, Upper Saddle River.

[235] Landis, J. Richard, and Gary G. Koch. ''The Measurement of Observer Agreement for Categorical Data.'' Biometrics 33, no. 1 (1977): 159–74. Accessed March 17, 2021. doi:10.2307/2529310.

[236] Koo, Terry K., and Mae Y. Li. ''A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research.'' Journal of Chiropractic Medicine 15, no. 2 (2016): 155–63. *https://doi.org/10.1016/j.jcm.2016.02.012.*

[237] Adams, J.L., Mehrotra, A., Thomas, J.W. and E.A. McGlynn, ''Physician Cost Profiling–Reliability and Risk of Misclassification,'' New England Journal of Medicine 362 (2010), 1014–21.

[238] Adams, John L., The Reliability of Provider Profiling: A Tutorial. Santa Monica, CA: RAND Corporation, 2009. *https://www.rand.org/pubs/technical_reports/TR653.html.*

[239] Taber, Keith S. ''The Use of Cronbach's Alpha When Developing and Reporting Research Instruments in Science Education.'' Research in Science Education 48, no. 6 (2017): 1273–96. *https://doi.org/10.1007/s11165-016-9602-2.*

[240] The Department of Education provides the following thresholds: ''Reliability of an outcome measure may be established by meeting the following minimum standards: (a) internal consistency (such as Cronbach's alpha) of 0.50 or higher; (b) temporal stability/test-retest reliability of 0.40 or higher; or (c) inter-rater reliability (such as percentage agreement, correlation, or kappa) of 0.50 or higher.'' (What Works Clearinghouse (WWC) Standards Handbook v4, p.78).

[241] The National Quality Forum (NQF) reviews measures on a case-by-case basis, and has endorsed many types of measures with reliability ranging from below 0.1 and above 0.9, accepting multiple varied reliability testing methods. For example, NQF endorsed the Percent of Residents Who Lose Too Much Weight (NQF #0689) facility-level outcome measure, which had a signal-to-noise ratio of 0.078. Alternatively, NQF has also endorsed the Routine Cataract Removal with Intraocular Lens (IOL) Implantation (NQF #3509) episode-based cost measure with a mean reliability score of 0.94 at the individual clinician level and a 10 episode case minimum.

While limiting the measure scope to improve homogeneity improves the accuracy of assessing cost performance, this also reduces the number of episodes per clinician. Fewer episodes per clinician results in lower reliability compared with global population measures. However, episode-based measures balance this concern using selective service assignment; only including the costs of services that are clinically related to the condition or procedure in the measures' cost calculation improves reliability by keeping the ''signal'' while reducing the ''noise.'' [242] Overall, these measures prioritize capturing clinically appropriate, homogeneous care episodes over achieving results on certain testing mechanisms to meet the statutory objective of episode-based resource measurement and create more actionable measures for clinicians. As such, we continue to evaluate cost measures on a broader range of testing, along with the details of measure construction. For this reason, we continue to caution against placing too much emphasis on reliability results in isolation as we noted in the CY 2018 Quality Payment Program proposed rule (82 FR 30050 through 30051).

As we discussed in the CY 2018 Quality Payment Program proposed rule (82 FR 30050 through 30051), while a higher case minimum generally improves measure reliability, these incremental increases must be considered against decreases in the coverage of the measure. There are several important implications for clinicians and the program. Increasing the case minimum reduces the number of clinicians that can have their performance assessed by that measure. This can limit the applicability of episode-based measures to larger group practices with sufficient case volume, leaving smaller practices and individual practitioners to be assessed only with population-based cost measures. In addition, for measures to have the potential to improve performance, they should apply to as many clinicians as can be reliably measured. Finally, it is important to recall that clinicians receive a cost performance category score which incorporates their scores across all applicable cost measures. Adding more measures that can be used in a category score increases the amount of data used to calculate the category score, which may improve the precision of overall assessment of cost performance. Additional measures also allows us to evaluate clinicians' cost category performance across a broader range of their care practice.

We examined the reliability of the 5 proposed episode-based measures, and Table 53 presents the percentage of TINs and TIN/NPIs that meet the 0.4 reliability threshold and the mean reliability for TINs and TIN/NPIs at our proposed case minimum for each of the episode-based measures. We previously established at § 414.1350(c)(4) a case minimum of 10 episodes for procedural episode-based measures and at § 414.1350(c)(5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures in the CY 2019 PFS final rule (83 59773 through 59774). For both the proposed Melanoma Resection procedural measure and the Sepsis acute inpatient medical condition measure, we found that the mean reliability for groups and individual clinicians exceeds 0.4 and that the majority of groups and individual clinicians meet the 0.4 reliability threshold when applying the established case minimum for the respective measure types. For the Colon and Rectal Resection procedural measure, at the established 10-episode case minimum for procedural measures, we found that the mean reliability does not exceed 0.4 for individual clinicians and that the majority of groups and individual clinicians do not meet the 0.4 reliability threshold. However, as displayed in Table 53, when the measure's case minimum is raised to 20 episodes, the mean reliability exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. As such, we proposed to raise the case minimum for the Colon and Rectal Resection procedural measure to 20 episodes, and corresponding revisions to § 414.1350(c)(4). For the chronic condition measures, we proposed at § 414.1350(c)(6), a case minimum of 20 episodes. At a 20-episode case minimum, the mean reliability for both measures exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. We believe that calculating the episode-based measures with these case minimums would accurately and reliably measure the performance of a large number of clinicians and clinician group practices.

[242] See for example Sandhu AT, Do R, Lam J, et al. Development of the Elective Outpatient Percutaneous Coronary Intervention Episode-Based Cost Measure. Circ Cardiovasc Qual Outcomes. Mar 2021;14:e006461.

TABLE 53: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold

Measure name (case minimum)	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Asthma/COPD (20 episodes)	88.23%	0.67	81.66%	0.60
Colon and Rectal Resection (20 episodes)	91.57%	0.56	76.10%	0.45
Diabetes (20 episodes)	82.51%	0.61	78.80%	0.57
Melanoma Resection (10 episodes)	100.00%	0.82	100.00%	0.80
Sepsis (20 episodes)	100.00%	0.68	79.89%	0.47

We received public comments on the reliability and case minimums of the proposed episode-based measures. The following is a summary of the comments we received and our responses.

Comment: A few stakeholders commented that CMS' use of 0.4 as the threshold for mean reliability is insufficient. Commenters urged CMS to increase the case minimums for the cost measures, stating that higher reliability with fewer clinicians being measured would be preferable.

Response: We thank the commenters for their feedback. We refer stakeholders to 86 FR 39400–39402 of the proposed rule where we discuss the 0.4 threshold in detail. As noted, we will continue to monitor the scientific evidence on reliability to consider whether the 0.4 threshold should be increased. At this time, we do not believe that there is sufficient evidence to substantiate a change to this threshold. In finding a balance between reliability and cost measures that have the potential to be impactful, we also consider stakeholder feedback about the need for clinicians to be assessed under episode-based cost measures. Since these measures are designed to be specific to a particular type of care, many clinicians would be attributed fewer of these episodes than of episodes for global or population-based cost measures. Using a moderate reliability threshold ensures the reliability of the measures while also guarding against the unintended consequences of excluding clinicians from episode-based cost measures.

After consideration of public comments, we are finalizing the proposal to raise the case minimum for the Colon and Rectal Resection procedural measure to 20 episodes, and corresponding revisions to § 414.1350(c)(4), as proposed. We are finalizing at § 414.1350(c)(6) a case minimum of 20 episodes for the chronic condition measures, as proposed.

(c) Process for Cost Measure Development by Stakeholders

(i) Background

Since 2017, we have conducted extensive stakeholder engagement to develop episode-based measures that cover a wide range of procedures, conditions, and specialties. This measure development process, as described in the CY 2019 PFS final rule (83 FR 59770), involves the measure development contractor convening hundreds of clinician experts to provide information to prioritize, conceptualize, and specify clinically refined cost measures and conducting national field testing on an 18-month timeline. The process involves engagement activities conducted by the measure development contractor to solicit expert input for measure development, gather feedback from individuals with lived experiences of the conditions in question, and collect stakeholder feedback on draft measure specifications that can inform how the measures can be improved. This approach follows CMS' standardized approach for developing, implementing, and maintaining measures. There are currently 18 episode-based measures in the cost performance category (CY 2020 PFS final rule (84 FR 62979)), and we are adding 5 more as discussed in section IV.A.3.d.(2)(b) of this rule. There are also 2 global or population-based measures, the Medicare Spending per Beneficiary Clinician measure and the total per capita cost measure which were most recently refined in the CY 2020 PFS final rule (84 FR 62969 through 62977).

Many stakeholders have expressed support for episode-based measurement and for a process that prioritizes clinician involvement (as noted in the CY 2018 QPP final rule (82 FR 53645)). In the CY 2021 PFS final rule (85 FR 84879), we noted that commenters expressed interest in expanding the limited inventory of cost measures available to assess cost performance applicable to specialties. Commenters believed that additional episode-based measures would address gaps in cost performance assessment for various specialties. Expanding the range of procedures, conditions, and specialties would enable more MIPS eligible clinicians from different specialties and sub-specialties to have their cost performance assessed under clinically relevant episode-based measures. An increase in the range of cost measures available in MIPS that can be linked with quality measures and improvement activities in future MVPs would support the assessment of clinician value in providing specific types of care.

A process outside of the current development process that would allow stakeholders to develop cost measures could expand the inventory of episode-based measures. However, this process must ensure that any cost measures developed are consistent with the goals of MIPS, align with CMS priorities, and consistent with the Meaningful Measures Framework (more information about the Meaningful Measures Framework can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/*

MMF/General-info-Sub-Page). Episode-based measures developed by stakeholders that meet the standards and criteria we outline in section IV.A.3.d.(2)(c)(iii) for selecting measures would contribute to the target of an estimated 50 percent of expenditures under Parts A and B, as described in section 1848(r)(2)(D)(i)(I) of the Act.

We proposed to establish a process, beginning in CY 2022, for the development of cost measures by stakeholders that would ensure that the cost performance category has consistency across measures. The sections below outline the proposals for the measure prioritization criteria, standards for measure construction, pre-rulemaking submission process and development support, which altogether comprises our proposed process of cost measure development by stakeholders.

(ii) Measure Prioritization Criteria

As described in the CY 2022 PFS proposed rule (86 FR 39396 through 39397) of this rule, the current process for prioritizing cost measures for development involves the measure development contractor identifying candidate clinical areas and episode groups informed by a TEP, patient and family engagement perspective, and clinician stakeholders. Criteria reflecting TEP input have guided strategic decisions and informed clinical subcommittees' considerations for measure prioritization. These criteria include:

- Clinical coherence of measure concept (to ensure valid comparisons across clinicians).
- Impact and importance to MIPS (including cost coverage, clinician coverage, and patient coverage).
- Opportunity for performance improvement.
- Alignment with quality measures and improvement activities to ensure meaningful assessments of value.

To inform cost measure development by stakeholders, we proposed to apply these criteria to an environmental scan to identify a list of priority areas and suggested measures for development. This would ensure that measures developed by stakeholders align with program needs, while also providing flexibility for stakeholders to apply their own clinical expertise when identifying the most important areas for value improvement within the criteria listed above. Stakeholders who choose to develop cost measures can access the Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint* and the Meaningful Measures Framework at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page* for further information.

We solicited public comments on the proposed measure prioritization criteria, as well as priority areas for future episode-based measure development, such as specialties, types of clinical care, or specific conditions or procedures that would support proposed or future MVPs.

The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of the proposal to establish a new measure development process by stakeholders. One commenter expressed support for the new process for cost measure development as it would be open to public and would grow the cost measure inventory. Another commenter stated that expanding the range of cost measures through this process could facilitate the transition away from the total per capita cost measure.

Response: We believe that the population-based measures like total per capita cost measure continue to play an important role in MIPS alongside episode-based measures. Its focus on primary care is an area that affects many beneficiaries with potential for cost improvement.

Comment: Another commenter suggested that instead of the proposed method to develop new cost measures, CMS should involve stakeholders to directly edit inclusion, exclusion, and selection criteria for existing measures.

Response: We encourage stakeholders to engage during the 18-month measure development process for new measures under development. As part of measure development, all stakeholders can participate in the national field testing and observe clinical expert workgroup meetings via a listen-only line. Stakeholders are also encouraged to provide feedback about the specifications of current cost measures in MIPS via the QPP Service Center. We would consider these as part of the routine measure maintenance process.

Comment: One commenter was supportive of the current measure development process established by CMS, and stated that while it urged CMS to work with the specialty societies to develop new measures, it was apprehensive of the new process to develop cost measures outside of MVPs. To ensure adequate input from specialty societies, the commenter encouraged CMS to require any measure developer to demonstrate that they have the correct clinical and methodological input during the measure development process.

Response: We thank the commenter for the feedback. We believe that the measure criteria outlined in the proposed process for cost measure development by stakeholders (86 FR 39403) addresses the need for a measure developer to demonstrate clinical coherence of the measure and to ensure its alignment with quality measures and improvement activities, so that the measure can be incorporated into MVPs. Additionally, for a cost measure to be implemented in MVPs, it needs to go through the notice-and-comment rulemaking process, as well as the MAP's review of the methodological approach and empirical testing results of the measures.

Comment: One commenter urged CMS to consider using other types of measures in the MIPS cost performance category as a proxy for cost. These could include measures for time spent in the ICU, transfusions, ventilator times, or length of stay. Another commenter recommended that cost measures do not just assess when there is waste in the system, but also promote clinically appropriate utilization of health care services, including for clinicians treating significant portions of older adults.

Response: To clarify, cost measures encourage reduction in spending by minimizing waste in the system and incentivizing appropriate level of utilization of healthcare services for patients. Measures used in the cost performance category are intended to be based on care episode and patient condition groups, as outlined in section 1848(r)(2) of the Act. Using other types of measures as a proxy for cost would not align with this direction. In regards to frailty, we continue to explore ways to include indicators of frailty in the episode-based measures, where appropriate. We are also tracking ASPE's research into validating and expanding claims-based algorithms of frailty and functional disability for value-based care and payment (more information on the research is available on the ASPE's website at *https://aspe.hhs.gov/validating-expanding-claims-based-algorithms-frailty-functional-disability-value-based-care-payment*).

Comment: A commenter highlighted the importance of using clinician-led clinical data registries, in addition to the comprehensive Medicare claims data, to support the development of meaningful cost measures.

Response: We have concerns about the feasibility of calculating cost

measures that use clinical registry data as part of their construction and the potential unintended consequences of excluding certain clinicians and beneficiaries if registry data is not available. To ensure that cost measures incorporated into MIPS are meaningful, measures submitted for CMS consideration would be evaluated for potential use against the standards for measure construction and criteria outlined in section IV.A.3.d.(2)(c)(iii) of this rule, such as whether the measure has been tested for reliability and validity.

Comment: A few commenters stated that specialty societies should be involved in the proposed measure development process. One stakeholder suggested that all specialty societies that would benefit from the new measures should be involved in the development process, while another encouraged CMS to partner with specialty societies similar to the current cost measure development approach.

Response: We encourage specialty societies that are interested in cost measure development to coordinate and engage with other societies that may have common expertise in cost measure concepts. This process for cost measure development is separate from CMS' current approach where a cost measure development contractor engages with specialty societies and other stakeholders.

Comment: One commenter requested more information on how CMS intends to use the prioritization criteria outlined in the proposed rule. The commenter also urged CMS to seek input from stakeholders on the measurement gaps in the MIPS cost performance category.

Response: We do not have any additional information on how we intend to use the prioritization criteria beyond what was proposed in the CY 2022 PFS rule (86 FR 39403). Regarding the stakeholder's second comment, we would apply the prioritization criteria to an environmental scan that would inform stakeholders of priority areas and suggested measures for development. This list would provide flexibility for stakeholder to then apply their own clinical expertise when determining the most important areas for measure development based on the measurement gaps identified by CMS. We also encourage stakeholder to reference the Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint* and the Meaningful Measures Framework at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page* for further guidance.

(iii) Standards for Measure Construction

Our current rigorous cost measure development process has included a series of standards that ensure measures are effective in assessing clinician cost performance within MIPS. These standards have been developed and vetted over time by a standing TEP and further refined through discussions with clinical subcommittees and clinician expert workgroups convened by the measure development contractor around areas of care and specific measures, respectively. For further detail, we refer readers to our detailed discussion of the measure development process and framework in response to stakeholder comments in the CY 2019 PFS final rule (83 FR 59770). To ensure that cost measures developed by stakeholders meet the same standards applied during the current measure development and testing process, we proposed to apply the following standards when considering stakeholder developed measures:

- Measures must assign services that accurately capture the role of attributed clinicians.
- Measures must have clear, ex ante attribution to clinicians.
- Measures must be based on episode definitions that have clinical face validity and are consistent with practice standards.
- Measures' construction methodology must be readily understandable to clinicians.
- Measures must hold clinicians accountable for only the costs they can reasonably influence.
- Measures must convey clear information on how clinicians can alter their practice to improve measured performance.
- Measures must demonstrate variation to help distinguish quality of care across individual clinicians.
- Measure specifications must allow for consistent calculation and reproducibility using Medicare claims data.

To implement these standards and to meet the methodology requirements of section 1848(r)(5) of the Act, we believe that it is necessary to ensure that measures within the cost performance category are consistent and share the same key features. Specifically, cost measures must be based on a standard set of measure components informed by the standards outlined above. These include: (1) Episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment.

Regarding item (1) episodes must be defined based on trigger codes for services, which are identifiable on Medicare claims, indicate the occurrence of the episode, and determine the patient cohort. Trigger codes must be based on services, and can incorporate diagnosis and other service information to define an episode. The patient cohort may be stratified into mutually exclusive stratifications (or ''episode sub-groups'') for meaningful clinical comparison to ensure that measures fairly compare clinicians with similar patient case-mix. Regarding item (2), episodes must be attributed to MIPS eligible clinician groups and clinicians who render the trigger services and are responsible for the patient's care and management. It is important that the attribution methodology allows for the most appropriate clinicians who have a significant role in a patient's care to be attributed and receive actionable feedback on their performance. Regarding item (3), all services that are clinically related to the attributed clinician's role in managing patient care must be included. This includes cases where the clinician can influence the frequency or intensity of services. The measure must include enough services to allow the measure to demonstrate that it captures variation in clinician performance. To address any potential concern around care stinting, the measure must cover a sufficiently long timeframe and broad enough services to capture downstream services. This includes expected follow-up care, rehabilitation, post-acute care (required if inpatient hospitalizations are included) and other support services, as well as complications, readmissions, and other consequences of care. Clinically unrelated services must not be assigned to the measure. Regarding item (4), measures must include applicable exclusions, which can be applied to the patient cohort or the episodes. Certain patients must be excluded for data cleaning or to ensure completeness of data. For example, patients who do not have Medicare as their primary payer or were not continuously enrolled in Medicare Parts A and B and not C must be excluded as we would not be able to observe their complete care. Certain episodes must be excluded to improve episode homogeneity and to remove unique groups of patients from the measure in cases where it may be impractical or unreasonable to compare the costs of caring for these patients to the costs of

caring for the measure cohort as a whole. Regarding item (5), measures must be adjusted for patient risk. Risk adjustment aims to isolate variation in clinician costs to only the costs that clinicians can reasonably influence by accounting for risk factors. The determination of an appropriate risk adjustment approach should be based on empirical testing. A base risk adjustment model must include standard risk adjustors (Hierarchical Condition Category [HCC] codes, interaction variables for certain comorbidities, age, disability status, end-stage renal disease status, recent use of institutional long-term care), as well as additional measure-specific risk factors. Finally, measures must include payment standardized claims data.

We have outlined in section IV.A.3.d.(2)(b)(iii) of this final rule a new methodological framework for assessing the cost of care for chronic conditions. This new chronic condition framework meets all the standards we outline above, and could serve as a basis for chronic condition measures developed by stakeholders that would ensure consistency with other MIPS measures. We proposed to apply the standards for measure construction and measure components outlined above when considering stakeholder-developed measures to ensure that these measures follow the same standards as cost measures currently used in MIPS.

We solicited public comments on our proposed standards for measure construction and measure components, as well as the challenges that stakeholders may encounter in the development of cost measures along with any resources that would assist stakeholders in development.

The following is a summary of the comments we received and our responses.

Comment: One commenter specifically expressed support for the proposed standards for measure construction and measure components.

Response: We thank the commenter for their support.

Comment: One commenter pointed out the lack of flexibility in the approach to develop cost measures, as under the proposed Standards for Measure Construction and the Measure Prioritization Criteria, measure developers would be constrained by the structure and scope of existing cost measures.

Response: We believe that it is important for cost measures to share key common features for consistency within the performance category. These features have been identified through extensive stakeholder input as being essential for cost measures to accurately reflect care within the reasonable influence of the attributed clinician; this in turn is essential for clinicians to be able to make practice changes for cost improvement. Having consistency across cost measures is important to make it easier for stakeholders to understand how they are being assessed on cost and guards against the risks and unintended consequences that would result from creating different standards for similar types of care. We believe that establishing standards and criteria helps provide clarity for stakeholders before they begin development, and that this approach achieves an appropriate balance between the goal of a coherent cost measure inventory and encouraging innovative ways of assessing clinicians on cost performance.

Comment: One commenter urged CMS to use common episode definitions across MIPS cost measures and information required by price transparency regulations. This would provide consistent information to clinicians and patients.

One commenter requested that episodes use more comprehensive definitions by looking at care from the perspective of the patient, rather than charges under the control of a single clinician. They also emphasized the importance of the team-based nature of care, and stated that shared accountability for care should be encouraged by cost measures.

Response: The episode-based measures include the cost of services furnished by clinicians providing care that is related to the condition or procedure being measured. That is, an episode for a knee arthroplasty procedure could include the cost of the surgery performed by the orthopedic surgeon, anesthesia services provided by an anesthesiologist or CRNA, the cost of walking aids to assist with recovery, and physical therapy services provided by a physical therapist to help regain function. By including these services, the attributed clinician is incentivized to coordinate with these members of the care team in providing care for the patient. In these instances, common episode definitions would not be appropriate because episode-based measures require episodes specific to the condition or procedure. However, the total per capita cost and Medicare Spending Per Beneficiary Clinician measures do address the concern that there should be a more comprehensive definitions of cost; these measures are designed to be a global cost measure where a clinician is responsible for the costs of all services provided to a patient. We therefore believe that there is an important role for both global or population-based cost measures and episode-based cost measures as they have different yet complementary measure intents. Finally, given that the price transparency regulations are newly implemented, we will continue to assess the potential ways to align cost measures and the price transparency regulations.

Comment: One commenter encouraged CMS to add two standards for cost measure construction: Actionability and alignment of cost and quality. The commenter also stated that field testing must be conducted as part of the measure development process, and encouraged CMS to minimize the number of cost measures that is in development at one time, to ensure stakeholders are able to comprehensively review the measures being developed.

Response: We believe that the standards we would apply when considering stakeholder developed measures ensure that the measures implemented in MIPS would be actionable, by requiring the methodology to be understandable and that the developers convey clear information on how clinicians can improve their performance. In addition, submissions to the MUC list require measure developers to demonstrate a measure's actionability (please see section IV.A.3.d.(2)(c)(iv) for more information on MUC submission criteria). Additionally, one of the measure construction criteria is alignment with quality measures and improvement activities to ensure meaningful assessments of value. We agree that field testing is an important step in assessing newly developed measures and gathering feedback from stakeholders. We have worked to improve our field testing materials and outreach so that stakeholders can more easily understand the measures and provide meaningful feedback. We will take your suggestion to limit the number of cost measures in development at one time into consideration for future measure development cycles.

(iv) Cost Measure Submission to the Measures Under Consideration (MUC) List and Development Support

We proposed that cost measures developed by stakeholders for potential use in MIPS would undergo the pre-rulemaking process described in section 1890A(a) of the Act. More details on the pre-rulemaking process can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.* As with the process for the

call for quality measures, we proposed that the submission process for cost measures developed by stakeholders would begin with a Call for Cost Measures, where stakeholders would be invited to submit their candidate cost measures. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53635 through 53637) for details on the process for quality measure submissions and selection. During the Call for Cost Measures period, we would organize webinars and office hours to provide stakeholders with information about the process and be available to answer questions. We would also provide templates of written materials, such as the measure codes lists for stakeholders to use. At the end of this period, stakeholders would submit their candidate measures for review by completing the required data fields required for submission to the MUC list and if approved, measures would be placed on the final MUC List, which we publicly post on December 1 of every year. Measures submitted to the MUC List must be fully specified and tested for reliability and validity.

Submissions to the MUC list must include all required information and would be reviewed against a set of inclusion criteria identified below to determine whether they should be considered for use in MIPS. The inclusion criteria for cost measures developed by stakeholders are based on the criteria outlined in the MUC List submission template, as well as relevant criteria that the MIPS quality performance category follows as indicated in the CY 2020 PFS final rule (84 FR 62953 through 62954). For purposes of our review, we proposed that stakeholders who wish to submit measures must submit measure specification information, testing results, and related research to address the following inclusion criteria:

- *Applicable:* There is clinical coherence and comparability in clinician treatment; measures ensure alignment with quality indicators.
- *Feasible:* Measures use Medicare claims data; there is a high degree of data completeness and limited frequency of missing data.
- *Scientifically acceptable:* measures are clinically valid assessments of cost performance; testing is available for reliability at different case minima; beta testing and statistical testing are conducted.
- *Not be duplicative of existing measures:* measures assess opportunities and gaps based on CMS priorities and goals; there is an assessment of duplicate measures to see which would be the better measure.
- *Fully developed:* measures are fully developed and ready for implementation at the time of submission.
- *Consistent:* the measure is constructed using a methodology to assess resource use that is consistent with sections 1848(r)(2) through (5) of the Act, consistent with other MIPS cost measures.
- *Fulfill a clinical performance gap:* environmental scans and literature reviews show evidence for measures, performance gaps, and opportunities for improvement; there is evidence for measures' impact and importance to MIPS.

We solicited comments on this proposed approach, and challenges stakeholders may encounter in the development of cost measures.

The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for holding cost measures to the same review and submission process (that is, the pre-rulemaking process submission) as the quality measures.

Response: We thank the commenter for their support.

Comment: A few commenters expressed concerns that the outlined proposal does not address the obstacles faced by potential measure developers, mostly noting the challenges in obtaining the necessary data. Several other commenters requested that CMS provide greater development support, also around data access. One commenter believed the proposal would not be successful at creating cost measures for MVPs starting in 2025 as the process would be time-consuming and burdensome.

Response: We appreciate the interest in cost measure development. The proposed process for cost measure development by stakeholders is intended to align with the process that has been available to developers of quality measures. The public can access Medicare claims data through the process described on the CMS ResDAC website at *https://resdac.org/research-identifiable-files-rif-requests.* ResDAC's process has multiple safeguards in place to protect the sensitive data that is available for researchers. Stakeholders also have access to the Physician and Other Supplier Public Use Files (Physician and Other Supplier PUFs), which contain information on procedures and services provided to Medicare patients by physicians and other healthcare professionals in a given year.

After consideration of public comments, we are finalizing the process for cost measure development by stakeholders as proposed.

(d) Substantive Changes Criteria for Cost Measures

On an annual basis, we review the MIPS measures that have been adopted and consider updates to the cost measures. Changes to measures are an important part of the measure maintenance process to ensure that measures are continuing to function as intended, and may be substantive or non-substantive. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive changes to quality measures to be proposed and identified through notice-and-comment rulemaking. Although this section of the Act does not establish this requirement for cost measures, we believe that similar considerations should apply to cost measures. As discussed in prior rulemaking, examples of non-substantive changes to cost measures include maintenance changes such as updated diagnosis or procedure codes or changes to existing exclusions to the patient populations or definitions, while substantive changes to a measure are changes that result in what are considered new or different measures (83 FR 59767 and 84 FR 62961). As we evaluate existing cost measures to determine whether such measures need to be updated, we believe that it is important to establish criteria for determining whether a measure change is substantive. Thus, we proposed to establish several criteria for determining whether a cost measure change is substantive starting with the MIPS CY 2022 MIPS performance period/2024 MIPS payment year. The criteria include, but are not limited to, the following:

- Whether the change modifies the premise and/or objective of the measure;
- Whether the change modifies the scope of the measure (such as patient population eligible for the measure or a new category of costs); and
- Whether the change to the measure calculation significantly impacts how a measure is assessed.

Certain changes to a measure may affect multiple elements of a measure, requiring an overall assessment of the measure specifications. The following are some examples of potential substantive and non-substantive changes:

- *Measure objective:* The measure objective refers to what is being assessed; in general, changes to the measure objective would be considered substantive. The question of what is being assessed can generally be thought of as: What type of care is the measure

assessing, who is providing this care, and who is in the patient cohort. Specifically, under this criterion, a change to the measure objective could include updates to the triggering logic, measure exclusions, attribution rules, or other aspects of the specifications. While the effect of such updates may also be relevant while considering whether the change is substantive or not, the effect is secondary to the intention behind changes to the measure. Consider the following example: A hypothetical episode-based measure focuses on major joint repair, and is updated to cover all joint procedures by adding a range of trigger codes. This likely would be a substantive change, as the measure would be evaluating different joints and procedures than the initial measure objective.

- *Types of Costs being Assessed:* In general, new rules about which costs are being captured by a measure would be considered substantive if they change which categories or types of costs are included in a measure, and non-substantive if they merely refine how an existing category is captured. For example, a change to an episode-based measure's service assignment rules which adds a new category of costs (for example, adding Part D costs to a measure that did not previously include any Part D costs) likely would be a substantive change. By contrast, a measure update to reflect new codes for existing types of codes, for instance, where a code is split into sub-codes for greater granularity, likely would be considered non-substantive.
- *Risk Adjustment:* The purpose of risk adjustment is to account for factors outside of the clinician's or clinician group's reasonable influence. In certain cases, it is necessary to make changes to the risk adjustment model and/or individual risk adjustors to ensure that the risk adjustment approach is working as intended. Generally, changes to risk adjustment variables and the mechanics of the regression would be considered non-substantive if they continue to give effect to the measure's intent. However, some changes to the risk adjustment approach may be substantive, such as changes to the type of risk adjustors used (for example, the addition of non-claims-based variables when the model previously only used claims-based data), or changes to the stratification that modify the interpretation of what the measure score represents.

We note that there are degrees in any evaluation of whether a change is substantive. For instance, there may be important differences in the effect of adding one service or code compared to a suite of services and codes that we would also consider as part of determining whether a change is substantive or not. We believe the proposed substantive change criteria for cost measures would help us to determine whether a change to a cost measure should be made through notice-and-comment rulemaking before it is implemented in MIPS. We solicited public comments on our proposed criteria for determining whether a change to a cost measure is substantive.

The following is a summary of the comments we received and our responses.

Comment: Two commenters agreed with an approach for evaluating substantive changes to cost measures, and one commenter stated that substantive changes (for example, updates to the risk adjustment methodology) must go through the pre-rulemaking and rulemaking processes. The commenter also suggested that a contractor may facilitate this process. Finally, the commenter emphasized that service assignment codes and other measure elements should be reviewed annually.

Response: We appreciate the commenters' support for this proposal. Currently, contractors can facilitate the process for evaluating substantive changes. All cost measures undergo a measure maintenance process that includes annual updates, and comprehensive re-evaluation to ensure that measures continue to meet program goals and priorities. Annually, CMS reviews measures to identify potential updates and assess the nature of these updates to determine the appropriate process for implementing substantive and non-substantive changes. These updates take into consideration any changes in payment policies or clinical practices, as well as empirical data. The comprehensive re-evaluation process occurs on a 3-year cycle, aligning with the CMS Blueprint for measure development. This process draws upon input from clinician experts to identify any thorough updates that may be required to address stakeholder concerns raised during annual maintenance or to make refinements to the measure set.

Comment: One commenter also encouraged CMS to conduct a year-to-year analysis examining the impacts on performance scores that occurred because of a substantive change versus the actual changes in performance.

Response: We appreciated the commenter's request to conduct an analysis to examine the impacts on performance scores that occurred due to a substantive change versus the actual changes in performance, and note that we do conduct analyses that compare year-to-year changes to cost measures as part of regular monitoring.

After consideration of public comments, we are finalizing the criteria for determining whether a cost measure change is substantive as proposed.

The previously established and finalized measures for the cost performance category for the CY 2022 performance period/2024 MIPS payment year and future periods are summarized in Table 54.

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TABLE 54: Summary Table of Cost Measures for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Performance Periods

Measure Topic	Measure Type	Measure Status
Total Per Capita Cost	Population-Based	Currently in use for 2022 Performance Period and Beyond
Medicare Spending Per Beneficiary Clinician	Population-Based	Currently in use for 2022 Performance Period and Beyond
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Knee Arthroplasty	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Screening/Surveillance Colonoscopy	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition episode-based	Currently in use for 2022 Performance Period and Beyond
Simple Pneumonia with Hospitalization	Acute inpatient medical condition episode-based	Currently in use for 2022 Performance Period and Beyond
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition episode-based	Currently in use for 2022 Performance Period and Beyond
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Elective Primary Hip Arthroplasty	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Femoral or Inguinal Hernia Repair	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Hemodialysis Access Creation	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition episode-based	Currently in use for 2022 Performance Period and Beyond
Lower Gastrointestinal Hemorrhage *(at group level only)*	Acute inpatient medical condition episode-based	Currently in use for 2022 Performance Period and Beyond
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Lumpectomy, Partial Mastectomy, Simple Mastectomy	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Renal or Ureteral Stone Surgical Treatment	Procedural episode-based	Currently in use for 2022 Performance Period and Beyond
Melanoma Resection	Procedural episode-based	Finalized for 2022 Performance Period and Beyond
Colon and Rectal Resection	Procedural episode-based	Finalized for 2022 Performance Period and Beyond
Sepsis	Acute inpatient medical condition episode-based	Finalized for 2022 Performance Period and Beyond
Asthma/Chronic Obstructive Pulmonary Disease (COPD)	Chronic condition episode-based	Finalized for 2022 Performance Period and Beyond
Diabetes	Chronic condition episode-based	Finalized for 2022 Performance Period and Beyond

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(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 through 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), and the CY 2021 PFS final rule (85 FR 84881 through 84886). We also refer readers to §§ 414.1305 for the definition of improvement activities and attestation, 414.1320 for the performance period, 414.1325 for the data submission requirements, 414.1355 for the improvement activity performance category generally, 414.1360 for data submission criteria, and 414.1380(b)(3) for improvement activities performance category scoring.

We proposed in the CY 2022 PFS proposed rule (86 FR 39405 through 39409) for the CY 2022 performance period and future years: (1) To revise group reporting requirements for the 50 percent threshold to address subgroups; (2) to revise the timeframe for improvement activities nominated during a PHE; (3) to revise the required criteria for improvement activity nominations received through the Annual Call for Activities; (4) to suspend activities that raise possible safety concerns or become obsolete from the program when this occurrence happens outside of the rulemaking process; (5) to add 7 new improvement activities, modify 15 existing improvement activities, and remove 6 previously adopted improvement activities; (6) to revise the ''Drug Cost Transparency to include requirements for use of real-time benefit tools'' improvement activity; and (7) to add the COVID–19 ''Clinical Data Reporting with or without Clinical Trial'' improvement activity.

(b) Group Reporting

In the CY 2020 PFS final rule (84 FR 62981 through 62988), we revised § 414.1360(a)(2) to state that, beginning with the CY 2020 performance period, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance period.

In the CY 2021 PFS final rule (85 FR 84844 through 84849), we finalized to update the MIPS Value Pathways guiding principle #2 as follows: ''2. MVPs should include measures and activities that will result in providing comparative performance data that is valuable to patients and caregivers in evaluating MIPS eligible clinician performance and making choices about their care; MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.''

In the CY 2022 PFS proposed rule (86 FR 39372 through 39373), we proposed the details of subgroup reporting for MVPs, and we refer readers to section IV.A3.b.(2) of this final rule for further details regarding the adoption of such policies. We noted in the proposal that, in order to implement group requirements in relation to subgroup reporting, we must modify our policy regarding group reporting for improvement activities. We stated our belief that a 50 percent threshold is achievable and appropriate because, if a group or virtual group has implemented an improvement activity, the activity should be recognized and adopted throughout much of the practice to improve clinical practice, care delivery, and outcomes (86 FR 39405). Similarly, we stated that it makes sense to allow subgroups to perform and attest to their improvement activities separately and apply the 50 percent threshold within their subgroup. Therefore, we proposed to revise § 414.1360(a)(2) to state that, beginning with the CY 2022 performance period, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance period.

Over the past year, we have received many inquiries through the Quality Payment Program help desk [243] requesting clarification on how to apply the 50 percent threshold to groups. Many clinicians requested that their groups be allowed to account for the 50 percent threshold by specialty or as subgroups as they have more in common than their groups when considering applicable improvement activities. We note that our proposal is responsive to these stakeholder requests because it provides the ability to attest to improvement activities at the subgroup level, including the ability to compose subgroups by specialty for reporting MVPs.

We received public comment on our proposal to revise § 414.1360(a)(2). The following is a summary of the comment we received and our response.

Comment: One commenter supported the proposal to ensure that subgroups have the same improvement activities reporting requirements as MIPS eligible clinicians in traditional MIPS. The commenter stated that aligning requirements ensures that MIPS eligible clinicians reporting through a subgroup are meaningfully contributing to an improvement activity rather than relying on others in the group to receive credit.

Response: We appreciate the commenter's support of this proposal.

After consideration of the public comment, we are finalizing this policy as proposed.

(c) Improvement Activities Inventory

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory (81 FR 77817 through 77830) consisting of approximately 95 activities. We took several steps to ensure the Inventory was inclusive of activities in line with statutory and program requirements. We discussed that we had conducted numerous interviews with highly performing organizations of all sizes, and had conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category, including the patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), CAHPS surveys, and AHRQ's Patient Safety Organizations. In addition, we reviewed the CY 2016 PFS final rule with comment period (80 FR 70886) and the comments received in response to the MIPS and APMs RFI regarding the improvement activities performance category.

For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities

[243] The Quality Payment Program help desk tracks, documents, and resolves inquiries submitted by MIPS eligible clinicians and groups. Stakeholders may submit inquiries to the help desk via 1–866–288–8292 (Monday–Friday 8 a.m.–8 p.m. ET) or email *QPP@cms.hhs.gov.*

Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including the requirement to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing improvement activity, the stakeholder must submit a nomination form available at *www.qpp.cms.gov* during the Annual Call for Activities.

(A) Timeframe for the Annual Call for Activities

We refer readers to the CY 2019 PFS final rule (83 FR 59781 through 59782) for our most recent policies with respect to the timeframe for the Annual Call for Activities. We did not propose any changes to this policy for CY 2022. However, we refer readers to section IV.A.3.d(3)(c)(i)(B)(aa) of this final rule where we adopt changes to the timeframe for nominating new improvement activities during a PHE.

(B) Changes for Nominating New Improvement Activities

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77190), the initial improvement activities Inventory was not based on established criteria. Rather, it was compiled via stakeholder input; an environmental scan; MIPS and APMs RFI comments; subsequent working sessions with AHRQ and ONC; and additional communications with CDC, SAMHSA, and HRSA. In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory. We stated that we would use the criteria when selecting measures for inclusion in the program. In the CY 2019 PFS final rule (83 FR 59778 through 59779), we adopted one new criterion and removed a criterion from the improvement activities nomination criteria. We also clarified our considerations in selecting improvement activities. In the CY 2022 PFS proposed rule (86 FR 39405 through 39408), we proposed: (1) Changes to the timeframe for improvement activities nomination during a PHE; (2) two new improvement activities criteria; (3) to increase the required minimum number of criteria that must be met for improvement activities nominations; and (4) to separate required from optional criteria for improvement activities nominations. These proposals are discussed in detail below.

(aa) Changes to the Timeframe for Nominating New Improvement Activities During a PHE

In the CY 2021 PFS final rule (85 FR 84882 through 84883), we finalized an exception to the Annual Call for Activities providing that, during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1 through July 1 each year, we adopted a policy to accept nominations for the duration of the PHE, as long as the improvement activity is still relevant. No other aspect of the Annual Call for Activities process was affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies all still apply). We noted that we continue to believe that it is important for stakeholders to be able to comment on improvement activities. Therefore, any improvement activity related to the PHE considered for inclusion in the Inventory will need to be finalized through rulemaking.

In 2020, we used several IFCs to propose necessary policies due to the PHE for COVID–19, including adding and modifying the COVID–19 Clinical Data Reporting with or without Clinical Trial (IA_ERP_3) for implementation in the same year. However, we want to be clear that we are not limited to implementing policies through IFCs, and those vehicles may not be the most timely or feasible for a particular situation. In a typical year, we use various fiscal and calendar year rules to implement policy (for example, the IPPS, Inpatient Psychiatric Facility Prospective Payment System (IPF PPS), OPPS, etc. rules). In order to best operationalize our policy for improvement activities nominated during a PHE, we proposed to modify our policy such that these nominations should be submitted by January 5 of the year in which the activity is targeted for implementation, unless otherwise specified by CMS, in order to maximize the chance that a potential improvement activity could be implemented in the same year via the most timely rulemaking vehicle.

We received public comments on our proposal regarding the improvement activities nominations received during a PHE. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' proposals for nominating new improvement activities during the national PHE for COVID–19.

Response: We appreciate the support of commenters.

After consideration of public comments, we are finalizing this policy as proposed.

(bb) Currently Adopted Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule (82 FR 53660), we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria: Stakeholders should apply one or more of the below criteria when submitting nominations for improvement activities. In addition, in the CY 2019 PFS final rule (83 FR 59779) we added a ''public health emergency as determined by the Secretary'' criterion, and in the CY 2021 PFS final rule (85 FR 84883 through 84884) we added an ''Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible'' criterion. The current criteria are listed below.

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;

- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible;
- Include a PHE as determined by the Secretary; or
- CMS is able to validate the activity.

(cc) Proposed Two New Criteria

We proposed two new criteria beginning with the CY 2022 Annual Call for Activities MIPS improvement activities: Activities (1) should not duplicate other improvement activities in the Inventory; and (2) should drive improvements that go beyond standard clinical practices. Regarding the first proposed criterion, we believe that there should not be duplicate activities in the Inventory as MIPS eligible clinicians could get double credit for doing the same activity. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77185), while the minimum reporting period for one improvement activity is 90 days, the maximum frequency for which an improvement activity may be reported is once during the 12-month performance period. It is important that stakeholders review the current Inventory to ensure there is not a broader improvement activity that MIPS eligible clinicians could attest to for the same activity. Regarding the second proposed criterion, we believed that improvement activities should drive improvements that go beyond standard clinical practices and should be innovative, to have the potential for significant patient benefit when MIPS eligible clinicians learn and implement the activities.

We received public comments on our proposal regarding the two new criteria for considering new improvement activities. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the addition of these additional criteria stating that they believe the new criteria will ensure high quality improvement activities. Many commenters supported the proposal of two new criteria, agreeing that new improvement activities should not be duplicative.

Response: We appreciate the support of these commenters.

After consideration of public comments, we are finalizing this policy as proposed.

(dd) Minimum Requirement

We have received feedback from stakeholders through the Annual Call for Activities process and during the CY 2021 PFS rulemaking process that the nomination acceptance process is unclear, stakeholders are frustrated by nominating improvement activities that are not accepted, and our reasoning for not accepting their nominations is not clear.

Our current policy requires that stakeholders apply one or more of the established criteria when submitting a nomination through the Annual Call for Activities process for a new improvement activity (82 FR 53660). Through past Annual Calls for Activities, we have found that many of the nominations that we receive meet the minimum one criterion, but are not appropriate for inclusion in the Inventory for other reasons. We often receive submissions describing practices that are standard and submissions that are too specific to a particular specialty. We believe that when evaluating nominations, we should use multiple factors in deciding on the selection of submitted improvement activities, not all of which can be listed up front. Ultimately, we must rely on our internal processes and expertise in determining whether or not a nominated improvement activity meets the criteria and needs of the program. However, in an effort to increase transparency, we have reevaluated our criteria and believe there are a number of significant criteria that improvement activity proposals should meet to be included in the Inventory. Therefore, beginning with nominations submitted during the 2022 nomination period for the Annual Call for Activities, we proposed to increase the number of criteria stakeholders are required to meet when submitting an activity proposal, from a minimum of one to eight criteria, which include the two newly adopted criteria described in section IV.A.3.d(3)(c)(i)(B)(cc) of this final rule.

We believed that the following eight criteria, six of which are on the current list and two of which were proposed (in italics), should be the foundation for all improvement activities:

1. Relevance to an existing improvement activities subcategory (or a proposed new subcategory) (82 FR 53660);
2. Importance of an activity toward achieving improved beneficiary health outcomes (82 FR 53660);
3. Feasible to implement, recognizing importance in minimizing burden, including, to the extent possible, for small practices, practices in rural areas, or practices in areas designated as geographic HPSAs by the Health Resources and Services Administration (HRSA) (82 FR 53660);
4. Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes (82 FR 53660);
5. Can be linked to existing and related MIPS quality, Promoting Interoperability, and cost measures as applicable and feasible (85 FR 84884);
6. CMS is able to validate the activity (82 FR 53660);
7. *Does not duplicate other improvement activities in the Inventory;* and
8. *Should drive improvements that go beyond purely common clinical practices.*

When we previously finalized the first six criteria in prior rulemakings, we did not specifically require activity nominations to meet all the criteria. In crafting this proposal, we noted that we are seeking to minimize improvement activity nominations that do not meet program standards and to increase nominations that will substantively contribute to improved patient care and outcomes.

We also considered whether any of the above proposed required criteria should be optional (see section IV.A.3.d(3)(c)(i)(B)(cc) of this final rule). Ultimately, we proposed that the above criteria should not be optional because we believe these reflect the minimum standard for improvement activities in the Inventory and will help increase transparency in our decisions.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

(ee) Optional Factors

We proposed that the remaining six previously established factors would serve as optional factors beginning with nominations submitted during the 2022 nomination period for the Annual Call for Activities as we believe they may be relevant to certain nominations, but not all. We stated that meeting one or more of the optional factors may increase a nomination's chances of being added to the Inventory. The proposed optional factors were:

1. Alignment with patient-centered medical homes (82 FR 53660);
2. Support for the patient's family or personal caregiver (82 FR 53660);
3. Responds to a PHE as determined by the Secretary (83 FR 59779);
4. Addresses improvements in practice to reduce health care disparities (82 FR 53660);
5. Focus on meaningful actions from the person and family's point of view (82 FR 53660); and
6. Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for

example, primary care, specialty care) (82 FR 53660).

The following is a summary of the comments we received and our responses.

Comment: One commenter requested that CMS clarify what is considered ''standard clinical practice.'' Another commenter stated that the criteria of driving improvements that go beyond standard clinical practices might be unrealistic. They stated that if there are gaps in standard clinical practice that need improvement, those gaps should be addressed, particularly for members in niche specialties or particularly high risk or vulnerable populations. They believe that the current weighting system for Improvement Activities is sufficient to help MIPS eligible clinicians prioritize high weight activities that go beyond standard clinical practice.

Response: We thank the commenter for their perspective on standard clinical practice. We consider standard clinical practice to be the standard of care: Actions that all clinicians should do all the time as part of their care. Examples include obtaining an informed consent before surgery or counting instruments/suture needles at the end of a surgery to ensure nothing was left in the patient. We believe that improvement activities should drive improvements that go beyond the floor for competent clinical practices and should be innovative, in order to have the potential for significant patient benefit when MIPS eligible clinicians learn and implement the activities.

After consideration of public comments, we are finalizing these policies as proposed.

(C) Improvement Activity Removal

In the CY 2020 PFS final rule (84 FR 62988 through 62990), we finalized the factors for consideration in removing improvement activities from the Inventory. Under this process, we fully examine each activity prior to its removal and commenters have an opportunity to provide their input during notice-and-comment rulemaking.

(aa) Improvement Activity Suspension Policy

We noted that a circumstance came to our attention that required us to examine the specifics of the improvement activities removal of activities policy in relation to the performance period. Following the publication of the CY 2021 PFS proposed rule, we became aware that the underlying program for one of the improvement activities in the Inventory had expired on March 31, 2020. Therefore, MIPS eligible clinicians could no longer complete the activity from April 1 through December 31, 2020. To avoid any potential confusion or incorrect attestation, we removed this activity in the CY 2021 PFS final rule (85 FR 84885). We stated that this occurrence alerted us to the potential that other activities could become obsolete or be impacted by clinical practice guideline changes that affect the activity and could potentially result in patient harm, and that we may not learn about this information during the rulemaking timeframes. Because changes made in rulemaking do not apply until the following performance period, this timing could affect an improvement activity that needs to be urgently addressed.

As a result, beginning with the CY 2022 performance period, we proposed that in the case of an improvement activity for which there is a reason to believe that the continued inclusion raises possible patient safety concerns or is obsolete, we would promptly suspend the improvement activity and immediately notify MIPS eligible clinicians and the public through the usual communication channels, such as listservs and Web postings. We stated that we would then propose to remove or modify the improvement activity as appropriate in the next rulemaking cycle.

We received public comments on the improvement activity removal outside of the rulemaking cycle. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to suspend and remove improvement activities that the agency believes raise patient safety concerns or are obsolete.

Response: We thank commenters for their support.

Comment: One commenter stated that declaring an activity ''obsolete'' during the performance period seems inappropriate. There should be adequate review ahead of the start of the performance period to remove any improper activities. Another commenter questioned what would happen if a MIPS eligible clinician selects an improvement activity and begins implementation and later in the year the improvement activity is suspended.

Response: While it is not our preference to remove improvement activities during the performance period, despite our best efforts, we may become aware that an improvement activity is obsolete during the performance period. Therefore, we believe that it is necessary to be able to remove activities during the performance period—especially in situations where all or part of the improvement activity is not available for MIPS eligible clinicians to utilize. In instances where we do remove an improvement activity during the performance period, the MIPS eligible clinician completed the activity, they will still be able to attest for that activity and will not need to select a different improvement activity.

After consideration of public comments, we are finalizing these policies as proposed.

(ii) Changes to the Improvement Activities Inventory

(A) Background

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538), and Tables A, B, and C in the Appendix 2 of the CY 2021 PFS final rule (85 FR 85370 through 85377) for our previously finalized improvement activities Inventory. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2020* for a complete list of the current improvement activities. In this final rule, we are adding 7 new improvement activities, modifying 15 existing improvement activities, and removing 6 previously adopted improvement activities for the CY 2022 performance period and future years. We refer readers below and to Appendix 2 of this final rule for more details.

(B) Changes to Adopted Improvement Activities

(aa) Changes to the ''Drug Cost Transparency To Include Requirements for Use of Real-Time Benefit Tools'' Improvement Activity

In the CY 2020 PFS final rule (84 FR 63515), we adopted IA_BE_25, titled ''Drug Cost Transparency to include requirements for use of real-time benefit tools'' beginning with the 2020 performance year and for subsequent years. This activity description reads as follows:

To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the MIPS eligible clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s)).

Thus, this activity allows a RTBT to be one source of information for the pricing of pharmaceuticals, which provides to the prescriber real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary.

The 2021 Consolidated Appropriations Act (H.R. 116–133, Pub. L. 116–260) included section 119 in Division CC entitled ''Increasing the use of real-time benefit tools to lower beneficiary costs.'' Subsection (c) of section 119 includes a provision called ''Inclusion of Use of Real-Time Electronic Information in Shared Decision-Making Under MIPS.'' This provision amends section 1848(q)(2)(B)(iii)(IV) of the Act to require that this subcategory shall include as an activity, for performance periods beginning on or after January 1, 2022, the use of a RTBT as described in section 1860D–4(o) of the Act. In addition, the amendment provides that the Secretary may establish this activity as a standalone activity or as a component of another activity.

In accordance with this statutory requirement, we proposed to modify the IA_BE_25 improvement activity such that, beginning with the CY 2022 performance period and for subsequent years, the activity will require the use of an RTBT. As previously finalized, use of an RTBT was optional. We refer readers to Appendix 2 of this final rule for additional details regarding our adoption of this policy, including a summary of the comments received and our responses.

(bb) Changes to the COVID–19 Clinical Data Reporting With or Without Clinical Trial (IA_ERP_3) Improvement Activity

We refer readers to the March 31 IFC for COVID–19 (85 FR 19276 through 19277) and the September 2 COVID–19 IFC (85 FR 54848 through 54851) for a regulatory history of this improvement activity. In the September 2 COVID–19 IFC, we extended the modified COVID–19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the continued COVID–19 infections we were experiencing nationwide. We anticipated the need for COVID–19 clinical trials and data collection/sharing through registries to continue through CY 2021 at which time we will reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these types of data are not needed.

We again proposed to extend the COVID–19 Clinical Data Reporting with or without Clinical Trial improvement activity for the CY 2022 performance period and future years due to the continued COVID–19 infections we are experiencing nationwide and the need for further research. We stated that clinicians will continue to treat beneficiaries with COVID–19, and we anticipate the need for COVID–19 clinical trials and data collection/sharing through registries to continue, through CY 2022 and future years. For each year after 2022, we intend to reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these types of data are not needed. We believe that it is important for MIPS eligible clinicians to be able to attest to this improvement activity if it is still pertinent. Further, we believe that participation in this improvement activity is likely to result in improved outcomes by improving the collection of data that MIPS eligible clinicians use for the care of their patients as they monitor and manage COVID–19. We will continue to reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these types of data are not needed and will discontinue the activity through notice-and-comment rulemaking as needed. We also refer readers to Appendix 2 of this final rule for details regarding our adoption of this policy, including a summary of the comments received and our responses.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record technology (CEHRT) as a performance category under the MIPS. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category.

(b) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2021 PFS final rule at § 414.1320(g)(1) (85 FR 84886), for the 2024 MIPS payment year, and each subsequent MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the CY 2024 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within CY 2022, up to and including the full CY 2022 (January 1, 2022 through December 31, 2022). We did not propose any changes to the Promoting Interoperability performance category performance period that we established under § 414.1320(g)(1) (85 FR 84886).

(c) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

(A) Measure Background

We have adopted a Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing objective. For background on this measure, we refer readers to the CY 2019 PFS final rule (83 FR 59800 through 59803) and the CY 2020 PFS final rule (84 FR 62992 through 62994). In the CY 2021 PFS final rule (85 FR 84887 through 84888), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2021 performance period/CY 2023 MIPS payment year.

(B) State PDMPs' Progress and Previous Stakeholder Feedback

In the CY 2020 and CY 2021 PFS final rules (84 FR 62992 through 62994 and 85 FR 84887 through 84888), we described the concerns expressed by stakeholders that they believed it was premature for the Promoting Interoperability performance category to require the Query of PDMP measure and score it based on performance. In the CY 2022 PFS proposed rule (86 FR 39410) we discussed our support of efforts to expand the use of PDMPs, describing federally supported activities aimed at developing a more robust and standardized approach to EHR–PDMP integration, and additional discussions on the feedback we have received from health IT vendors and MIPS eligible clinicians thus far. For more detailed information, we refer readers to the CY 2022 PFS proposed rule (86 FR 39410).

(C) Measure Changes

Given current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), our ongoing review of alternative measure approaches, and stakeholder concerns about the current readiness across States for implementation of the existing measure, we believe that at least 1 more year is needed prior to potentially requiring the Query of PDMP measure.

While we appreciate the concerns that stakeholders have shared, we continue to believe that this measure can play an important role in helping to address the opioid crisis. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions. Maintaining this as an optional measure with bonus points signals to the MIPS eligible clinician and vendor community that this is an important measure to address a current gap that can help spur development and innovation in order to reduce barriers and challenges.

Therefore, in the CY 2022 PFS proposed rule (86 FR 39409 through 39410), we proposed to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 10 bonus points for the CY 2022 performance period/CY 2024 MIPS payment year. We received public comments on our proposal, and the following is a summary of the comments we received.

Comment: All commenters were supportive of our proposal to maintain the Electronic Prescribing Objective's Query of PDMP measure in the CY 2022 MIPS performance period/CY 2024 MIPS payment year as optional and worth 10 bonus points. One commenter shared that PDMP data has the capacity to improve patient care, and could aid in addressing the opioid crisis. A few commenters shared that 10 bonus points provides MIPS eligible clinicians enough incentive for participation.

Response: We acknowledge that the time required for State programs to advance EHR–PDMP integration may vary, and we will continue to collaborate with the Office of the National Coordinator for Health Information Technology (ONC) to develop additional approaches to sharing data with PDMPs. Finalizing this proposal provides at least 1 additional year for States and other stakeholders to make greater progress toward improving interoperability across systems.

Comment: Several commenters supported our proposal, but suggested that this measure should remain optional indefinitely, unless or until all States and EHRs share the same functional capabilities. Some commenters suggested that the measure remain as a ''yes/no'' attestation, rather than being considered as a numerator/denominator measure in the future.

Response: We thank commenters for sharing their suggestions for the Query of PDMP measure in the future. We believe the Query of PDMP measure will be a useful and informative measure as more State PDMPs and EHR systems are effectively integrated. We refer readers to the CY 2022 PFS proposed rule (86 FR 39410) for an overview of the key efforts aimed towards improving the technical approaches to EHR–PDMP integration, including the implementation of key provisions from the SUPPORT for Patients and Communities Act. We may take commenters' feedback under consideration in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to maintain the Query of PDMP measure as optional and worth 10 bonus points for the CY 2022 performance period/2024 MIPS payment year. The maximum total points available for the Electronic Prescribing Objective will remain at 20 points for the CY 2022 performance period/2024 MIPS payment year. Last, we received many public comments in response to our request for comment in the CY 2022 PFS proposed rule (86 FR 39410 through 39411) regarding the future of the Electronic Prescribing Objective's Query of PDMP measure. We thank commenters for this feedback and may consider this information to inform future rulemaking.

(ii) Changes to the Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

(A) Background

In the CY 2019 PFS final rule (83 FR 59812 through 59815), we renamed the Patient Electronic Access Objective to the Provider to Patient Exchange Objective, which includes the Provide Patients Electronic Access to Their Health Information measure. For more information about the Provide Patients Electronic Access to Their Health Information measure, we refer readers to the following preamble discussions in prior rulemaking: 84 FR 62995 and 62999 through 63000, 83 FR 59812, 82 FR 53674, 81 FR 77228, 80 FR 62841 through 62851, 77 FR 54007, and 75 FR 44353.

(B) Data Availability Requirement for MIPS eligible clinicians

The Provide Patients Electronic Access to Their Health Information measure requires, for at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT (84 FR 62999 through 63000 and 82 FR 53674). In the CY 2022 PFS proposed rule (86 FR 39411 through 39412), we proposed to modify this measure to require MIPS eligible clinicians to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician's CEHRT. MIPS eligible clinicians would be required to ensure this information remains available indefinitely (that is, not merely for a defined period of time). The proposed requirement would apply beginning with the performance period

in 2022, and would include all patient health information from encounters on or after January 1, 2016.

Currently, the Provide Patients Electronic Access to Their Health Information measure does not specify how long MIPS eligible clinicians are required to make patient data available, or to ensure that patient data remain available to patients in the event that a MIPS eligible clinician switches EHR vendors (81 FR 77228). In an effort to minimize stakeholder burden, we wanted to align the date under our proposal for making information about encounters available, with the date of service start date (January 1, 2016) as finalized in the Patient Access and Interoperability final rule (85 FR 25528), and as proposed for the Promoting Interoperability Program for eligible hospitals and CAHs in the FY 2022 IPPS/LTCH proposed rule (86 FR 25631). As an alternative to our proposal, we considered different encounter start dates, such as encounters on or after January 1, 2012, or encounters on or after January 1, 2019. We believed, however, that a requirement for MIPS eligible clinicians to ensure patient health information remains available indefinitely, as well as an encounter start date of January 1, 2016, would provide the most benefit to patients when accessing their health information as compared to the burden and costs to MIPS eligible clinicians implementing these proposed requirements.

We sought public comment on our proposal to modify the Provide Patients Electronic Access to Their Health Information measure, as well as the alternatives we considered and discussed above, and received the following comments.

Comment: One commenter supported our proposal, stating that the benefit to patients outweighs the burden to MIPS eligible clinicians.

Response: We would like to thank this commenter for their support, and agree that providing patients (or their patient authorized representatives) access to their data is beneficial.

Comment: Many commenters supported the principle that patients should have prompt access to their data with minimal effort, but did not support our proposal as it was proposed. Several commenters stated that the lack of clarity around key terminology was a main concern. Specifically, commenters requested additional clarification on how CMS is defining an ''indefinite'' timeline, what specific data would be included in ''all patient health information,'' and how we will address software platform changes and/or system updates given these terms. Last, many commenters asked that we provide exclusions for this measure to allow exceptions for those unable to meet the measure requirements, as exclusions were not discussed in the proposed rule.

Response: We agree that patients (or their patient authorized representatives) should have access to their data with minimal effort. We appreciate the requests from commenters requesting additional clarification on the terms used in the proposal, including ''indefinite'' and ''all patient health information''. We agree with commenters that we need to more clearly define what an ''indefinite'' timeline entails, as well as to more clearly define what specific data should be included in ''all patient health information.'' We agree with commenters that we need to consider defining and allowing for exclusions as well, with the understanding that there are varying limitations between eligible clinicians. We agree that as proposed, this modification needs additional clarification, and for these reasons, we are not finalizing this proposal at this time. In the future, we will be seeking additional feedback from MIPS eligible clinicians, in the event that we decide to propose changes to the measure in future rulemaking.

Regarding software platform changes, we would like to note that the ONC 21st Century Cures Act final rule established a new criterion, ''electronic health information export'' at 45 CFR 170.315(b)(10), which requires a certified health IT module to electronically export all electronic health information (EHI), as defined in § 171.102, that can be stored at the time of certification by the product of which the health IT module is a part (85 FR 25690 through 25693). A health IT developer of certified health IT products, which, at the time presented for certification electronically stores EHI, must certify such products to this new criterion and make these products available to their customers by December 31, 2023. We believe this certified functionality will further support the capability to seamlessly transfer electronic health information between systems.

Comment: A few commenters shared concerns regarding potential conflict between State laws and our proposed data availability requirement, and also potential conflict between State laws and our proposed requirement to make ''all patient health information'' available. One example shared by commenters is that different States have different requirements for data retention (mentioned were 7 and 10 years), as opposed to our proposal for an ''indefinite'' availability period. Another commenter shared that some States have laws requiring that physicians withhold certain patient health information from being released (specifically, California protected health information laws were shared), where our proposal included ''all patient health information,'' non-specific of any exclusions. Commenters have requested that CMS continue to work alongside ONC and the Patient Access and Interoperability teams to ensure that we address these discrepancies between State and Federal policy.

Response: We agree with commenters that we need to continue our collaborative efforts with the CMS Patient Access and Interoperability team and ONC as we consider how we might address these issues in future rulemaking. We also agree with commenters that we need to address varying data availability requirements between individual States, potential discrepancies between State and Federal policy, and ensure that we also account for State protected personal health information. For these reasons, we are not finalizing our proposal at this time. Instead, we may hold a listening session in the future where we welcome feedback as we continue to consider potential revisions to this measure amidst the feedback we have received.

Comment: Many commenters did not support our proposal but offered suggestions for CMS to consider. A few commenters suggested that CMS consider setting expectations on a forward-looking basis rather than taking a retrospective approach. Some commenters suggested that CMS consider working more closely with ONC to clearly distinguish between USCDI and the larger set of electronic health information as defined in the ONC Information Blocking rules. Another commenter requested that CMS ensure this policy is aligned with ONC's requirements for certified health IT. One commenter suggested that CMS allow for a rolling timeframe where 6 years' worth of data are maintained, but that those years not be fixed.

Response: We agree with the commenters' suggestions and will continue to collaborate with the CMS Patient Access and Interoperability team and ONC, especially regarding the feedback commenters shared above. We agree with commenters that it is important to distinguish between the data included in the USCDI, which is relevant to the Provide Patients Access to their Health Information measure, and the information included in the

electronic health information definition. We agree with commenters that additional work is essential on this proposal and will not be finalizing it at this time. As mentioned previously, CMS may hold a listening session in the future where we welcome additional feedback as we consider this measure for future rulemaking.

After consideration of the public comments we received, we are not finalizing our proposed modifications to the Provide Patients Electronic Access to Their Health Information measure. We wish to emphasize that CMS and HHS strongly believe that a patient's health information should remain available to the patient (or patient-authorized representative) through the technology currently required to successfully report on the Provide Patient Access to the Health Information measure. We will take commenters' suggestions under consideration and will seek further input as we consider whether to propose changes to the measure in future rulemaking.

(iii) Modifications to the Public Health and Clinical Data Exchange Objective

(A) Background

In the CY 2019 PFS final rule (83 FR 59795, 59815 through 59817), for the Public Health and Clinical Data Exchange Objective, we finalized that a MIPS eligible clinician must submit a yes/no response for two different public health agencies or clinical data registries for any of the five measures associated with the Public Health and Clinical Data Exchange objective (Syndromic Surveillance Reporting; Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; and Public Health Registry Reporting) to earn 10 points for the objective. Failure to report on two different public health agencies or clinical data registries or submitting a ''no'' response for a measure will earn a score of zero. If an exclusion is claimed for one measure, but the MIPS eligible clinician submits a ''yes'' response for another measure, they will earn the 10 points for the objective. If a MIPS eligible clinician claims exclusions for both measures they select to report on, the 10 points will be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective.

Effective responses to public health events, such as the COVID–19 pandemic, require fast, accurate exchange of data between health care providers and Federal, State, tribal, local, and territorial public health agencies (PHAs). Health care providers collect these data for patient care and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

While our current approach has encouraged health care systems to stand up some of these capabilities, significant gaps remain, and absent stronger incentives it will be difficult to stand up the comprehensive data exchange needed for future public health response. Thus, we believe that a more assertive approach is needed.

(B) Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective

We proposed in the CY 2022 PFS proposed rule (86 FR 39412 through 39414) to require two of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the performance period in CY 2022: Immunization Registry Reporting; and Electronic Case Reporting. Requiring these two measures will put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening two important public health functions: (1) Vaccine uptake; and (2) case surveillance. Requiring these measures will enable automated case reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies.

The following is a summary of the comments we received and our responses.

Comment: Many commenters agreed with the proposed modifications to the reporting requirements for the Public Health and Clinical Data Exchange Objective. They stated that the COVID–19 pandemic has underscored the value of consistent and high quality reporting of these public health measures and the proposed requirements would certainly greatly accelerate adoption of reporting for these measures. This regulatory requirement, in concert with the increased capabilities for such reporting, will better position the U.S. to identify and respond to current and future public health challenges. Another commenter agreed with the requirement of the Immunization Registry Reporting measure and the Electronic Case Reporting measure of the Public Health and Clinical Data Exchange objective stating that the recent pandemic has highlighted the need for immediate access to patient data for greater public health. A commenter supported our proposals stating that requiring those measures is an excellent step toward improving real-time, electronic data exchange from eligible clinicians to public health agencies. This will help ensure that public health and clinical communities collaborate as a unified health system to act quickly and keep our people safe and healthy.

Response: We thank commenters for their support and we appreciate their rationales.

Comment: One commenter agreed with the value of and need for public health data exchange, but added that public health registries and other mechanisms for data exchange have not been universally adopted because they are not integrated into physicians' clinical workflow and CEHRT does not have a user-centered experience for data submission and use of these registries. They added that the problem is not that physicians are unwilling to report to public health registries, but rather that the current process for doing so is overly burdensome and in some cases prohibitively expensive.

Response: We thank the commenter for their feedback, and understand that physicians and other clinicians are eager to report to public health agencies. The ONC Health IT Certification Program ensures that the health care provider's health IT is capable of capturing and reporting data to PHAs. Moreover, we note that the eCR Now application and platform offered by the CDC and other partners is designed so that it operates in the background of the EHR system, using information that is captured in the EHR as part of care delivery, and does not interrupt the clinician's workflow. Automating the generation and transmission of case reports electronically reduces the burden on health care providers to accomplish this reporting requirement. To learn more about ways that eCR Now works, please visit *https://www.cdc.gov/ecr/index.html.* We also remind readers that there are exclusions available for the Immunization Registry Reporting and Electronic Case Reporting measures (83 FR 35929 through 35930).

Comment: Some commenters did not support our proposal and urged CMS to consider allowing practices to attest to their choice of any two of the registries from the objective as the requirements are currently structured. One added that allowing practices to choose any two of the available registries would enable most practices to be able to attest without having to claim an exclusion.

Response: We believe that letting clinicians choose to report any two different public health agencies or clinical data registries for the Public

Health and Clinical Data Exchange objective is no longer effective in our current PHE environment. Further, both immunization reporting and electronic case reporting are both supported with corresponding ONC Certification Criteria (§ 170.315(f)(1) and (f)(5)) that were finalized in 2015. We proposed the modifications to better prepare the healthcare system and public health agencies for future health threats and long-term pandemic recovery by strengthening critical public health functions through the use of CEHRT.

Comment: Many commenters urged CMS to delay implementing the requirement to report on the Immunization Registry Reporting and Electronic Case Reporting measures. One stated that clinicians need at least a year to find, register, and implement reporting to a public health agency without penalty. Therefore, CMS should, at most, announce its intention of implementing this change but delay the implementation until the performance year 2023 to give clinicians adequate time to meet the new requirements.

Response: We do not believe that it is necessary to delay these requirements. We established multiple exclusions for each measure for those MIPS eligible clinicians who may not be able to report on these measures due to the scope of their practice (83 FR 59815). We also established three levels of active engagement which indicate the progress a clinician is making toward sending production data to a public health agency (80 FR 62863 through 62864). We remind readers of option 1, the first level of active engagement—Completed Registration to Submit Data (80 FR 62863 through 62864): The MIPS eligible clinician registered to submit data with the PHA or, where applicable, the clinical data registry (CDR) to which the information is being submitted; registration was completed within 60 days after the start of the MIPS performance period; and the MIPS eligible clinician is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows MIPS eligible clinicians to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. MIPS eligible clinicians that have registered in previous years do not need to submit an additional registration to meet this requirement for each MIPS performance period.

(aa) Immunization Registry Reporting Measure

Immunizations are considered one of the ten great public health achievements and have resulted in declines in cases, hospitalizations, deaths, and health care costs associated with vaccine preventable diseases.[244] The benefits and value of immunizations are realized when public policy, health systems, and community-based intervention efforts are working in coordination. Ensuring the coordination of these efforts can achieve high immunization coverage is dependent on the availability of timely, accurate, and complete information on vaccinations received by individuals in a population.

Immunization registries (also called immunization information systems, or IIS) are powerful tools that allow collaboration between vaccine providers and public health agencies and enable coordination of population-based interventions. Immunization registries are confidential, population-based, computerized systems that record all vaccination doses administered by participating health care providers for individuals residing within a particular jurisdiction. At the point of clinical care, an immunization registry can provide consolidated immunization histories to assist vaccine providers in determining appropriate patient vaccinations. At the population level, immunization registries provide data on vaccination coverage assessment and program operations and in guiding public health action to improve vaccination rates.

Currently, 50 States, the District of Columbia, eight island territories, and three cities (New York City, Philadelphia, and San Diego) operate an immunization registry. CDC provides technical assistance and nationwide leadership to all State immunization registries to ensure the optimal use of immunization registries for determining vaccination coverage at local, State, and national levels. Immunization registries already have connections in place to capture administered doses in real-time for a substantial portion of the population, a process accelerated over the last 10 years by the Medicare and Medicaid Promoting Interoperability Programs. According to data from the most recent CDC IIS Annual Report (2019) available, immunization registries currently hold demographics and immunization data on 95 percent of children 0–6 years, 82 percent of adolescents, and 60 percent of adults.[245] While each State Immunization registry currently coordinates with health care providers and EHR systems to achieve interoperability and facilitate immunization reporting, varying State reporting policies limit the completeness and timeliness of records in immunization registries and the optimal use of immunization registries for determining vaccination coverage.

We proposed in the CY 2022 PFS proposed rule (86 FR 39412 through 39413) to make the Immunization Registry Reporting a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the CY 2022 performance period/CY 2024 MIPS payment year as it is critical for understanding vaccination coverage both at the jurisdiction level and nationwide and identifying where additional vaccination efforts are needed. For more information about the Immunization Registry Reporting measure, we refer readers to the preamble discussion in prior rulemaking at 81 FR 77230. Making standardized reporting to an immunization registry a required measure will provide an immediate benefit by increasing the COVID–19 vaccination records reported to these systems. Making the measure required will also improve the data quality of records in immunization registries and facilitate use of immunization registries for clinical decision support and tracking of vaccine administration and distribution.

We believe that making the Immunization Registry Reporting measure required will increase the reporting of immunization data by health care providers to public health agencies. Making the measure required is also critical for the COVID–19 vaccination response because it will provide a better view of the vaccines administered and distributed at national, State and local levels. This is a function that immunization registries currently provide for all public vaccines, but is particularly important for COVID–19 vaccines. In addition to the COVID–19 vaccination response is the equally important need for routine vaccination coverage to increase. Fear of COVID–19 has caused deferrals of routine vaccinations as patients limit their interactions, including with their family doctors. More complete data in immunization registries as a result of the required measure will also optimize the use of immunization registries to determine who has not been vaccinated, pockets of under vaccination, and identifying where interventions should be focused for routine and emergency response vaccines. Requiring the measure will reduce the regulatory and

[244] Ten Great Public Health Achievements—United States, 2001–2010 (*cdc.gov*).

[245] *https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/2019-data.html.*

administrative burden health care providers experience when exchanging information with immunization registries.

We did not propose any changes to the description of the measure including any of the exclusions that we established in CY 2019 PFS final rule at 83 FR 59815 through 59817.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to require the Immunization Registry Reporting measure. One stated that significant strides have been made in immunization reporting throughout the PHE that have enabled those that previously lacked the resources to successfully report on this measure to now do so. Another commenter strongly supported our proposal and stated that immunization reporting plays a critical role in improving vaccination at the point of clinical care, at the population health level, and to help address the health disparities which have only worsened during the pandemic. They stated that requiring the Immunization Registry Reporting measure could: (1) Increase reporting of immunization data into a centralized jurisdiction-based system—thereby increasing patient data completeness and quality in immunization registry reporting, (2) facilitate better inter- and intra-State data sharing between other immunization registry reporting, health systems, and other HIT systems, and (3) improve vaccination uptake and health equity by determining areas of under vaccination.

Response: We thank commenters for their support and we appreciate their rationales.

Comment: A commenter suggested that prior to requiring immunization registry reporting, CMS should ensure there are exclusions available if there is not a State immunization registry available for providers. Additionally, CMS should survey the State immunization registries to determine if there is readiness at the State level to conduct this level of exchange.

Response: The following exclusion has been available to MIPS eligible clinicians since the CY 2019 performance period/CY 2021 MIPS payment year (83 FR 35929): ''Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.'' Every State, in addition to the District of Columbia, eight island territories, and three cities (New York City, Philadelphia, and San Diego), operate an immunization registry. State reporting policies and the capability to receive immunization-related data vary across jurisdictions. CDC provides financial and technical support to improve data exchange within each jurisdiction. CDC publishes the Immunization Information Systems Annual Report (IISAR) which provides an assessment of jurisdictions' efforts in developing, maintaining, and enhancing IIS activities for a given calendar year. CDC has developed an accompanying dashboard which allows the user to view a jurisdiction's performance according to 26 domains, including interoperability and clinical-decision making.

After consideration of public comments, we are finalizing our proposal to make the Immunization Registry Reporting a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the CY 2022 performance period/CY 2024 MIPS payment year.

(bb) Electronic Case Reporting

Health care providers are required by State law to report certain diseases and conditions, a process called case reporting, which provides PHAs with data on approximately 120 diseases and conditions of public health significance.[246] Case reporting is a vital and longstanding tool that PHAs use to prevent the spread of infectious diseases. Case reporting serves as early notification to PHAs for potential outbreaks and includes information that enables PHAs to start contact tracing and other prevention measures. Case reports also include critical clinical information that will not be included in syndromic surveillance or laboratory reporting, and can help to illuminate the impact of comorbidities, treatments, and variable access to care. Information from the case reports can be used to further work on social determinants of health and ensure equal access to preventative care across populations. Electronic case reporting is the automated, real-time, bidirectional exchange of case report information between EHRs and PHAs. Electronic case reporting uses standard codes to trigger the transfer of relevant clinical data to PHAs for case investigation and follow-up. As of March 2021, most States do not require electronic submission of case reports as part of their regulations and case reporting often occurs through outdated manual methods (for example, fax, email, or phone), which results in delays, underreporting, and incomplete or inaccurate case data. Manual case reporting also imposes burdens on health care providers, taking staff time away from patients to submit case reports and comply with State reporting requirements. Electronic case reporting allows health care providers to fulfill mandated public health reporting requirements without imposing additional burden and disrupting the clinical workflow. This automated data exchange facilitates faster and more efficient disease tracking, case management, and contact tracing. Electronic case reporting provides more timely and complete data than manual reporting, including data on demographics, comorbidities, immunizations, medications, occupation, and other treatments.

Recent efforts by the CDC have sought to significantly improve the effectiveness of electronic case reporting through eCR Now, a strategic initiative that allows for rapid adoption and implementation of electronic case reporting for COVID–19 (*https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html*). As part of this initiative, CDC and its partners have developed an eCR Now FHIR® application (app) to establish electronic case reporting capability in EHR systems. EHR vendors can also implement the eCR functionality within their products to accomplish this reporting. The initiative also supports an electronic case reporting infrastructure that is helping to advance interoperability. This infrastructure supports the transmission of electronic case reports to a shared service platform, and not directly to a PHA, which means that any health care provider that has established an electronic case reporting connection also has a connection with every State PHA, many large local health departments, and some territories. This promotes nationwide interoperability and increases the availability of data for patients who may be traveling or spending time away from their home State. For example, if a patient is a resident of one State but seeks care in another State, this infrastructure will automatically route the case report to both States that would have jurisdiction over this report. This increases inter-jurisdictional reporting, allowing for more seamless case investigation at the national level. The interoperable infrastructure and the use of a standard data format also reduces the variability of case report forms across conditions

[246] CSTE State Reportable Condition Assessment page: *https://www.cste.org/page/SRCA.*

and jurisdictions, streamlining reporting forms for EHR vendors and health care providers.

As a result of the CDC effort to scale up eCR for COVID–19, all 50 States, the District of Columbia, Puerto Rico and 13 large local jurisdictions have connected to the shared services platform and are currently receiving electronic case reports, with more than 9,400 healthcare facilities on board and 11.6 million reports for COVID–19 received by PHAs as of October 5, 2021.[247] The eCR infrastructure is designed to rapidly scale for PHEs, such as COVID–19, and it is enabled to currently support data transmission for 99 reportable and notifiable conditions. While these are significant advancements, the piecemeal approach of encouraging adoption of these tools by individual health care providers has not been an effective or efficient means to quickly scale this effort nationally as has been needed for the COVID–19 PHE response.

We believe the uneven adoption of electronic case reporting creates a public health vulnerability. We proposed in the CY 2022 PFS proposed rule (86 FR 39413 through 39414) to make the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the performance period in CY 2022. For more information about the Electronic Case Reporting measure, we refer readers to the preamble discussion in prior rulemaking at 81 FR 77229. We believe making this a required measure will accelerate development of electronic case reporting capabilities in EHR systems, reduce health care administrative burden of complying with State-mandated disease reporting requirements, provide regulatory clarity for EHR vendors, and improve the timeliness, completeness, and utility of case report data for PHAs. We believe that requiring the Electronic Case Reporting measure will be feasible and beneficial for MIPS eligible clinicians. This change will encourage EHR vendors to make electronic case reporting available to their customers, which will make adoption of this capability relatively straightforward for MIPS eligible clinicians. To meet the CEHRT definition when reporting on this measure, in our EHR Incentive Program Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62870 through 62885) we established that health care providers are required to use a health IT module certified to the ''Transmission to public health agencies—electronic case reporting'' certification criterion at § 170.315(f)(5) that relates to how the health IT uses structured data within an EHR to trigger or indicate the generation of an electronic initial case report.[248] They may then transmit the report in the manner specified by the case reporting requirements of the entity to which they are transmitting a report.

We believe that requiring the Electronic Case Reporting measure will not only provide certainty to EHR vendors and facilitate an organized and industry-wide rollout of electronic case reporting capabilities, but will also reduce burden on health care providers to fulfill their public health reporting requirements.

We did not propose any changes to the description of the Electronic Case Reporting measure and the exclusions that we established in the CY 2019 PFS final rule at 83 FR 59815 through 59817 will remain available.

The following is a summary of the comments we received and our responses.

Comment: One commenter reported that their State is not ready for electronic case reporting. The State, EHR vendors and the providers need more time to adopt the functionality required to do electronic case reporting.

Response: All 50 States, DC, Puerto Rico, and several local public health agencies currently receive eCR messages supported under the eCR Now Initiative, which can enable successful completion of electronic case reporting. Based on information from the CDC and their extensive engagement with public health agencies, many public health agencies are in the process of updating their websites to reflect their readiness for public health measurement requirements in the Promoting Interoperability Program, including electronic case reporting.

For a current list of PHA websites that provide their readiness to receive information please see ONC's Interoperability Standards Advisory (*https://www.healthit.gov/isa/appendix-iv-state-and-local-public-health-readiness-interoperability*). If a PHA does not declare readiness, then the MIPS eligible clinician can claim an exclusion for this measure.

Comment: One commenter stated that if CMS requires clinicians to report to an electronic case reporting registry then a national, State, and local listing of available case registries to report on would be extremely helpful for organizations/clinicians to reference, ensuring they are meeting the requirements of MIPS.

Response: Electronic case reporting is not submitting to a registry. Rather, electronic case reporting replaces the manual disease reporting by clinicians to State or local public health agencies required under State or local law with the automated, real-time exchange of case report information between EHRs and public health agencies.

Comment: Many commenters stated that their EHRs are not certified for electronic case reporting. A few commenters stated that this measure and the use of the certified capability were not previously required, and clinicians may be unable to adopt a newly certified capability in a timely way prior to the start of their performance period. Commenters stated that requiring the electronic case reporting measure may pose issues for clinicians who do not possess the certified functionality product for this capability and may have difficulty procuring and implementing one by CY 2022. Commenters stated that clinicians often have little control over the CEHRT capabilities available to them especially when they are provided their CEHRT by a larger parent organization.

A commenter urged CMS to not impose reporting obligations on clinicians before the technology can facilitate such reporting. Another commenter stated the proposed reporting requirements for clinicians will burden EHR developers. Specifically, the commenter stated that the time between when the CY 2022 PFS final rule is issued and the start of CY 2022 is insufficient for developers to certify and deploy a solution for electronic case reporting. The commenter stated that not all of their EHR developers' products are certified to electronic case reporting. The commenter stated that these developers would need to develop, test, certify, and then deploy a certified solution within just a few months. The commenter urged CMS to add an exclusion to the electronic case reporting measure for instances where a clinician's CEHRT is not certified to electronic case reporting at the beginning of the performance period.

Several commenters recommended that CMS consider adding an exclusion for this measure for instances where the clinician's CEHRT developer does not yet offer products that are certified for electronic case reporting. One commenter suggested a 1-year, limited

[247] Healthcare Facilities in Production for COVID–19 Electronic Case Reporting | CDC.

[248] For more information about this certification criterion, please see the Certification Companion Guide at *https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting.*

exclusion could maintain the primary benefits of requiring the electronic case reporting measure while ensuring clinicians do not fail to satisfy the requirements of the Promoting Interoperability performance category if they are not able to meet the electronic case reporting measure.

Response: We have consulted with ONC, and they report that certification to the criterion for electronic case reporting at § 170.315(f)(5) has increased significantly since the publication of the proposed rule, so we do not believe that lack of certification will be an impediment to successfully reporting the Electronic Case Reporting measure. As ONC clarified earlier this year,[249] for health IT developers that do not already support electronic case reporting, these capabilities can be certified to the certification criterion for ''Transmission to public health agencies—electronic case reporting'' at § 170.315(f)(5) by providing their ONC-Authorized Certification Body documentation that sufficiently describes how the health IT module meets the functional requirements of the criterion and/or documentation of electronic case reporting implementation using the eCR Now FHIR application and the ability to meet paragraph (i) of this criterion. Health IT developers are encouraged to visit the 2015 Edition Cures Update Certification Companion Guide page (*https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting*) for more information. With appropriate prioritization, we believe health IT developers can rapidly and successfully implement electronic case reporting capabilities.

While we believe that the adoption of certified technology for electronic case reporting by eligible clinicians is achievable in 2022, and that the active engagement requirements (80 FR 62863 through 80FR 62864) and existing exclusions of the measure (83 FR 59815 through 59817) offer significant flexibilities that can ensure most clinicians will be able to meet the measure or claim an exclusion, we acknowledge the commenters' concerns about technology and vendor readiness and clinicians potentially not being ready to report the measure due to the functionality not being certified. Rather than delaying or not finalizing the proposal to require the measure, we are establishing a new 1-year exclusion for the Electronic Case Reporting measure only for the CY 2022 performance period/CY 2024 MIPS payment year: the MIPS eligible clinician uses CEHRT that is not certified to the electronic case reporting certification criterion at § 170.315(f)(5) prior to the start of the performance period they select in CY 2022. By requiring the Electronic Case Reporting measure beginning with the CY 2022 performance period/CY 2024 MIPS payment year, but also adding a new exclusion for the CY 2022 performance period/CY 2024 MIPS payment year only, we will be able to: (1) Ensure health care providers that possess certified functionality adopt and implement this functionality before CY 2023; and (2) signal to EHR developers that they must prioritize adding electronic case reporting to their products to ensure their customers can report on the measure once the exclusion is no longer available.

We believe that the flexibility provided by this additional exclusion should provide ample time for MIPS eligible clinicians to implement electronic case reporting using available options and for health IT developers to ensure that they have successfully completed certification.

Comment: A commenter suggested that prior to requiring the adoption of electronic case reporting, CMS needs to engage with ONC, the CDC and the vendor community to gauge the ability for electronic case reporting to be implemented and utilized by the proposed deadline of CY 2022.

Response: CMS, ONC, and CDC have worked together to evaluate the readiness of the EHR developer community. There are many developers who are working towards implementing electronic case reporting capabilities and making those capabilities available to their clients. According to the Certified Health IT Product List (*https://chpl.healthit.gov/*) 93 products are already certified to the electronic case reporting certification criterion.

In addition, vendors can provide electronic case reporting to their clients using the eCR Now FHIR app which uses a suite of ONC-required standards and backend services that should be invisible to front-line clinicians. As discussed in a recent blog, ONC has provided clarification that EHR vendors who support the eCR Now FHIR app can be certified for electronic case reporting certification criterion by providing their ONC-Authorized Certification Body with appropriate documentation as specified in the technical explanations and clarifications.[250]

Comment: One commenter suggested that prior to requiring the adoption of electronic case reporting CMS should determine if States are willing to move towards electronic data exchange. Many State agencies continue to mandate manual reporting. If States continue to do this and CMS mandates electronic reporting, physicians will be burdened with the need to report in two different formats.

Response: All 50 States, DC, Puerto Rico, and several local public health agencies currently receive electronic case reporting messages. In addition, based on conversations that CDC has had with public health agencies, there is a limited period of time when public health agencies require clinicians to report by sending data through electronic case reporting and through traditional means (for example, manual reporting). Public health agencies have reported to CDC that they will use this time to make modifications to their data systems, onboard staff who can review the data, establish policies and processes for quality reviews, and ensure that their electronic feeds meet quality standards before they can turn off other forms of data transmission. We understand that this may place additional burden on MIPS eligible clinicians, and we know that many public health agencies are working on accelerating their processes to reduce the amount of time in parallel production. To help States reduce the amount of time that MIPS eligible clinicians need to spend doing dual reporting, CDC has invested heavily in helping public health agencies implement eCR. This funding will help public health agencies develop processes to turn off manual reporting processes and accelerate the quality review of the electronic feeds.

After consideration of public comments, we are finalizing our proposal to require the Electronic Case Reporting measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the CY 2022 performance period/CY 2024 MIPS payment year. We are also establishing an additional one-year exclusion for the Electronic Case Reporting measure for the CY 2022 performance period/CY 2024 MIPS payment year only: The MIPS eligible clinician uses CEHRT that is not certified to the electronic case reporting certification criterion at § 170.315(f)(5) prior to the start of the performance period they select in CY 2022.

[249] *https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting.*

[250] *https://www.healthit.gov/buzz-blog/health-it/federal-agencies-align-to-promote-public-health-reporting.*

(cc) Scoring of the Public Health and Clinical Data Exchange Objective

We proposed in the CY 2022 PFS proposed rule (86 FR 39414) that beginning with the CY 2022 performance period/CY 2024 MIPS payment year, a MIPS eligible clinician will receive 10 points for the Public Health and Clinical Data Exchange objective if they report a ''yes'' response for each of the following required measures: Immunization Registry Reporting; and Electronic Case Reporting. In the event that a MIPS eligible clinician is able to claim an exclusion for one or more of these required measures, we proposed they will receive 10 points for the objective if they report a ''yes'' response for one measure and claim an applicable exclusion for which they qualify for the remaining measure. If the MIPS eligible clinician fails to report on any one of the two measures required for this objective or reports a ''no'' response for one or more of these measures, we proposed that the MIPS eligible clinician will receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Promoting Interoperability performance category. If a MIPS eligible clinician claims applicable exclusions for which they qualify for both required measures, we proposed to redistribute the points associated with the objective to the Provider to Patient Exchange objective.

We proposed in the CY 2022 PFS proposed rule (86 FR 39414) to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures, and to make them optional and available for bonus points beginning with the CY 2022 performance period/CY 2024 MIPS payment year. For more information about these measures, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77229) and the EHR Incentive Program Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62818 through 62825). We proposed a MIPS eligible clinician may earn 5 bonus points if they report a ''yes'' response for either the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure. Reporting on more than one of these optional measures will not yield additional bonus points.

In connection with our proposal to make these measures optional, we proposed to remove the three exclusions that we established in the CY 2019 PFS final rule at 83 FR 59815 through 59817 for the Public Health Registry Reporting measure, Clinical Data Registry Reporting measure, and the Syndromic Surveillance Reporting measure.

We solicited comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures, and to make them optional and available for bonus points beginning with the performance period in CY 2022.

Response: We appreciate commenters' support for our proposal.

Comment: One commenter stated that syndromic surveillance has played a critical role in evaluating and monitoring many public health events in their State, including the COVID pandemic. We strongly support submission of syndromic surveillance data from providers and believe that providing this as an optional measure in this rule strengthens our ability to maintain the robust system into which both public health and healthcare facilities have already made significant investments.

Response: We appreciate the support for this proposal.

Comment: One commenter stated that surveillance data is used to monitor short-and long-term health trends and to alert health professionals to the important changes in disease trends. Surveillance data also provide the basis for determining public health priorities and for planning and implementing prevention and control programs.

Response: While we considered requiring the Syndromic Surveillance Reporting measure as we had proposed and subsequently finalized it as a required measure for eligible hospitals and critical access hospitals participating in the Medicare Promoting Interoperability Program (86 FR 45472 through 45473), we did not propose it as a required measure for MIPS because majority of data comes from emergency departments and only a small number of MIPS eligible clinicians practice in that setting.

Comment: One commenter requested clarification on how bonus points for reporting an additional registry measure will be awarded when a clinician claims an exclusion for the two measures proposed to be required in 2022.

Response: The five bonus points for reporting an additional registry measure can be earned even if exclusions are claimed for the two required measures.

Comment: One commenter supported the allocation of bonus points for the Clinical Data Registry Reporting measure, the Public Health Registry Reporting measure, and the Syndromic Surveillance Reporting measure. However, the commenter stated that the Promoting Interoperability performance category and these measures should align with congressional intent to incentivize registry reporting. Further registry reporting outside of the proposed required measures should be worth ten or more bonus points to encourage the use of registry reporting.

Response: We disagree. We chose 5 bonus points to create an incentive for clinicians to report an additional measure for the Public Health and Clinical Data Exchange objective. We have allocated 10 points for the two required measures and believe that allocating 5 points for reporting an additional measure aligns with the scoring of the required measures. We are not aware of congressional intent to incentivize registry reporting within the Promoting Interoperability performance category.

After consideration of public comments, we are finalizing our proposals: Beginning with the CY 2022 performance period/CY 2024 MIPS payment year, a MIPS eligible clinician will receive 10 points for the Public Health and Clinical Data Exchange objective if they report a ''yes'' response for each of the following required measures: Immunization Registry Reporting; and Electronic Case Reporting. In the event that a MIPS eligible clinician is able to claim an exclusion for one or more of these required measures, they will receive 10 points for the objective if they report a ''yes'' response for one measure and claim an applicable exclusion for which they qualify for the remaining measure. If the MIPS eligible clinician fails to report on any one of the two measures required for this objective or reports a ''no'' response for one or more of these measures, the MIPS eligible clinician will receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Promoting Interoperability performance category. If a MIPS eligible clinician claims applicable exclusions for which they qualify for both required measures, we will redistribute the points associated with the objective to the Provider to Patient Exchange objective.

The Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures will be optional and available for bonus points beginning with the CY

2022 performance period/CY 2024 MIPS payment year. A MIPS eligible clinician may earn 5 bonus points if they report a ''yes'' response for either the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure. We are removing the three exclusions that we established in the CY 2019 PFS final rule at 83 FR 59815 through 59817 for the Public Health Registry Reporting measure, Clinical Data Registry Reporting measure, and the Syndromic Surveillance Reporting measure.

(d) SAFER Guides

(i) Background

ONC developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, and later updated them in 2016. This series of nine user guides support the ability of health care providers to address EHR safety.[251] Collectively, the SAFER Guides help health care organizations at all levels, from small practices to multi-system chains and tertiary care facilities, to conduct self-assessments which optimize the safety and safe use of EHRs in the three areas listed in Table 55. The SAFER Guides were intended to be utilized by EHR users, developers, patient safety organizations, and those who are concerned with optimizing the safe use of health IT. By completing an annual self-assessment using the SAFER Guides, providers can help develop a ''culture of safety'' within their organizations and ensure they are responsible operators of technology tools, including certified health IT products, which they utilize in the delivery of care. The SAFER Guides are based on the best evidence available at the time of publication, which included a literature review, expert opinion, and field-testing at a wide range of health care organizations, from small ambulatory care practices to large health systems.

In the case of system disruption, failure, natural disaster, the SAFER Guides provide recommended safety practices during planned or unplanned EHR unavailability, where end users are unable to access all or part of their EHR. Also included are back-up procedures to prevent the potential loss of clinical and administrative data, and how to utilize paper charting during such downtime. We believe that conducting an annual self-assessment starting with the High Priority Practices Guide will support consistent safety practices for all EHR users.

The High Priority Practices Guide identifies ''high risk'' and ''high priority'' recommended safety practices, intended to optimize the safety and safe use of EHRs.[252] This guide broadly discusses EHR safety concerns that are described in greater detail in the subsequent 8 SAFER Guides. The High Priority Practices Guide is considered the first to be completed of the 9 SAFER Guides.

TABLE 55: The SAFER Guides

Foundational Guides	- High Priority Practices - Organizational Responsibilities
Infrastructure Guides	- Contingency Planning - System Configuration - System Interfaces
Clinical Process Guides	- Patient Identification - Computerized Provider Order Entry with Decision Support - Test Results Reporting with Follow-Up - Clinician Communication

(ii) New SAFER Guides Measure

We proposed in the CY 2022 PFS proposed rule (86 FR 39414 through 39416), to add a new SAFER Guides measure to the Protect Patient Health Information objective, beginning with the CY 2022 performance period/2024 MIPS payment year. For this measure, we proposed that a MIPS eligible clinician must attest to having conducted an annual self-assessment using the High Priority Practices Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation accounting for the complete self-assessment using the High Priority Practices Guide. We proposed that this measure will be required, but it would not be scored, and that reporting ''yes'' or ''no'' will not affect the total number of points earned for the Promoting Interoperability performance category. We believe this measure would further enable the electronic exchange of health information to improve the quality of health care, such as promoting care coordination, as described in section 1848(o)(2)(A)(ii) of the Act. We also proposed to add corresponding regulatory text for this measure at § 414.1375(b)(2)(ii)(C).

In order to complete a ''self-assessment'' using the High Priority Practices Guide, we expect that each MIPS eligible clinician would complete a review and mark the associated checkboxes (fully, partially, or not implemented) of recommended practices included at the beginning of the Guide. Detailed worksheets with the rationales for, and examples of how to implement each recommended practice follow the checklist section of the High Priority Practices Guide. These worksheets also include likely sources of information where the practice can turn to, in order to complete their assessment of a particular practice, as well as fillable note fields to record follow-up actions.

We understand that every organization faces unique circumstances, and will implement a particular practice differently. As a result, some of the specific examples in the SAFER Guides for recommended practices may not be applicable to every organization. A ''self-assessment'' does not require an organization to confirm that it has implemented ''fully in all areas'' each practice described in a particular SAFER guide, nor will an organization be scored on how many of the practices the organization has fully implemented. Rather, the intent is for MIPS eligible clinicians to regularly

[251] *https://www.healthit.gov/topic/safety/safer-guides.*

[252] *https://www.healthit.gov/sites/default/files/safer/guides/safer_high_priority_practices.pdf.*

assess their progress and status on important facets of patient safety.

The recommended practices in the SAFER Guides are intended to be useful for all EHR users, and we recognize that the individuals responsible for the proposed annual assessment may vary across organizations. An optimal team for completing an annual review of the SAFER Guides might include representation from clinicians (including physicians, nurses, pharmacists, and allied health staff), and the technical staff responsible for implementing and maintaining a practice's EHR, as well as data connections with external partners, such as an HIE.

Regarding the frequency of completing the self-assessment for the High Priority Practices Guide, we proposed that a MIPS eligible clinician must attest to completing their assessment using the High Priority Practices Guide on an annual basis, following an initial completion of the assessment (some clinicians may have already completed an assessment using the SAFER Guides prior to implementation of this requirement). We would expect MIPS eligible clinicians to revisit this assessment to determine whether any changes have occurred for their organization. We believe that requiring MIPS eligible clinicians to periodically review this self-assessment would support a stronger culture of change management within organizations, and would assist organizations in actively understanding and addressing potential safety vulnerabilities, which may significantly impact an organization's safety posture. We recognize that organizations may be at different stages in their progress towards assessing patient safety vulnerabilities, and that MIPS eligible clinicians vary in the resources that they could devote to an annual self-assessment using the High Priority Practices Guide. Gathering this information may be time consuming for some, and others may not have the expertise available on staff to complete all of the requirements. For MIPS eligible clinicians with less experience in these areas, we note that there are a number of resources available, which may be able to assist with completing a self-assessment.

We invited public comments on our proposal to require an annual self-assessment of the High Priority Practices Guide from MIPS eligible clinicians. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to require an annual self-assessment of the High Priority Practices Guide. Commenters stated that this requirement will encourage program participants to regularly assess their progress on practices that optimize the safety and safe use of EHRs, and others agree that completion of the self-assessment will promote best practices for the safe use and maintenance of health IT by MIPS eligible clinicians.

Response: We agree that given the opportunity to regularly assess progress, the High Priority Practices Guide will help optimize the safety and safe use of EHRs, and allow MIPS eligible clinicians the opportunity to make improvements as necessary over time.

Comment: Several commenters supported our proposal, but have requested clarification and/or suggestions for improvement. A few commenters stated that much of the High Priority Practices Guide represents a one-time configuration or verification steps, which for many MIPS eligible clinicians, would remain unchanged from year to year. One commenter suggested that after the initial review, MIPS eligible clinicians should be able to focus subsequent self-assessments on areas of the High Priority Practices Guide that have changed or require additional focus. Another commenter suggested that CMS and ONC collaborate to ensure that all of the SAFER Guides be updated regularly to ensure the most current guidance is shared with MIPS eligible clinicians. Several commenters requested confirmation that this requirement will not be scored, and that an answer of ''yes'' and ''no'' are both acceptable, without affecting their total scores.

Response: As discussed above, the completion of the annual self-assessment would assist organizations in actively understanding and addressing potential safety vulnerabilities regularly. The ''self-assessment'' does not require an organization to confirm that it has implemented ''fully in all areas'' each practice, nor will the organization be scored on how many of, or to what degree the organization has implemented these practices. As commenters have mentioned, several components of the High Priority Practices Guide will require an initial assessment that may not change significantly unless the MIPS eligible clinician has made significant system upgrades or has transitioned between systems. Further, we agree that MIPS eligible clinicians should focus their efforts on areas of change or improvement after having completed the initial assessment, as much of the assessment will remain unchanged. Our larger focus is for MIPS eligible clinicians to regularly assess their progress and status on important facets of patient safety. We would like to thank commenters for their suggestions that CMS and ONC coordinate efforts to regularly assess and update the SAFER Guides and to consider expanding on Education and Outreach efforts. We will continue to collaborate with ONC and take these suggestions under consideration. Last, we do confirm that for CY 2022, both ''yes'' and ''no'' are acceptable, an attestation of ''no'' will not alter final scores, and an attestation of ''no'' will not affect one's ability to be considered a Meaningful EHR User for MIPS.

Comment: Few commenters did not support our proposal to require an annual self-assessment of the High Priority Practices Guide. One commenter expressed concern that the High Priority Practices Guide does not improve interoperability, but instead creates additional reporting burden on MIPS eligible clinicians. A few commenters have suggested that vendors be required to complete the annual assessments and upon initial implementation of the health IT, rather than placing the additional burden on MIPS eligible clinicians.

Response: With a central focus on patient safety, we disagree that the High Priority Practices Guide does not improve interoperability. We would like to remind commenters that the Protect Patient Health Information objective is essential to all aspects of meaningful use of CEHRT, and ensuring that Patient Health Information is protected and secure is a critical element of effectively using EHRs. Under the Protect Patient Health Information objective, the High Priority Practices Guides measure is one way that we can proactively assess individual readiness. For the commenter who raised concerns about the additional reporting burdens this measure may present, we appreciate this feedback. We would like to reiterate that MIPS eligible clinicians are not being scored on this measure in the 2022 performance year, and that an attestation of ''yes'' and ''no'' are both acceptable answers, and that an answer of ''no'' will not affect the total number of points earned for the Promoting Interoperability performance category. Last, after the initial self-assessment, eligible clinicians could simply confirm that their initial assessment is still accurate, barring vendor and/or system updates that may affect the assessment.

Comment: Several commenters raised concern that CMS did not explicitly establish expectations surrounding

group reporting for this measure. Commenters seek clarification on whether each MIPS eligible clinician within the group is required to attest to having completed an annual self-assessment of the High Priority Practices Guide, or, if existing reporting requirements apply to this measure.

Response: For those who participate in group reporting, the existing group reporting policies apply to this measure. We are not requiring an annual self-assessment of the High Priority Practices Guide from each MIPS eligible clinician within the group.

After consideration of the public comments we have received, we are finalizing our proposal to add the SAFER Guides measure to the Protect Patient Health Information objective beginning with the CY 2022 performance period/CY 2024 MIPS payment year. MIPS eligible clinicians must attest to having conducted an annual self-assessment using the High Priority Practices Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement accounting for the complete self-assessment using the Guide. We are finalizing that in the CY 2022 performance period/CY 2024 MIPS payment year, this measure will be required, but it will not be scored, and that an attestation of ''yes'' and ''no'' would not affect the total number of points earned for the Promoting Interoperability performance category. We are also finalizing our proposal to add corresponding regulatory text to § 414.1375(b)(2)(ii)(C).

(e) Incrementation of the Numerator and Denominator for Promoting Interoperability Performance Category Measures

In the CY 2019 PFS final rule (83 FR 59799), we summarized a comment we received in response to proposals we had made in the CY 2019 PFS proposed rule concerning the measures for the Promoting Interoperability performance category beginning with the performance period in 2019. The commenter indicated that for some measures, MIPS eligible clinicians and group practices should be able to get credit for actions that are taken outside of the 90-day performance period. We responded to the comment by stating that since the inception of the Quality Payment Program, we have limited the ability to increment the numerator and denominator of measures to actions occurring during the performance period chosen, with the exception of the Security Risk Analysis measure, for which the relevant actions may occur any time during the calendar year. We now understand that our response to this comment may have caused confusion, and we wish to clarify our response. Instead of referring to the inception of the Quality Payment Program, we should have stated that the measures we proposed beginning with the performance period in 2019 would limit the ability to increment the numerator and denominator to actions occurring during the performance period chosen, with the exception of the Security Risk Analysis measure, for which the relevant actions may occur any time during the calendar year. We note an additional exception is the SAFER Guides measure (as discussed in section IV.A.3.d.(4)(d) in this final rule) because the relevant actions may also occur at any time during the calendar year.

(f) Changes to the Scoring Methodology for the 2022 Performance Period

For ease of reference, Table 56 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2022 performance period/CY 2024 MIPS payment year as revised to reflect the policies finalized in this final rule. Table 57 lists the 2015 Edition certification criteria required to meet the objectives and measures.

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TABLE 56: Objectives and Measures for the Promoting Interoperability Performance Category in 2022

Objective	Measure	Numerator	Denominator	Exclusion
e-Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
e-Prescribing: Generate and transmit permissible prescriptions electronically.	Query of PDMP (bonus): For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
other health care providers into their EHR using the functions of CEHRT.				
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other health care providers into their EHR using the functions of CEHRT.	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles	HIE Bi-Directional Exchange	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
summary of care information from other health care providers into their EHR using the functions of CEHRT.				
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT,	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance

Objective	Measure	Numerator	Denominator	Exclusion
except where prohibited, and in accordance with applicable law and practice.				period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period: OR 4. for the CY 2022 performance period/CY 2024 MIPS payment year only, the MIPS eligible clinician uses CEHRT that is not certified to the electronic case reporting certification criterion at § 170.315(f)(5) prior to the start of the performance period they select in CY 2022.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health	Clinical Data	N/A (measure is	N/A (measure is Yes/No)	none

Objective	Measure	Numerator	Denominator	Exclusion
and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	Yes/No)		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Protect Patient Health Information	Security Risk Assessment	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	High Priority Practices Guide	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

TABLE 57: Promoting Interoperability Performance Category Objectives and Measures in 2022, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange	HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include, but are not limited to, technology certified to the following criteria: § 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation § 170.315(g)(7) Application access – patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access – all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(4) Transmission to public health agencies — transmission to cancer registries § 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
Protect Patient Health Information	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)	None

Table 58 reflects the scoring methodology for the Promoting Interoperability performance category for the performance period in CY 2022.

TABLE 58: Scoring Methodology for the Performance Period in CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)*
Health Information Exchange -OR-	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
Health Information Exchange (alternative)	Health Information Exchange Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following 2 measures:* • Immunization Registry Reporting • Electronic Case Reporting	10 Points
	Report on any one of the following measures: • Public Health Registry Reporting OR • Clinical Data Registry Reporting OR • Syndromic Surveillance Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
* Signifies a proposal finalized in this CY 2022 PFS final rule.

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We also refer readers to section IV.A.3.d.(4)(f) of this final rule, where we finalized our proposed changes to the regulatory text for scoring the Promoting Interoperability performance category at § 414.1380(b)(4)(ii).

(g) Actions To Limit or Restrict the Compatibility or Interoperability of CEHRT

(i) Background

Section 106(b)(2) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) includes the heading ''Preventing Blocking The Sharing Of Information.'' Section 106(b)(2)(A) amended section 1848(o)(2)(A)(ii) of the Act to require that, to be a meaningful EHR user, a clinician demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the clinician has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology. To implement these provisions, we established and codified at § 414.1375(b)(3)(ii) attestation requirements for the Promoting Interoperability performance category to support the prevention of information blocking, which consist of three statements containing specific representations about a MIPS eligible clinician's implementation and use of CEHRT. For further discussion on these requirements, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77028 through 77035). The attestation statements finalized for MIPS eligible clinicians at § 414.1375(b)(3)(ii) are:

- *Statement A:* Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.
- *Statement B:* Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.
- *Statement C:* Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

Section 4004 of the 21st Century Cures Act added section 3022 to the Public Health Service Act (PHSA) (the ''PHSA information blocking provision,''), which describes practices by health care providers, health IT developers, and HIEs and networks, that constitute information blocking, and provides for civil monetary penalties and other disincentives for those who engage in information blocking.

In the ONC 21st Century Cures Act final rule published in the May 1, 2020 **Federal Register**, ONC finalized a definition of information blocking and identified reasonable and necessary activities (''exceptions'') that do not constitute information blocking (85 FR 25642). For health care providers (as defined in 42 U.S.C. 300jj), information blocking means a practice that, except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information; and if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (45 CFR 171.103).

The 21st Century Cures Act provides for civil monetary penalties for any individual or entity that is a developer, network, or exchange that has committed information blocking (see section 3022(b)(2)(A) of the PHSA). Regarding health care providers, the

21st Century Cures Act provides that ''Any [health care provider] determined by the [HHS] Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking'' (section 3022(b)(2)(B) of the PHSA).

(ii) Changes to the Attestation Statements

Although there could be some degree of overlap between conduct described in the attestation statements under § 414.1375(b)(3)(ii) and conduct that could be considered information blocking under section 3022 of the PHSA and ONC's implementing regulations at 45 CFR 171.103, it is important to note these are separate and distinct authorities. For instance, the ONC 21st Century Cures Act final rule finalized a definition for what constitutes information blocking, and exceptions to information blocking that are not reflected in the previously finalized attestation statements under § 414.1375(b)(3)(ii). While we previously stated in the CY 2017 QPP final rule that these attestations statements did not impose ''unnecessary or unreasonable requirements'' on health care providers (81 FR 77029), after careful review of these attestation statements in light of the information blocking regulations at 45 CFR part 171, we believe that statements B and C are no longer necessary. Thus, beginning with the performance period in CY 2022, we proposed in the CY 2022 PFS proposed rule (86 FR 39423 through 39425) to no longer require statements B and C. We believe that the similarities between practices described under statements B and C, and the practices that could constitute information blocking under section 3022 of the PHSA and ONC's implementing regulations will create confusion for stakeholders. To this point, the practices that could constitute information blocking under 45 CFR part 171 are much broader than those described in the attestation statements. We discuss specific instances of potential confusion below.

Statement B requires attestation to a series of statements regarding the use of certified technology and a designated manner for implementing certified technology. For instance, attestations to the implementation of technology compliant with the standards for certified health IT at 45 CFR part 170, and use of functionality to support health information exchange with other health care providers. However, as noted above, the definition of information blocking finalized in the ONC 21st Century Cures Act final rule is not specific to, nor limited to the use of certified technology, which is compliant with certain standards or the use of certain functionality. Under the ONC 21st Century Cures Act final rule, a health care provider may still be determined to have engaged in practices likely to interfere with access, exchange, or use of electronic health information (information blocking) regardless of whether they are using certified technology.

Regarding statement C, we stated in the CY 2017 QPP final rule that ''technical, legal, and other practical constraints may prevent a health care provider from responding to some requests to access, exchange, or use electronic health information in a health care provider's certified EHR technology'' (81 FR 77033). Subsequently, in the ONC 21st Century Cures Act final rule, ONC established a set of reasonable and necessary activities that are not considered information blocking when responding to a request for EHI. The reasonable and necessary activities established under the ONC 21st Century Cures Act final rule now provide more specific direction to health care providers when responding to a request for EHI than the general ''technical, legal, and other practical constraints,'' which we described in the CY 2017 QPP final rule. Accordingly, we believe that continuing to require statement C may introduce confusion for those health care providers who are obligated to comply with the regulations finalized in the ONC 21st Century Cures Act final rule when responding to a request for EHI.

In order to distinguish the attestation required by section 106(b)(2)(A) of MACRA from information blocking under section 3022 of the PHSA, we further proposed in the CY 2022 PFS final rule (86 FR 39423 through 39425) to modify the headings of §§ 414.1375(b)(3) and (b)(3)(ii), add § 414.1375(b)(3)(iii), and modify the definition of ''meaningful EHR user for MIPS'' under § 414.1305 to specify that the clinician does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, which reflects the language used in section 106(b)(2)(A) of MACRA. In addition, we proposed to no longer require attestation statements B and C beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year and we proposed corresponding regulatory text amendments at § 414.1375(b)(3)(ii) and (iii). We finalized a similar proposal for the Medicare Promoting Interoperability Program in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45481 through 45482).

We received public comments on our proposal to remove Statements B and C under § 414.1375(b)(3)(ii), beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, and here are our responses.

Comment: All commenters supported our proposal to no longer require Statements B and C under § 414.1375(b)(3)(ii). Commenters shared appreciation for our efforts to eliminate duplicative reporting burden, eliminate redundancies, and our efforts towards streamlining our requirements.

Response: We would like to thank commenters for their support.

Comment: One commenter requested that CMS remain involved with the information blocking issue, as challenges will continue to persist. Another commenter shared a similar concern, and further urged that CMS seek public comment prior to introducing any ''appropriate disincentives'' in the future.

Response: We do consider Information Blocking an important issue, and believe that in finalizing this policy, we are addressing concerns regarding improving clarity and reducing redundancies. We will take the suggestion of seeking public comment prior to introducing any ''appropriate disincentives'' for future rulemaking.

After consideration of the public comments, we are finalizing our proposal to modify the headings of §§ 414.1375(b)(3) and 414.1375(b)(3)(ii), add § 414.1375(b)(3)(iii), and to modify the definition of ''meaningful EHR user for MIPS'' under § 414.1305 to specify that the clinician does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, which reflects the language used in section 106(b)(2)(A) of MACRA. In addition, we are finalizing our proposal to no longer require attestation statements B and C beginning with the CY 2022 performance period/CY 2024 MIPS payment year, and we are finalizing our proposed corresponding regulatory text amendments at §§ 414.1375(b)(3)(ii) and (iii).

(h) Additional Considerations

(i) Reweighting the Promoting Interoperability Performance Category for MIPS Eligible Clinicians in Small Practices

We previously established under § 414.1380(c)(2)(i)(C)(9) a significant

hardship exception for MIPS eligible clinicians in small practices as defined in § 414.1305. In the CY 2018 Quality Payment Program final rule (82 FR 53682 through 53683), we established that we will reweight the Promoting Interoperability performance category to zero percent of the MIPS final score for MIPS eligible clinicians who qualify for this hardship exception. We established that a MIPS eligible clinician seeking to qualify for this exception must submit an application to us demonstrating that there are overwhelming barriers that prevent them from complying with the requirements for the Promoting Interoperability performance category, and that the exception is subject to annual renewal. In the CY 2018 Quality Payment Program final rule (82 FR 53579 through 53581), we also established that we will determine the size of small practices by utilizing claims data. This policy was further modified in the CY 2019 PFS final rule (83 FR 59727 through 59730) so that beginning with the CY 2021 MIPS payment year, a small practice is a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period.

In the CY 2018 Quality Payment Program proposed rule (82 FR 30076), we stated that we believed that special consideration should be available for MIPS eligible clinicians in small practices based on concerns previously identified by commenters, including small practices not being able to afford the upfront investments (including investments in EHR technology), and small practices not adopting EHRs due to the administrative and financial burden. Although some commenters requested that we automatically apply the proposed hardship exception to clinicians in small practices, at the time we disagreed and stated that we believed that many small practices will be able to successfully report for the Promoting Interoperability performance category (82 FR 53683).

We have been monitoring the submission of data for the Promoting Interoperability performance category by small practices and individual clinicians who are part of a small practice, and the numbers remain low despite the no-cost technical assistance we offered small practices through the Small, Underserved, and Rural Support Initiative. Data from CY 2019 revealed that of the 49,278 clinicians in small practices who were scored as an individual for MIPS, 84 percent of them did not submit Promoting Interoperability performance category data and did not apply for a small practice hardship exception application even though they may have qualified for the exception. Among clinicians who did not qualify for Promoting Interoperability performance category reweighting, only 29 percent of small practices compared to 61 percent of practices with more than 15 clinicians billing under the practice's TIN submitted data for the Promoting Interoperability performance category. Although we had expected many small practices would be able to successfully report data for the Promoting Interoperability performance category, we are concerned to see such low numbers of them either reporting data or applying for the small practice hardship exception, as such inaction would result in a score of zero for this performance category.

We want to support small practices and help them successfully participate in MIPS. As our analysis of the data suggests that successfully participating in the Promoting Interoperability performance category may be particularly challenging for small practices, in the CY 2022 PFS proposed rule (86 FR 39424 through 39425) we proposed a modification of our policy. Beginning with the CY 2022 performance period/CY 2024 MIPS payment year, we proposed to no longer require an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting. We proposed instead to assign a weight of zero percent to the Promoting Interoperability performance category and redistribute its weight to another performance category or categories (as discussed further in section IV.A.3.e. of the proposed rule) in the event no data is submitted for any of the measures for the Promoting Interoperability performance category by or on behalf of a MIPS eligible clinician in a small practice. We proposed that if data is submitted for a MIPS eligible clinician in a small practice, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weight prescribed by section 1848(q)(5)(E) of the Act. We proposed the small practice significant hardship exception still will be subject to annual renewal, and we will verify whether a practice meets the definition of a small practice under § 414.1305 on an annual basis. We proposed corresponding revisions to § 414.1380(c)(2)(i)(C)(9).

While we proposed this policy at this time, it is not our intention that this policy be in place for the long term, but rather only for a few years, as we would like to increase participation of small practices in the Promoting Interoperability performance category. We sought comment on potential options to increase small practice participation in the Promoting Interoperability performance category.

We proposed that in the case of an APM Entity that also meets the definition of a small practice, we will continue applying the Promoting Interoperability performance category reporting and exception requirements at the group level, as described at § 414.1317. However, if the APM Entity is composed of a single TIN which itself meets the definition of a small practice, all TINs within the APM Entity (that is, the single TIN) will be eligible for this exception, and therefore, the Promoting Interoperability performance category will be reweighted for the APM Entity and the performance category reweighting described above will be applied.

We received public comments on the proposal to automatically reweight the Promoting Interoperability performance category for MIPS eligible clinicians in small practices. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to automatically reweight the Promoting Interoperability performance category for MIPS eligible clinicians in small practices. Several commenters stated that they believe that it will reduce the administrative burden for small practices. Other commenters suggested that MIPS eligible clinicians in small practices have not applied for the hardship exception because they are not aware of it or because it is a burden to apply. Several commenters stated that small practices have not applied due to resource constraints. One commenter stated that MIPS eligible clinicians in small practices do not apply because they are afraid of being audited.

Response: We thank commenters for their support and agree the proposal may reduce administrative burden for small practices that face overwhelming barriers that prevent them from complying with the requirements for the Promoting Interoperability performance category.

Comment: One commenter applauded CMS' continued flexibility for small practices and believed the availability of hardship exceptions for small practices for the Promoting Interoperability performance category is necessary, but they do not agree with CMS' proposal to automatically reweight the Promoting Interoperability performance category for small practices. This proposal removes an incentive for practices to move towards the adoption of EHRs

which has been CMS' goal for many years. In line with CMS' messaging, their organization has also been pushing their membership towards EHR adoption to comply with MIPS reporting and the increasing requirements to avoid a negative payment adjustment. Because of this, they expressed concerns that this proposal sends the wrong message to practices newly adopting EHRs and practices with EHRs who have been diligently working to meet the requirements of this category. Another commenter did not support the proposal to automatically reweight Promoting Interoperability performance Category for small practices. They believe small practices should have to request reweighting. The Promoting Interoperability performance category has encouraged clinics of all sizes to engage their patients through the use of technology, such as patient portals and use of HIEs, improving access to care. By reweighting Promoting Interoperability performance Category, clinics may disable or neglect these features to the determent of the patient experience. They suggested that CMS consider reducing the number of measures within the Promoting Interoperability performance category for these smaller clinics, such as 2 or 3 measures, instead of a total reweight of 0 for all the measures.

Response: We understand these concerns and we stated in the CY 2022 PFS proposed rule (86 FR 39425) that it is not our intention for this policy to be in place for the long term. Too many small practices neglect to apply for the small practice hardship exception so we believe that putting this automatic reweighting policy in place in concert with increased outreach will help to reduce administrative burden for small practices. As we intend this policy to be temporary we hope that there will still be an impetus for small practices to strive to adopt CEHRT and report on the Promoting Interoperability performance category. We remind readers that if a small practice submits data for the Promoting Interoperability performance category, the data will be scored and the Promoting Interoperability performance category will not be reweighted. We appreciate the suggestion to reduce reporting requirements for small practices, and this is something that we may consider in future rulemaking.

Comment: One commenter urged CMS to use several methods to communicate in clear and unambiguous language that if the small practice submits data for the Promoting Interoperability performance category that the reweighting will be cancelled. Another commenter requested that CMS undertake an extensive educational campaign, partnering with specialty societies, to ensure that all small practices and their vendors are aware of this automatic reweighting and the fact that if they report any data for the Promoting Interoperability performance category, they will receive a Promoting Interoperability performance category score and not be reweighted.

Response: We thank commenters for these suggestions. We intend to include this policy in our educational materials and work with specialty societies to help disseminate this information.

We received comments in response to the questions we posed in the CY 2022 PFS proposed rule (86 FR 39425) related to small practice participation in the Promoting Interoperability performance category. We will analyze all of the comments that we received and may use them to inform future rulemaking and outreach initiatives.

After consideration of public comments, we are finalizing our proposal such that beginning with the CY 2022 performance period/CY 2024 MIPS payment year, we will no longer require an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting. We will assign a weight of zero percent to the Promoting Interoperability performance category and redistribute its weight to another performance category or categories (as discussed further in section IV.A.3.e.(2)(b) of this final rule) in the event no data is submitted for any of the measures for the Promoting Interoperability performance category by or on behalf of a MIPS eligible clinician in a small practice. If data is submitted for a MIPS eligible clinician in a small practice, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weight prescribed by section 1848(q)(5)(E) of the Act. The small practice significant hardship exception still will be subject to annual renewal, and we will verify whether a practice meets the definition of a small practice under § 414.1305 on an annual basis. We are making corresponding revisions to § 414.1380(c)(2)(i)(C)(*9*).

(ii) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

We established a policy at § 414.1380(c)(2)(i)(A)(*5*) for the performance periods in 2017 through 2021 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act.

As in past years, we intend to use data from prior performance periods to further evaluate the participation of NPs, PAs, CRNAs, and CNSs in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. We have analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category and have discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. Although we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For the 2017 performance period, approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. For the 2018 performance period, we reported that of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually, approximately 34 percent submitted data for the Promoting Interoperability performance category. However, after further review and the refinement of our analytics it was revealed that the percentage was not 34 percent but was 24 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs that submitted data individually for the Promoting Interoperability performance category. For the 2019 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually, approximately 30 percent submitted data individually for the Promoting Interoperability performance category, a modest increase from 2018. We continued our reweighting policy in 2020 but have not yet analyzed the data

to determine what proportion of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs that submitted data individually for MIPS also submitted data for the Promoting Interoperability performance category.

We believe that having these clinician types using CEHRT and submitting data for the Promoting Interoperability performance category is important for increased interoperability and data exchange. We are exploring the possibility that these clinician types are able to submit data but are choosing not to due to our current reweighting policies. In the future we may use other factors besides the submission data to determine whether to continue to reweight the Promoting Interoperability performance category for these clinicians. We solicited comments as to whether these clinician types are using CEHRT and are able to submit data on the measures for the Promoting Interoperability performance category.

While we are encouraged by the increasing numbers of NPs, PAs, CRNAs, and CNSs submitting data for the Promoting Interoperability performance category, we believe that the low numbers warrant the continued reweighting of the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the CY 2022 performance period/CY 2024 MIPS payment year. Thus, in the CY 2022 PFS proposed rule (86 FR 39425 through 39426), we proposed to continue the existing policy for the CY 2022 performance period/CY 2024 MIPS payment year and proposed to revise § 414.1380(c)(2)(i)(A)(*5*), which is being redesignated as § 414.1380(c)(2)(i)(A)(*4*)(*ii*), to reflect the proposal.

We did not receive comments on our proposal. We are finalizing our proposal to continue the existing policy to reweight the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the CY 2022 performance period/2024 MIPS payment year and have revised § 414.1380(c)(2)(i)(A)(*5*), which is being redesignated as § 414.1380(c)(2)(i)(A)(*4*)(*ii*). We thank commenters for their responses to our requests for comment and may consider this information to inform future rulemaking.

(iii) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2020 PFS final rule (84 FR 63003 through 63004), we adopted a policy at § 414.1380(c)(2)(i)(A)(*4*) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs to other types of MIPS eligible clinicians who are NPPs (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2020. We stated that because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category. We extended this policy for the performance period in 2021 (85 FR 84895). As these clinicians were first eligible to participate in MIPS in the CY 2020 performance period/CY 2022 MIPS payment year, we have not yet analyzed the data to inform a potential modification to our current policy and do not anticipate a completed analysis being available prior to the release of this final rule. In the CY 2022 PFS proposed rule (86 FR 39426) we proposed to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the CY 2022 performance period/2024 MIPS payment year. We proposed to revise § 414.1380(c)(2)(i)(A)(*4*), which is being redesignated as § 414.1380(c)(2)(i)(A)(*4*)(*i*), to reflect this proposal.

We received public comments on the proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition professionals. The following is a summary of the comments we received and our responses.

Comment: One commenter fully supported reweighting the Promoting Interoperability performance categories for these clinicians. In addition to similar difficulties in data capture as NPs, PAs, etc., many of the measures are not clinically applicable to these specific clinicians. Some would not prescribe medications (nutrition professionals), administer vaccines (immunization registry reporting) and/or reconcile certain clinical data. Although we believe many of these professionals are an integral part of the patient's care team, we do not believe they should be required to individually report Promoting Interoperability performance category data.

Response: We appreciate the support of the commenter.

Comment: One commenter appreciated CMS extending the reweighting policy for the Promoting Interoperability performance category data for occupational therapy practitioners for CY 2022 performance period/CY 2024 MIPS payment year. Non-physician clinicians are still at a disadvantage because not all Promoting Interoperability performance category data are applicable to their practices. The commenter requested that CMS review measure applicability and adjust measure requirements to allow for NPP reporting if the Promoting Interoperability performance category data is to become a requirement in future years.

Response: As we have stated previously, we will continue to monitor the participation of NPPs in the Promoting Interoperability performance category. We will use this data to inform future policy proposals.

Comment: Commenters requested that CMS confirm that psychologists and certain other non-physician eligible clinicians will continue to have the Promoting Interoperability performance category reweighted to zero given that they never had the opportunity to receive Federal funds to invest in EHRs. It is critical that all psychologists, including those in practices with more than 15 eligible clinicians, continue to have the Promoting Interoperability performance category reweighted to zero unless they choose to report Promoting Interoperability performance category measures or are provided with Federal funding to invest in EHRs.

Response: We proposed (86 FR 39426) and are finalizing our proposal to continue to reweight clinical psychologists for the Promoting Interoperability performance category for the CY 2022 performance period/CY 2024 MIPS payment year.

After consideration of public comments, we are finalizing our proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the CY 2022 performance period/2024 MIPS payment year. We are finalizing our revisions at § 414.1380(c)(2)(i)(A)(*4*),

which is being redesignated as § 414.1380(c)(2)(i)(A)(*4*)(*i*).

(iv) Clinical Social Workers and Certified Nurse-Midwives (CNMs)

We proposed at 86 FR 39426 to add clinical social workers and CNMs to the definition of a MIPS eligible clinician. These clinician types were not eligible to participate in the Medicare Promoting Interoperability Program to earn incentive payments for meaningful use of CEHRT or receive reduced Medicare payments for failing to meaningfully use CEHRT. Clinical social workers were not eligible for Medicaid EHR incentive payments and thus may lack experience with the adoption or use of CEHRT. CNMs were eligible for the Medicaid EHR incentive payments, and the majority did earn incentives. For the CY 2022 performance period/CY 2024 MIPS payment year, we proposed in the CY 2022 PFS proposed rule (86 FR 39426) to apply the same Promoting Interoperability reweighting policy we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to clinical social workers as we believe that there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to clinical social workers. We will assign a weight of zero only in the event that a clinical social worker does not submit data for any of the measures specified for the Promoting Interoperability performance category. We proposed to add § 414.1380(c)(2)(i)(A)*(4)*(*iii*) to reflect this proposal for clinical social workers.

We believe there are sufficient measures applicable and available to CNMs under the Promoting Interoperability performance category because of their experience with the Medicaid Promoting Interoperability Program. Many of them have adopted CEHRT and earned a Medicaid incentive payment, and the measures for the Medicaid Promoting Interoperability Program generally are the same or slightly modified versions of the Promoting Interoperability performance category measures. Thus, we did not propose to apply the same Promoting Interoperability reweighting policy we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to CNMs. However, we solicited comments on whether there are in fact sufficient measures applicable and available to CNMs under the Promoting Interoperability performance category, and whether barriers exist that prevent CNMs from complying with the requirements of the Promoting Interoperability performance category and may warrant reweighting. Like other types of MIPS eligible clinicians, a CNM may be able to qualify for a significant hardship exception from and reweighting of the Promoting Interoperability performance category under the existing policies at § 414.1380(c)(2)(i)(C), depending on their circumstances.

We received public comments on reweighting the Promoting Interoperability performance category for clinical social workers and CNMs. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the reweighting of the Promoting interoperability performance category for clinical social workers and added that they do not prescribe medications or administer vaccines.

Response: We appreciate the support for our proposal and remind readers that if clinical social workers choose to submit data for the Promoting interoperability performance category they will be scored and not reweighted.

Comment: A few commenters expressed their opposition to requiring CNMs to report for the Promoting Interoperability performance category as CMS reweights all other non-physician clinicians eligible under MIPS. They acknowledged CMS' rationale for not applying the same Promoting Interoperability reweighting policy previously adopted for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to CNMs given that they were an eligible professional type under the Medicaid EHR Incentive Program, but stated that NPs were also eligible professional types under that Program and have been reweighted for the Promoting Interoperability performance category since the CY 2017 performance period/CY 2019 MIPS payment year. They requested that CMS also reweight CNMs.

Response: When we established the reweighting policy for NPs, we stated that their low numbers of participation in the Medicaid EHR Incentive Program may have indicated that the EHR Incentive Program measures were not applicable or available to them. (81 FR 77243 through 77244). For CNMs, we believe that there are sufficient measures applicable and available. Many CNMs have adopted CEHRT and earned Medicaid EHR Incentive Program/Medicaid Promoting Interoperability Program payments. Further the measures under these Medicaid Programs are the same or slightly modified versions of those required for the MIPS Promoting Interoperability performance category. We did request comments on whether barriers exist that prevent CNMs from complying with the requirements of Promoting Interoperability performance category but we did not receive any comments related to barriers.

After consideration of public comments, we are finalizing our proposals as proposed. For the CY 2022 performance period/CY 2024 MIPS payment year, we will apply the same Promoting Interoperability reweighting policy we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to clinical social workers as we believe that there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to clinical social workers. We will assign a weight of zero only in the event that a clinical social worker does not submit data for any of the measures specified for the Promoting Interoperability performance category and we are adding § 414.1380(c)(2)(i)(A)(*4*)(*iii*) to reflect this policy.

(i) Technical Corrections to the Regulations

In the CY 2019 PFS final rule (83 FR 59798 through 59817), we adopted objectives and measures for the Promoting Interoperability performance category that will apply beginning with the performance period in 2019. The requirement for MIPS eligible clinicians to report on these objectives and measures can be found under § 414.1375(b)(2). In the CY 2021 PFS rulemaking, we inadvertently neglected to update this provision of the regulation text, although our intention was a continuation of the policy we established for the CY 2021 and 2022 MIPS payment years. We proposed a technical correction to § 414.1375(b)(2)(ii) to specify that the reporting requirements apply beginning with the 2021 MIPS payment year. We solicited comments on this proposal.

We did not receive public comments on this proposal, and therefore, we are finalizing as proposed.

(j) Requests for Information (RFI)

The CY 2022 PFS proposed rule contained the following RFIs (86 FR 39427 through 39428):

- Request for Information on Additional Objectives Adopting FHIR®-based API Standards
- Request for Information on a Patient Access Outcomes Measures
- Request for Information on Clinical Notes

We thank commenters for their responses to these requests for information. We may consider this

information to inform future rulemaking.

(5) APM Entity Level Participation for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

In the CY 2021 PFS final rule (85 FR 84896), we finalized our policy to terminate the APM scoring standard effective January 1, 2021, and to retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with the CY 2021 MIPS performance period. Therefore, we redesignated, in part, the regulation that describes APM Entity group determinations, from § 414.1370(e) to § 414.1317, and titled that section ''APM Entity Groups.''

(b) APM Entity Level Reporting of Facility-Based Measures

In the CY 2021 PFS final rule (85 FR 84896), we finalized a policy to allow APM Entities to report to traditional MIPS using the same quality measures available to other groups, according to all applicable MIPS quality scoring policies. It has been brought to our attention that we did not make it clear whether APM Entities may be eligible for facility-based scoring. In the CY 2022 PFS proposed rule (86 FR 39429), we clarified that because facility-based measures are not submitted, but rather are collected by CMS using group-level participation scores used for the Hospital Value Based Purchasing Program, it would be impossible for CMS to calculate a score for a facility-based measure that represents the performance of an APM Entity. Therefore, facility-based scoring is not available to APM Entities under MIPS quality scoring rules, as described at § 414.1330. We also noted that participants in APM Entities that are eligible for facility-based scoring at the individual or group level would still be eligible to receive these scores for purposes of individual or group MIPS scoring.

(c) APM Entity Performance Category Weights

In the CY 2021 PFS final rule (85 FR 84896), we finalized a policy to weight the cost performance category at zero percent of the final score for APM Entities in MIPS APMs. We codified the weight of the cost performance category at § 414.1317(b)(2), but we did not discuss in the CY 2021 PFS final rule how the weight that otherwise would have applied to the cost performance category will be redistributed among the other performance categories. In the CY 2022 PFS proposed rule (86 FR 39429), for purposes of clarity, we proposed to add to § 414.1317(b)(2) that the performance category reweighting scenarios under § 414.1380(c)(2) apply to an APM Entity.

We explained that because APM Entities are participating in traditional MIPS and generally are being scored according to traditional MIPS scoring rules at § 414.1380 unless otherwise specified, the performance category reweighting scenarios under § 414.1380(c)(2) are applicable to APM Entities. Using the 2021 MIPS performance period/2023 MIPS payment year as an example, if the cost performance category is the only performance category weighted at zero percent for an APM Entity, the performance category weights would be as follows under § 414.1380(c)(2)(ii)(E): Quality 55 percent, cost zero percent, improvement activities 15 percent, and promoting interoperability 30 percent. If both cost and promoting interoperability are weighted at zero percent, then quality would be 85 percent and improvement activities would be 15 percent. For the remaining reweighting scenarios for the 2021 MIPS performance period/2023 MIPS payment year, we refer readers to Table 6 under § 414.1380(c)(2)(ii)(E). The reweighting scenarios applicable to APM Entities for the 2022 MIPS performance period/2024 MIPS payment year can be found in Table 7 under § 414.1380(c)(2)(ii)(F). We refer readers to section IV.A.3.e.2 of this final rule where we discuss our proposal to apply the reweighting policy finalized for the 2022 MIPS performance period/2024 MIPS payment year at § 414.1380(c)(2)(ii)(F) to the 2025 MIPS payment year and each subsequent MIPS payment year. In the event we establish additional reweighting scenarios, they would also apply to APM Entities.

We did not receive any comments on this proposal and are finalizing as proposed.

e. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the CY 2022 performance period/2024 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years. The scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. We proposed to update many of our scoring policies, focusing on removing transition policies. Specifically, we proposed to—

- Change certain terminology related to scoring.
- Amend our scoring flexibility policy to include quality measures with omitted or deactivated codes in the finalized measure specifications.
- Implement benchmarking and topped out scoring policies that are responsive to potential low reporting rates for the CY 2020 performance period/2022 MIPS payment year due to the national PHE for COVID–19 and establishing a benchmark when measures are suppressed in the baseline period.
- Amend policies for scoring quality measures based on achievement and measures that do not meet case minimum or have a benchmark and introduce scoring policies for new measures.
- Amend the minimum case requirement policy.
- End the high priority and end-to-end reporting bonuses in the quality performance category.
- Continue improvement scoring in the quality performance category.
- Implement a scoring flexibility policy for changes that impact cost measures during the performance period.
- Revise certain provisions of the regulation text for the Promoting Interoperability performance category.

We did not propose changes to scoring policies for the improvement activities performance category.

We also maintained our approach to how MIPS eligible clinicians are scored against performance standards for each performance category, receive a final score comprised of their performance category scores, and how the final score is calculated according to the final score methodology. We refer readers to § 414.1380 for policies on scoring.

(b) Terminology Updates

We proposed updates to § 414.1380 in an effort to more clearly and concisely capture previously established policies (86 FR 39429). These proposed updates were not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We proposed to change the term ''performance category percent score'' to ''performance category score'' in §§ 414.1380(b)(1)(vi)(C) and (E) related to improvement scoring, 414.1380(b)(1)(vii) related to scoring the quality performance category score, 414.1380(b)(2)(iii) and (v) related to scoring the cost performance category, 414.1380(c) and (c)(2)(ii)(A) on calculating the final score and final score reweighting, and

414.1380(e)(6)(iv) and (v) related to facility-based scoring. Again, these changes were not intended to change the underlying policies reflected in the regulation text. Initially, the quality and cost performance categories used the term ''performance category percent score'' because those categories had improvement scoring and have a slightly different approach to calculation than the Promoting Interoperability and improvement activities performance category. However, the terms ''performance category percent score'' and ''performance category score'' have been used in the same way. For that reason, we proposed to consolidate our language and use only the latter aforementioned term.

We received public comments on our terminology updates. The following is a summary of those comments.

Comment: One commenter supported the change in terminology.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing this proposal as proposed.

(c) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913). We proposed in the CY 2022 PFS proposed rule to amend policies finalized in prior years to simplify scoring in MIPS as we transition to MVPs (86 FR 39429 through 39430).

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period or Prior to Implementation

We refer readers to CY 2018, CY 2019, and CY 2021 Quality Payment Program final rules (82 FR 53714 through 53716, 83 FR 59845 through 59847, and 85 FR 84898 through 84901 respectively) and § 414.1380(b)(1)(vii)(A) for our previously establish scoring flexibilities policy.

In the CY 2018 Quality Payment Program Final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD–10 coding changes during the performance period based only on the first 9 months of the 12-month performance period. We noted that we believe that 9 months of data is sufficient to assess performance when 12 months of data is not available. We finalized that we would publish a list of measures requiring 9 months of data on the CMS website by October 1st of the performance period if technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period) (82 FR 53716). We refer readers to § 414.1380(b)(1)(viii) for more on our policy for scoring flexibility for ICD–10 changes.

In the CY 2019 Quality Payment Program final rule (83 FR 59845 through 59847), we finalized policies beginning with the 2019 performance period/2021 MIPS payment year to reduce the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise no longer be comparable to a historic benchmark. We wanted the flexibility to respond to instances in which the clinical evidence and guidelines change and approved measures no longer reflect the most up-to-date clinical evidence and could even result in a practice that is harmful to patients. We finalized expanding the list of reasons that a quality measure may be impacted during the performance period in addition to revising when we will allow scoring of the measure with a performance period truncation (to 9 months of data) or the complete suppression of the measure if 9 months of data are not available.

In the CY 2021 Quality Payment Program final rule, we finalized a consolidation of the CY 2018 and CY 2019 scoring flexibilities policy that allowed, beginning with the 2021 performance period/2023 MIPS payment year, truncation of the performance period or suppression of a quality measure if CMS determines that revised clinical guidelines, measure specifications or codes impact clinician's ability to submit information on the measure or may lead to potentially misleading results. Based on the timing of the changes to clinical guidelines, measure specifications or codes, we will assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we will suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted (85 FR 84898 through 84901).

In previous rules, we noted that we believe that there may be instances when there are changes after the final approval of quality measures including changes to the measure specification, or updates to coding that may lead to misleading results (85 FR 84899). Additionally, we believe that there may be instances in which there is an inadvertent omission of codes, or inclusion of deactivated codes in the measure specifications that do not have the correct status. Typically, codes that are contained within the measure specifications either have a reimbursable status or a non-reimbursable status that still allows processing for purposes of quality reporting programs. We have encountered instances where CMS has been alerted that codes have inadvertently received an inactive status which results in the associated codes not being processed and stored in the National Claims History (NCH) database, and therefore, not available for quality purposes. As the measure specifications are considered technical documents that include several fields such as, but not limited to: The numerator, denominator, measure description, denominator exclusions, clinical guidance statements, and codes relevant to how the measure should be captured. The measure specifications are finalized and published in coordination with the final rule, and prior to the start of the performance period. An inadvertent omission of codes, or inclusion of inactive codes in the measure specifications, may result in misleading results by affecting clinicians who submit the measure. In these instances, implementation errors could lead to misleading performance rates by failure to reflect accurate numerator and/or denominator values for calculation of the measure. These are not changes that occur during the performance period, but errors that would affect the performance period.

It recently came to our attention through Help Desk inquiries that Medicare Administration Carriers (MACs) were rejecting 2021 Part B Claims submissions for Quality Measure ID (QID) 001: Hemoglobin A1c (HbA1c)

Poor Control (>9%) and QID 117 Diabetes: Eye Exam due to an inactive status for certain CPT II codes. The omission of these claims from the total denominator population of the measure could skew scores and lead to misleading results. We believe suppression of the measures is consistent with current § 414.1380(b)(1)(vii)(A). Information on the suppression of the Part B claims collection type of these measures for the 2021 MIPS performance period/2023 MIPS payment year was announced via the QPP listserv on July 1st, 2021. For more information please refer to our website *qpp.cms.gov.*

We proposed to amend § 414.1380(b)(1)(vii)(A) to clarify our intended policy on instances in which we become aware of changes to the active or payable status of the codes and/or implementation errors included in the measure specifications as finalized that would lead to misleading results. Accordingly, we proposed to revise § 414.1380(b)(1)(vii)(A) to change ''significant changes'' to ''significant changes or errors'' and to include the omission of codes or inclusion of inactive or inaccurate codes to provide that for each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of paragraph (b)(1)(vii)(A), ''significant changes or errors'' means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes, or inclusion of inactive or inaccurate codes; changes to clinical guidelines; or measure specifications. We will publish on the CMS website a list of all measures scored under paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than data submission deadline at § 414.1325(e)(1).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters offered additional suggestions. One commenter suggested that, for each circumstance, CMS work with stakeholders to assess whether it would be appropriate to measure a practice on 9 months of data for a quality measure with a 12-month performance period. One commenter requested a better way to address errors in measures besides suppression and truncation as measure stewards need more flexibility to adjust measures with errors. The commenter noted that if a measure with an error is suppressed immediately and there is no opportunity for the error to be fixed, measure stewards will not be incentivized to put forth corrections to CMS.

Response: We thank the commenters for their comments. The policy to truncate the performance period to 9 months may be used when there are changes in the final quarter of the performance period that are substantial enough to significantly impact the measure. In instances in which measures include significant changes or errors at the time of finalization, we would not have 9 months of appropriate data to assess. When these errors come to CMS' attention, the agency works with measure stewards to correct the issue. Whether or not the measure can be corrected is contingent upon the timing of discovery of the errors. In instances in which measures can be corrected, we believe that measure stewards are incentivized to correct them in as timely a manner as possible to support their presence and use in the program. We also believe that measures stewards want their measures in MIPS and will work to ensure that their measures are maintained and that errors are corrected. We will continue to work with measure stewards both to ensure measure specifications are correct before finalization, as well as correct any errors that are finalized.

Comment: A few commenters supported the expanded list of reasons that a quality measure may be impacted to include errors included in the measure specifications as finalized as cause to suppress or truncate a measure. One commenter appreciated that the policy will prevent scores from being negatively affected based on changes to measures.

Response: We thank the commenters for their response and their support of the edits to the scoring flexibilities policy.

After consideration of public comments, we are finalizing our proposal as proposed by revising § 414.1380(b)(1)(vii)(A) to change ''significant changes'' to ''significant changes or errors'' and to include the omission of codes or inclusion of inactive or inaccurate codes to provide that for each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of paragraph (b)(1)(vii)(A), ''significant changes or errors'' means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes, or inclusion of inactive or inaccurate codes; changes to clinical guidelines; or measure specifications.

We will publish on the CMS website a list of all measures scored under paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than data submission deadline at § 414.1325(e)(1).

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017, CY 2018, CY 2019, CY 2020, and CY 2021 Quality Payment Program final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, 83 FR 59841 through 59842, 84 FR 63014 through 63016, and 85 FR 84901 through 84904) for our previously established benchmarking policies.

In the CY 2017 QPP final rule (81 FR 77277 through 77282), we finalized that we will use performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or where we do not have comparable data from the baseline period, for which we will set the benchmarks using performance in the performance period. We defined the baseline period to be the 12-month CY, that is, 2 years prior to the performance period for the MIPS payment year. For example, for the CY 2022, the baseline period two performance periods prior will be the CY 2020 performance period (81 FR 77277). Additionally, we further clarified that CMS can establish benchmarks either by the applicable baseline or performance period in the

CY 2019 PFS final rule (83 FR 59842), where we finalized the terminology change amending § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

Because of the flexibility provided to MIPS eligible clinicians to allow for no data submission for the 2020 performance period (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1198/2020%20MIPS%20Automatic%20EUC%20Fact%20Sheet.pdf*), we may not have as representative of a sample of data as we will have had without the national PHE for COVID–19. Therefore, we want to revisit our benchmarking policy for the 2022 performance period/2024 MIPS payment year similarly to how we revisited the benchmarking policy for the 2021 performance period/2023 MIPS payment year (85 FR 84901 through 84902). We anticipate that we may have a gap in our data due to receiving fewer submissions for CY 2020, which could skew the benchmarking results. We believe this gap in data could result in different distributions of scores from what we normally see; thus, skewing the benchmarks when using CY 2020 data as the baseline for the CY 2022 performance period/2024 MIPS payment year. Additionally, we anticipate that only those not experiencing a hardship will submit data, thus skewing benchmarks much higher than normal. We ultimately, did not finalize this proposal for CY 2021 because analysis of the submitted data from the CY 2019 performance period/2021 payment period showed that it was suitable for use in calculating benchmarks. However, as we know from the events of 2020, we anticipate that the effects of the national PHE for COVID–19 may be more significant for the CY 2020 performance period.

For this reason, we considered two benchmarking options for the CY 2022 performance period/2024 MIPS payment year. We proposed to use performance period benchmarks for the CY 2022 performance period/2024 MIPS payment year in accordance with § 414.1380(b)(1)(ii). As discussed in the CY 2021 PFS final rule (85 FR 84902), this would mean that benchmarks for the CY 2022 performance period/2024 MIPS payment year are based on the actual data submitted during the CY 2022 performance period. Last year, we received comments supportive of our proposal to use performance period benchmarks citing that the performance period benchmarks will capture any changes in care due to the national PHE for COVID–19 and avoid unfairly penalizing practices for variation in performance compared to data from prior to the national PHE for COVID–19 (85 FR 84902 through 84903). We also received comments that opposed the use of performance period benchmarks, as clinicians would not have advance notice of performance targets. As a result, we also considered and sought feedback as an alternative to performance period benchmarks, utilizing the historic benchmarks from the 2021 MIPS performance period (which are based on submissions for CY 2019 MIPS performance period/2021 MIPS payment year) for the CY 2022 performance period/2024 MIPS payment year. We believed that this option would allow clinicians to continue to receive advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures for the CY 2022 performance period/2024 MIPS payment year. However, we remained concerned that utilizing outdated data could also potentially result in distributions of scores used for benchmarks that no longer reflect the standard of care especially as care changes in response to the PHE. Additionally, any new or substantively changed measures in the CY 2022 performance period/2024 MIPS payment year will lack a benchmark, as would measures that were suppressed in the CY 2019 performance period/2021 MIPS payment year alternate baseline period. We noted that we would analyze the CY 2020 performance period data and compare the distribution of the CY 2020 performance period data to that of previous years to assess if we could in fact use data from the CY 2020 performance period for benchmarks for the CY 2022 performance period/2024 MIPS payment year and if not, we would evaluate the suitability of the alternatives.

Additionally, we proposed to expand the definition of the baseline period. In instances in which a measure is suppressed two performance periods prior in the standard baseline period and cannot be used to calculate a benchmark, we proposed to use the data from three performance periods prior to calculate benchmarks in the event that a performance period benchmark cannot be calculated. This will mean that for the CY 2022 performance period/2024 MIPS payment year, if a measure was suppressed in the 2020 performance period and a performance period benchmark could not be calculated using the 2022 performance period data because it was not reported by 20 different clinicians or groups that met data completeness and case minimum requirements, we would calculate a benchmark from performance period data from CY 2019. If a measure had undergone a substantive change or was also suppressed in the baseline period 3 performance periods prior, we would not use it to calculate benchmarks and the measure will be subject to our scoring policies for class 2 measures. We would not use benchmarks calculated from performance periods that are older than 3 performance periods prior. We believed it is important to continue using the most up-to-date data to drive clinical quality improvement. We believed that this policy will reduce burden to clinicians and allow them to continue to have performance targets in the event that a measure is suppressed.

We solicited public comments on our intent to use performance period benchmarks for the CY 2022 performance period and to expand the baseline period to three performance periods prior for measures that are suppressed two performance periods prior. Table 59 reflects a summary of the benchmarking hierarchy in our proposal.

TABLE 59: Quality Performance Category: Proposed Benchmarking Hierarchy

Policy Hierarchy	Baseline period used to calculate Benchmark	Condition
1	Historical Baseline Period: Two Performance Periods prior to the applicable performance period	A benchmark can be calculated from the historical baseline period defined as two performance periods prior to the applicable performance period.
2	Performance Period Benchmark	A benchmark cannot be calculated from the historical baseline period, but 20 or more clinicians report on a measure and meet or exceed the case minimum of 20 cases during the performance period.
3	Alternate Historical Baseline Period: Three Performance periods prior to the applicable performance period	A measure is suppressed in the historical baseline period two years prior to the applicable performance period and a performance period benchmark cannot be calculated, but a benchmark can be calculated from the alternate historical baseline period defined as three performance periods prior to the applicable performance period can be calculated because the measure had not undergone a substantive change in the time since the data was collected or been suppressed in the baseline period.
4	No baseline: Subject to class 2 scoring policy	A benchmark cannot be calculated from the historical baseline period, the performance period, or the alternate baseline period.

We received public comments to the quality measure benchmarks. The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that CMS undertake more analysis on the impact of the use of 2019, 2020 and 2021 data on setting benchmarks and risk adjustment models before moving forward with its proposed policy to use 2022 benchmark data. One commenter supported the plan to apply the same process used for evaluating 2019 performance year data to 2020 performance year data to determine if data are sufficient to establish benchmarks. A few urged CMS to evaluate CY 2021 data to determine if there are data anomalies that will require the avoidance of using that data, as well.

Response: Based on analysis of CY 2020 performance period/2022 MIPS payment year submissions data, we believe there is sufficient data to calculate historical benchmarks and do not believe it is necessary to use either of the proposed alternative approaches. Overall, despite a modest decrease in submission volume, average scores remained consistent to those observed in CY 2019 performance period/2021 MIPS payment year. The analysis showed minimal to no impact for the Part B Claims and MIPS CQM collection types. However, we did see moderate distributional effects in 64 measures. We note that these 64 measures are less commonly reported and the effects seen are not categorically different than the change in the performance distribution that would be observed in any given year, although it is possible that the observed effects may be greater than they would otherwise be as a result of the COVID–19 PHE.

Ultimately, we believe that the best option available is to use the CY 2020 performance period/2022 MIPS payment year data. These data will provide clinicians with advance notice of performance targets that are more representative samples of performance as a result of the PHE than the use of performance period benchmarks. Additionally, we believe that data from the CY 2020 performance period/2022 MIPS payment year, which is the most recent available dataset, is more appropriate for use than the historical benchmarking data from the CY 2019 performance period/2021 MIPS payment year. We believe that it is important to benchmark performance using data that reflects care provided during the PHE. We also believe that the CY 2020 performance period/2022 MIPS payment year data better represents this care. Data collected during the CY 2019 performance period was largely not affected by the COVID–19 PHE, rather we saw effects during the associated submission period which occurred during the first calendar quarter of 2020 which affected the number of submissions, but would not reflect a performance period in which clinicians were facing the PHE. We note that we could not analyze data from the CY 2021 performance period/2023 MIPS payment year as it is not currently available. This data will be submitted from the close of the performance period through March 31, 2022 (§ 414.1325(e)). For this same reason we could not use this data to set benchmarks for the CY 2022 performance period/2024 payment year. We are committed to using the most up-to-date representative data available. For that reason, we are not finalizing the proposal to use performance period benchmarks and will calculate benchmarks according to the standard baseline period policy.

Comment: One commenter suggested that CMS exclude CY 2020 data from all future reporting due to COVID–19 and maintain consistency in excluding 2020 reporting year data as was proposed in the 2022 Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS) regulations.

Response: We believe the commenter is misunderstanding policies in the IPPS and OPPS regulations. In March 2020, prior to either the CY 2022 OPPS/ASC proposed rule or the FY 2022 IPPS/LTCH PPS proposed rule, we issued an extraordinary circumstance exception (ECE) [253] for a number of Q1 and Q2 2020 requirements in hospital pay-for-reporting and value-based purchasing programs, including the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program.

In the FY 2022 IPPS final rule, we established a measure suppression policy in a number of value-based purchasing programs, including the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program and the Hospital-Acquired Conditions Program. This measure suppression policy allowed for

[253] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

suppression of measures if we determine that circumstances caused by the COVID–19 PHE have affected those measures (86 FR 45266). Additionally, for the FY 2022 for Hospital VBP program year, because of wide-spread measure suppression, it was finalized that we would not calculate total performance scores nor issue any penalties or incentive payments as awarding negative or positive incentive payment adjustment percentages using TPSs calculated using the current scoring methodology would not provide a representative score of a hospital's overall performance in providing quality of care during a pandemic (86 FR 45276). We did not propose any additional policies related to suppression or exclusions in the CY 2022 OPPS/ASC proposed rule as the comment suggested. We do not believe it will be necessary to exclude CY 2020 performance period data from MIPS. As stated above, our analysis supports the use of CY 2020 performance period/2022 MIPS payment year data to calculate quality measure benchmarks.

Comment: Many commenters supported the use of performance period benchmarks. These commenters stated that such benchmarks would be more representative of the care provided during the COVID–19 pandemic and would be ''more appropriate'' than using historical benchmarks. Many commenters agreed with CMS' concern that 2020 performance data may not be a representative sample of historic data and benchmarks for 2022 will be more accurate and reliable. To support the use of performance period benchmarks, one commenter encouraged CMS to release the 2021 performance year benchmarks as soon as possible in 2022. One clinician supported providing 2019 historic benchmarks to give clinicians a target while the performance period benchmarks are used for scoring.

Response: We agree that performance period benchmarks would provide the most up-to-date data to calculate benchmarks; however, we also believe there is significant value in the advance notice of performance targets. Participants may have difficulty meeting relevant performance targets if they lack advance notice of the target as they may not be able to determine the appropriate level of resources necessary to achieve the performance target. Participant concerns regarding this issue may be particularly acute where performance may result in a payment adjustment. We thank the commenters for their suggestions, but we believe that it is most appropriate to continue to rely on historical benchmarks for the CY 2022 performance period/2024 MIPS payment year. We will continue to monitor the impact of the national PHE on performance benchmarks. We note that the CY 2019 performance period/2021 MIPS payment year benchmarks are currently available in the resource library on the QPP website (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip*). The historical benchmarks based on CY 2020 performance period/2022 MIPS payment year will be available prior to the CY 2022 performance period. The CY 2023 historical benchmarks which are calculated from CY 2021 performance period/2023 MIPS payment year data will be available spring/summer of CY 2022 at the earliest.

Comment: Many commenters did not support the use of performance period benchmarks because clinicians would not know the benchmarks ahead of time and performance period benchmarks would prevent meaningful assessment in advance of the performance year and would hinder the ability to select measures that will maximize scoring in advance of the year. One commenter stated that advanced notice of targets is essential to ensure fair and meaningful incentives for high quality, efficient health care. One commenter noted that as payment consequences associated with MIPS scores increase, it becomes more important to provide clinicians with adequate information to enable appropriate selection of measures. One commenter stated that any value gained by using performance period benchmarks is outweighed by the negative impact on clinicians as they would not have benchmarks available for comparison and performance improvement.

Response: As noted above, we agree that the use of performance period benchmarks would not allow clinicians the opportunity to fully prepare for the respective performance period. We will not finalize the use of performance period benchmarks for the CY 2022 performance period/2024 MIPS payment year. We believe the use of data from the CY 2020 performance period/2022 MIPS payment year will be representative of performance and allow clinicians advanced notice of performance targets to aid in measure selection and help clinicians to work towards improvement on quality measures.

Comment: Many commenters supported using CY 2019 performance period/2021 MIPS payment year data to create quality benchmarks since clinicians appreciate notice on which measures will have benchmarks and the CY 2019 performance period/2021 MIPS payment year data would allow clinicians time to review and compare data to drive improvement based on the known benchmark. A few commenters noted that, to maintain consistency and predictability of MIPS performance through the pandemic, CMS should use CY 2019 performance period/2021 MIPS Payment year historic data as benchmarks. One commenter supported the use of CY 2019 performance period/2021 MIPS payment year historic benchmarks as EHRs and registries track performance in real time relative to the benchmark as the only way for clinicians to determine if there are deviations in their quality performance which can occasionally indicate real clinical issues, such as complication rates, that need to be addressed. One commenter stated that for measures with substantive changes since CY 2019, CMS should use the CY 2022 performance year/2024 MIPS payment year data, that is, use a performance period benchmark, to determine the score, but the general use of CY 2019 quality measure data for benchmarks would allow clinicians to have some ability to know what they are being benchmarked against. One commenter suggested that CMS should provide clinicians with historic benchmarks using CY 2019 performance period/2021 MIPS payment year data and calculate historic and performance period benchmarks and use the more favorable to score.

Response: We agree that the opportunity to review and compare data helps to drive improvement against the known benchmark and enables clinicians track performance in real time to respond to any clinical issues that the data indicates. These benefits provide value to clinicians and support their meaningful participation in the program. This is ultimately the reason our existing policy establishes the preference to use historical benchmarks. In this instance, we believe that the use of CY 2020 performance period/2022 MIPS payment year to calculate benchmarks better balances issues that arise from using historical data than the use of CY 2019 performance period/2022 MIPS payment year data. Ultimately, as stated in a previous response, we believe that it is most appropriate to base a benchmark on the more up-to-date historical data and on the historical data that is most representative of the current standard of care.

We agree with the commenters' suggestion that measures suppressed in the CY 2019 performance period/2021 payment year should use performance

period data for benchmarking and will apply this approach to measures suppressed in the CY 2020 performance period/2022 MIPS payment year, as this is our current approach. Historical benchmarks from the CY 2019 performance period/2021 MIPS payment year are currently available in the resource library in the QPP website.

Comment: A few commenters did not support expanding the definition of the baseline period to calculate a benchmark because the underlying data would be too retrospective and not reflective of current performance and that this approach would not address the concerns of using a representative sample of historic data since many of the baseline periods would include data from 2019, 2020, and 2021 data—all of which are impacted by the COVID–19 pandemic. One commenter encouraged CMS to avoid the use of these data for benchmarking purposes.

Response: We believe there is value in the advance notice for quality measures, but agree that extending the baseline period would be too retrospective and fails to reflect current performance that could come as a result in advances in care. For this reason, we are not finalizing the proposal to add an alternate historical baseline period defined as three performance periods prior.

Comment: A few commenters supported the proposal to add an alternate baseline period of three performance periods prior for measures that are suppressed two performance periods prior. One commenter suggested that it would be better to use the Alternate Historical Baseline Period at level 2 in the proposed benchmarking hierarchy and set the Performance Period Benchmark as level 3 since CMS has expressed concern that alternate historical benchmarks could become too outdated to accurately reflect the current standard of care. Moving the Alternate Historical Baseline to level 2 within the proposed benchmarking hierarchy would allow CMS to give providers advanced notice using historical benchmarks, while still having the discretion to use concurrent performance period benchmarks if determined that the standard of care has changed too significantly to use the alternate historical data.

Response: We thank commenters for their support, but will not be finalizing this proposal for the reasons cited in the previous response. Our proposal was to allow for scoring of measures that had been suppressed in the baseline period two performance periods prior when a performance period benchmark could not be calculated. For the reasons stated above, we prefer to use the most-up-to date historical data that is available in the program and believe using an alternate baseline period of three performance periods prior may be too retrospective. We will continue to use our use of performance period benchmarks for measures that lack a benchmark in the baseline period.

After consideration of public comments, we are not finalizing our proposal to use performance period benchmarks in the CY 2022 performance period/2024 MIPS payment year or a historic benchmark calculated from CY 2019 performance period data. Instead, we will calculate benchmarks from the CY 2020 performance period/2022 MIPS payment year data as is our standard policy according to § 414.1380(b)(1)(ii). Any measures suppressed in the CY 2020 performance period/2022 MIPS payment year will have a performance period benchmark calculated for scoring purposes. Additionally, we are not finalizing our proposal to define an alternative baseline period for benchmarking defined as three performance periods priors for measures suppressed in the baseline period two performance period prior.

(iii) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1)(i) for more details on our current policies for scoring performance on quality measures (81 FR 77276 through 77307, 82 FR 53694 through 53701, 83 FR 59841 through 59856, 84 FR 63011 through 63019, and 85 FR 84906 through 84907).

(A) Scoring Measures Based on Achievement

We previously established at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as each administrative claims measure. MIPS eligible clinicians receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77282), we established that measures with a benchmark based on the performance period (rather than on the baseline period) will continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, we stated that we will revisit the 3-point floor in future years. For the 2021 performance period/2023 MIPS payment year, we maintained the application of the 3-point floor for each measure that can be reliably scored against a benchmark.

For the 2022 performance period/2024 MIPS payment year, we proposed to remove 3-point floor for each measure that can be reliably scored against the benchmark and score the measure from 1 to 10 points. As we move towards the MVP framework discussed the CY 2021 PFS final rule (85 FR 84904), we are moving towards a simplified scoring standard in which we can score quality measures from 1 to 10 for measures in MVPs and as such will amend the MIPS program to begin promoting this alignment. As a result, we previously discussed that we would wait until there is further policy development under the MVP framework before removing the 3-point floor (85 FR 84904). However, with the delay in the implementation of MVPs, we will begin the transition to MVPs by removing policies established on the transition years of MIPS. We have signaled through rulemaking for several years that we would revisit policies established during the transition years of the program from the legacy programs to MIPS. As the legacy programs have been sunsetted for many years now, we believe that it is appropriate to transition the MIPS program to its mature state. Additionally, we believe that transitioning MIPS to its mature state will serve as a transition period to allow clinicians to adjust to the simplified scoring standard that we will be using in MVPs.

Accordingly, we proposed to revise § 414.1380(b)(1)(i) to add beginning the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians would receive between 1 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 (86 FR 39432).

We solicited public comments on our proposal to remove the 3-point floor for each measure that can be reliably scored against a benchmark for the 2022 performance period/2024 MIPS payment year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter did not support the removal of the three-point

floor and noted that it would likely be an additional challenge for practices that are already struggling with the pandemic. Another commenter suggested that the proposal to remove the 3-point floor should be delayed and should be implemented as part of the CY 2023 rulemaking process as the pandemic has shifted clinician focus off of the mechanics of MIPS and very few clinicians may be ready for such a significant change during the CY 2022 performance period.

Response: We agree that the national PHE for COVID–19 has affected the health care sector in unprecedented ways and has understandably shifted clinician focus off of participation in MIPS. We agree that delaying the implementation of the removal of the 3-point scoring floor until the CY 2023 performance period/2025 MIPS payment year would recognize this hardship and would avoid harshly penalizing clinicians for any changes in performance that may be observed during this time. CMS does remain committed to the removal of transition policies and moving towards a simplified scoring standard in MVPs.

Comment: A few commenters opposed the removal of the scoring floor along with the higher performance threshold. The commenters requested that CMS account for the challenges that will result from an increased performance threshold and retain the scoring floor instead of removing many of the possibilities of avoiding a negative payment adjustment.

Response: We agree that removing the scoring floors and raising the performance threshold at this time, particularly with the ongoing PHE, could present challenges to clinicians. However, we do not want to continue masking true performance on quality measures. As discussed in section IV.A.3.f.(2) of this final rule, beginning with the CY 2022 performance period/2024 MIPS payment year, section 1848(q)(6)(D)(i) of the Act requires the performance threshold to be the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Accordingly, we proposed to use a performance threshold of 75 points which was the mean final score from CY 2017 performance period/2019 MIPS payment year (86 FR 39454). As this represents an increase of about 15 points from the previous year's performance threshold, we understand clinicians' concern. For this reason, we are delaying the removal of the 3-point scoring floor for measures that can be reliably scored against a benchmark until the CY 2023 performance period/2025 MIPS payment year. We believe this will allow clinicians some leniency as we they adjust to a higher performance threshold and continue to face the PHE.

Comment: One commenter stated that CMS should assess scoring 1–10 points before removing the 3-point floor. The commenter encouraged CMS to review how frequently eligible clinicians have performance rates that place them below the 3-point floor, particularly clinicians in small and rural practices.

Response: We thank the commenter for their suggestion and will perform these analytics. To further assist MIPS eligible clinicians in the transition of removing the 3-point scoring floor, we will begin providing information on deciles below 3 in our forthcoming benchmark file, as technically feasible before the removal of the 3-point floor in 2023.

Comment: One commenter stated that the methodology to estimate the quality performance category score and the transition from old scoring policies to new are too complicated as clinicians need to understand how their scores are calculated and which measures to select to optimize performance.

Response: We believe that removing the 3-point scoring floor and scoring measures that can reliably be scored against a benchmark from 1–10 will make scoring simpler. The 3-point scoring floor was established when the performance threshold was 3 points during the transition year of the MIPS in order to avoid penalizing clinicians at the start of the program (81 FR 77287). As the performance threshold has since changed and clinicians have more familiarity with reporting through MIPS, this policy is no longer relevant. In order to move towards complete and meaningful scoring, scores will be evenly distributed across a range from 1 to 10. This allows CMS to more accurately distinguish performance amongst clinicians. We believe that the changes in quality measure comparison will also provide great benefits to clinicians by reducing score inflation in the quality performance category and by enabling payment adjustments that reflect meaningful distinctions in quality of care. We currently provide a tool on the QPP website for clinicians to explore measures and activities to aid in measure and activity selection (*https://qpp.cms.gov/mips/explore-measures*). We offer this tool and provide clinicians with performance targets (historical benchmarks) before the start of the performance period in order promote transparency in scoring and support clinicians in making decisions to support fair and meaningful participation in program.

After consideration of public comments, we are not finalizing the policy to remove the 3-point scoring floor as proposed. We are finalizing the removal of the 3-point scoring floor for measures that can be reliably scored against a benchmark to be implemented in CY 2023 and revise § 414.1380(b)(1)(i) to add beginning the 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians will receive between 1 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. We believe that delaying the implementation of this policy allows clinicians to acclimate to other changes in the program such as the increase of the performance threshold and the removal of the scoring bonuses in the quality performance category. Additionally, we believe this policy provides some flexibility to clinicians in response to the national PHE.

(B) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We refer readers to § 414.1380(b)(1)(i)(A) and (B) for more on our current scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement (84 FR 63012).

In the 2017 QPP final rule (81 FR 77288) and the 2018 QPP final rule (82 FR 53727), we identified ''classes of measures'' which were intended to characterize measures for the ease of discussion. Class 1 measures are measures that can be scored based on performance because they have a benchmark, meet the case minimum and data completeness requirements. Class 2 measures are measures that cannot be scored based on performance because they do not have a benchmark or do not meet the case minimum which is generally 20 cases. Class 3 measures are measures that do not meet the data completeness requirement. We also noted that policies for Class 2 and Class 3 measures will not apply to measures submitted with the CMS Web Interface or administrative claims-based measures.

In the CY 2022 PFS proposed rule, we proposed to modify how we score these measures within MIPS, as we considered policies for transitioning to MVPs (86 FR 89433). For class 2 measures, for the 2022 performance period/2024 MIPS payment year, we proposed to remove special scoring policies for measures that meet the data completeness requirement but do not have a benchmark, due to fewer than 20 individual clinicians or groups adequately reporting the measure, or meet the case minimum requirement except in the case of small practices, for which we will maintain the 3-point floor. Practices of other sizes would receive zero points.

We noted that, as we move to MVPs, we are seeking to simplify scoring by removing transition policies. To encourage complete and meaningful reporting, we cannot continue to award measure achievement points for measures that cannot be reliably scored against a benchmark. In a quality measurement program such as MIPS, we noted that it is imperative that we can reliably measure performance on clinical quality measures to achieve the goals of the program and incentivize clinicians that are providing the high-quality care. However, we remained concerned that it may be harder for smaller practices to reach case minimums, and as such, we are maintaining the 3-point floor policy for small practices. We believed that measure selection that is better reflective of the care most commonly provided in a practice would increase the value of the program by allowing us to score for achievement in clinical quality and subsequently drive changes in performance on clinical quality measures.

Measure benchmarks are posted in advance of the MIPS performance period and can be used to drive clinician measure selection. While not all measures relevant to a clinician's practice may have a historic benchmark posted, clinicians have the option to make informed decisions about their participation in the MIPS program. Additionally, we believe that while clinicians do not have control over the case volume and mix that their practices treat, under normal circumstances, they can anticipate which measures would be most reflective of the care generally provided by said practices. Scoring 3 points for class 2 measures was established as a policy during the transition years of the program, when the performance threshold was 3 points and scoring 3 points for quality will help clinicians transitioning to the program without receiving scores for poor performance. The intent of the policy was to provide time for clinicians to acclimate to the scoring standard before being held fully accountable for their participation in the program (81 FR 77287). As we believe we have provided sufficient time for clinicians to acclimate to our reporting requirements and scoring practices, we believe that we can hold clinicians accountable for their meaningful participation in the program.

We remain concerned about that case minimums and the availability of a benchmark are in some instances out of the control of the clinician, but we believe that clinician choice of measure allows us to move forward with the removal of transition scoring policies. We note that we also have policies in place to account for the calculation of a performance period benchmark if a historical benchmark is unavailable. Simulations of the effects of this policy show minimal effects of removing the 3-point floor as described above, with only a 0.4 point-decrease in median quality performance category score and 0.2 point-decrease in mean performance quality performance category score when compared to a baseline score that maintains the previously finalized class 2 measure scoring policy (86 FR 39433). We noted that we considered other approaches to address this issue such as a denominator reduction for class 2 measures; however, we remained concerned over the potential for gaming under this approach, such as where a clinician only selects class 2 measures resulting in their quality performance category score being reweighted.

We did not want this policy to discourage the reporting of new measures in the program because they may lack a benchmark or fail to meet the case minimum requirement. For this reason, we proposed a 5-point floor for new measures in the program for all collection types for their first 2 years in the program, as well as a new class for these measures. Measures in either their first or second performance period in the program would be classified as class 4 measures. Measures that can be reliably scored against a benchmark because they meet data completeness requirement can have a performance period benchmark calculated, and meet case minimum requirements would be considered class 4a and scored from 5 to 10 measure achievement points. In the event that a measure cannot be reliably scored against a benchmark because it lacks a benchmark or does not meet case minimum, but meets the data completeness requirement, it would be considered class 4b and receive a score of 5. Measures that cannot be scored because they do not meet the data completeness requirement would remain subject to the class 3 measure policy and receive a score of zero for clinicians other than small practices, while small practices will continue to receive three points.

We noted our belief that a 5-point floor for new measures would allow us to introduce new, applicable measures into the program, by reducing the burden to clinicians in selecting them. We also noted our belief that this policy was responsive to stakeholder concerns that new measures run the risk of lacking enough data to have a benchmark and clinicians earning only 3 points according to the current policy on measures that cannot be reliably scored against a benchmark. We believed that the possibility of earning 5 points for a measure that lacks a benchmark will not unfairly penalize clinicians who report on new measures. Additionally, clinicians have the possibility of earning up to 10 points with the lowest possible score of 5. The 5-point floor would only be in place for a measure's first 2 years in the program to ease their transition, and will be scored in accordance with policies for standard class 1, 2, and 3 measures thereafter, to maintain a simplified scoring methodology. In the CY 2017 Quality Payment Program final rule, we received comments of support on our proposal to provide a scoring floor for new measures citing that a scoring floor for new measures would encourage clinicians to report new measures and prevent gaming. Commenters were also supportive other approaches to reducing the burden of reporting new measures such as reducing the weight of new measures in the performance category score (81 FR 77281).

Accordingly, we proposed to revise § 414.1380(b)(1)(i)(A)(*1*) to provide that except as provided in paragraph (b)(1)(i)(A)(*2*) and (*3*) of this section, for the 2017 through 2021 CY performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement. Beginning within the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians other than small practices receive zero measure achievement points for each such submitted measures and small practices receive three measure achievement points

We also proposed to add the policy for new measures at § 414.1380(b)(1)(i)(C)(*1*) to provide that beginning with the CY 2022

performance period/2024 MIPS payment year, MIPS eligible clinicians receive between 5 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. We also proposed to add a policy at § 414.1380(b)(1)(i)(C)(*2*) to provide that for purposes of this section ''new measures'' means a quality measure this is in its first 2 years in the program.

We solicited public comments on our proposal to modify the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement for the MIPS 2024 payment year and to introduce a 5-point scoring floor for new measures in for their first 2 years in the program. Table 60 reflects a summary of our proposed policies.

We received public comments on the scoring measures that do not meet case minimum, data completeness, and benchmark requirements. The following is a summary of the comments we received and our responses.

Comment: Many commenters did not support the removal of the 3-point floor for Class 2 measures, especially while the COVID–19 pandemic is ongoing. A few commenters stated that there are often changes to quality measure specifications or calculations and as such a benchmark cannot be established for these measures and there are groups of all sizes that cannot make the case minimum for certain measures and that no such groups should receive zero points. One commenter noted that this scoring policy would disincentivize the use of these measures as the measures would then never accrue enough data for a benchmark, and clinicians would hesitate to use them—creating a self-perpetuating cycle. One commenter noted that with a measure score of zero points, and even with the 3-point floor, there is no incentive for groups to branch out and implement workflows to capture data for specialty specific measures if no benchmarks are set. One commenter suggested that instead of scoring zero points for measures with no benchmarks, CMS should provide credit to clinicians who take the time to report on more focused measures and contribute to the building of performance benchmarks. A few commenters noted that measures without benchmarks for multiple years will never get enough data for a benchmark if they are scored at zero points. One commenter noted that this could be harmful to QCDRs as measures do not always have a benchmark because it is submitted by a limited group of specialists. One commenter stated that finalizing this policy could lead to important measures being overlooked because of the lack of a benchmark. One commenter recommended maintaining the 3-point scoring policy for measures that were introduced during PY 2020 because of the impacts of the extreme and uncontrollable circumstances policies on reporting. A few commenters stated the CMS should not make any significant changes to scoring policies during the COVID–19 PHE. One commenter stated that CMS needs to address the lack of sufficient, relevant measures before further reducing scoring for measures not meeting the case minimum or benchmark criteria.

Response: We understand that our current and proposed class 2 measure policy presents risk in reporting measures, including measures that have undergone substantive changes and had their benchmarks reset, that may not have a benchmark calculated, or in instances in which a clinician or group cannot meet the case minimum requirements. We cannot, however, provide scores for measures for which we cannot reliably distinguish meaningful differences in performance nor can we continue to award points for reporting as MIPS moves out of its transition phase. To support meaningful participation in MIPS, we provide clinicians with benchmarks in advance, as well as other tools to support measure selection (*https://qpp.cms.gov/mips/explore-measures*). We believe that there is little to no value in maintaining underreported measures for which we cannot establish benchmarks, and therefore, we cannot score.

As described in section IV.A.3.h.(1)(d)(iii) of this final rule, QCDR measures that do not meet case minimums or cannot have a benchmark calculated after their first two performance periods in the program must submit a participation plan or run the risk of being removed from the program as established in § 414.400(b)(4)(i)(B)(*10*)(*i*). We proposed the new measure policy to reduce the risk associated with reporting new measures that may not receive a benchmark. However, we recognize that there are important areas that require measurement such as specialty specific measures that may be currently underreported. We believe that the new measure policy can help to incentivize reporting of more applicable measures over those that are historically underreported. We will monitor the effect that these policies have on the reporting of specialty specific measures and continue to explore alternative scoring solutions to solve for this problem such as MVPs. Ultimately, we are delaying implementation of the removal of the 3-point floor policy until CY 2023 in order to be responsive to clinician concerns about reporting through MIPS during the COVID–19 PHE. We believe this delay in implementation takes a phased approached to simplifying scoring as we transition to MVPs.

Comment: Many commenters supported maintaining a 3-point floor when scoring small practice clinicians on quality measures. One commenter supported this proposal as small practices face a greater administrative burden when reporting for MIPS and they support any effort to lessen this burden on those practices in particular.

Response: As noted above in section IV.A.3 e.(1)(c)(iii)(A) of this final rule, we have decided to maintain the 3-point scoring floor for practices of all sizes until the CY 2023 performance period/2025 MIPS payment year in response to concerns about the PHE, a higher performance threshold, and the removal of quality performance category bonuses. We believe this phased approached to simplifying scoring as we transition to MVPs by delaying the removal of the scoring floor policies while finalizing our proposals to remove the high priority and end-to-end electronic bonuses will provide flexibility during the COVID–19 PHE. We appreciate the commenters support to maintain the scoring floor for small practices.

Comment: One commenter did not support removing the 3 points for many practices while keeping the 3 points for small practices and stated that there should not be a difference in the size of practices for point allocation. One commenter noted that if a measure now does not have a benchmark, a clinician would not get any benefit from submitting a measure without a benchmark compared to the 3 points provided previously. A few commenters mentioned that measure reporting rates are not necessarily an indication of a low value measure, particularly for highly specialized procedures or patient populations and these trends may instead be a result of program policies that disincentivize the uptake of these measures.

Response: We believe it is important to support small practices so that they may meaningfully engage in MIPS. We did not want to penalize smaller

practices that may find it harder to reach case minimums. Additionally, we believe that maintaining the 3-point floor on class 2 measures for small practices would offset some of the additional challenges to reporting that small practices face, that practices of other size do not. We understand that removing the 3-point floor makes reporting measures that do not have a benchmark riskier for clinicians, we however, do not want to continue offering points for reporting. We want to award points for high performance and demonstrated improvements in clinical care. We will continue to assess our policies and find ways to encourage the uptake of high value, but underutilized measures that do not involve offering points for reporting.

Comment: Many commenters supported and appreciated the proposed 5-point floor for Class 4 measures in their first 2 years of the program as it will allow for greater utilization of innovative measures that show evidence of driving improvements in care and encourage the use of newly developed measures. One commenter recommended that CMS indicate and communicate which measures will be considered Class 4 measures so clinicians can plan appropriately. One commenter suggested that CMS expand this policy to existing measures that may add additional collection types. One commenter noted that this policy will incentivize the use of QCDR measures and increase the robust nature of the measures.

Response: We agree that providing a scoring floor for new measures will incentivize greater utilization of innovative, newly developed measures; QCDR measures; and increase the robust nature of the measures. We will not apply this policy to measures that have existed as a MIPS measure but are being introduced for a new collection type. For example, if a measure is currently available as a MIPS CQM and it becomes newly available as an eCQM, that would not be considered ''new'' under this policy. Those changes are considered substantive changes, but not new measures as they usually will share the same measure ID. CMS will communicate which measures will be considered class 4 from Appendix 1 and resources that will be available in the resource library on the QPP website.

Comment: Several commenters requested CMS raise the floor for reporting on new measures to 7 points, instead of the proposed 5 to ensure that this incentive will be sufficient to encourage practices to take the risk of using these measures, which will then allow for greater understanding of their evidence base, the ability to ensure patient-centeredness, and actionability. A few commenters note that a higher incentive will encourage clinicians to take on the risk of reporting on a new measure and investing in new protocols and workflow, which often require IT and practice redesign costs. A few commenters requested that the measures be considered new for 3 years, instead of the proposed 2 years. One commenter suggested higher point floors for measures that are high priority or outcome measures. A few commenters requested that the measures be considered new for 3 years. A few additional commenters requested that CMS expand the new measures proposal to 4 years, instead of the proposed 2 years, as this would prevent ''premature'' removal of meaningful measures from the program and would recognize the valuable practice resources that are necessary to begin using new measures.

Response: We agree that a higher 7-point floor would be a greater incentive for clinicians to invest in new protocols and workflow in order to support reporting on new measures. Additionally, we believe that introducing a 7-point floor for new measures could be effective in incentivizing the reporting of new measures over topped out measures though we had not previously considered the connection between these two policies previously. However, 7-points is a high score and we do not want to introduce new sources of scoring inflation or gaming into the program. For this reason, we believe a phased scoring floor policy would be an appropriate solution. This approach would introduce a 7-point scoring floor for new measures across all collection types in their first year in the program, then dropping the scoring floor to 5-points for measures in their second year in the program. After their first 2 performance periods in the program, measures would be subject to our standard class 1 and 2 measure policies. We believe this approach incentivizes early adoption of new measures, while limiting the duration of potential scoring inflation and gaming. Additionally, we believe that the eventual mandatory reporting of MVPs would reduce the impact of scoring inflation and gaming in MIPS. We will monitor these measures to assure that they are having the intended effect and not being used to game the program. Policies related to QCDR measures in MIPS at § 414.1400(b)(3)(iv)(J) discuss a period of two performance periods after which measures may be reassessed. We proposed a two-performance period timeframe in which measures will be considered class 4 measures in alignment with this previously establish policy related to QCDR measures. We will also monitor the application of this policy to assure that the 2-performance period new measure period is adequate. If analytics supports a longer new measure period, we may revisit this topic in later rulemaking.

Comment: A few commenters requested clarification on the logistics of the policy and if it applies to QCDR measures and if this methodology only applies to measures in their lifecycle going forward or if it would be applied to measures finalized starting in 2021. Another commenter suggested that CMS apply this policy retroactively for measures introduced in CY 2020 and CY 2021.

Response: The modified Class 4 measure policy would apply a 7-point scoring floor to new measures in their first performance period in the program across all collection types including QCDRs and a 5-point scoring floor to measures in their second year, thereafter being subject to scoring policies for Class1 and 2 measures. We believe this policy should begin effective the CY 2022 performance period/2024 MIPS payment year, meaning measures new to the program in CY 2022 will receive a 7-point scoring floor. We do not believe there is a benefit in applying this policy retroactively to CY 2020 or CY 2021 performance periods/2022 or 2023 MIPS payment year as a retroactive policy would inflate scores without providing the corresponding incentive for clinicians to adopt new measures. Additionally, measures in their second year in the CY 2022 performance period/2024 MIPS payment year, will receive a 5-point scoring floor.

Comment: One commenter opposed the creation of Class 4 measures as practices are already incentivized to submit data for measures that are relevant to their practice, and therefore, quickly establish benchmarks for a measure.

Response: We have heard form stakeholders that the possibility that new measures or Class 4 may not be reliably scored is a deterrent from reporting such measures. We believe that it is important to provide incentives to report new measures that so that there is less risk in reporting these new measures.

Comment: One commenter suggested that CMS suppress new measures to account for high performance threshold.

Response: We will not suppress new measures. We seek to encourage the reporting of new high-quality measures

in the program and have delayed the removal of the class 2 measure policy to 2023 in order to provide flexibilities in response to the PHE, higher performance threshold, and removal of the high priority and end-to-end-electronic reporting quality performance category bonuses.

After consideration of public comments, we are finalizing our proposed policies with modification. We will delay the removal of the 3-point floor for all practice sizes until CY 2023, maintaining it only for small practices thereafter and revise § 414.1380(b)(1)(i)(A)(*1*) to provide that except as provided in paragraph (b)(1)(i)(A)(*2*) and (*3*) of this section, for the 2017 through 2022 CY performance periods/2019 through 2024 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement. Beginning within the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians other than small practices receive 0 measure achievement points for each such submitted measures and small practices receive 3 measure achievement points.

Additionally, we are modifying our proposal regarding new measures at § 414.1380(b)(1)(i)(C) to provide that, beginning with the CY 2023 performance period/2025 MIPS payment year, for each measure in required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340, MIPS eligible clinicians receive between 7 and 10 measure achievement points (including partial points) for such each measure in its first year in MIPS and between 5 and 10 measure achievement points for each such measure in its second year in MIPS. In adopting this final policy with modification, we have consolidated paragraphs (b)(1)(i)(C)(*1*) and (*2*) into a single paragraph (b)(1)(i)(C).

We are also finalizing our policy at § 414.1380(b)(1)(i)(A)(*3*) to provide that, beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive 7 measure achievement points for each submitted measure in its first year in MIPS and 5 measure achievement points for each submitted measure in its second year in MIPS that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

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TABLE 60: Quality Performance Category: Finalized Scoring Policies for the CY 2022 MIPS Performance Period*

Measure type	Description	Current Scoring Policy for CY 2021	Scoring Policy for CY 2022
Class 1	Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Meets case minimum; and (3) Meets the data completeness standard (generally 70 percent for 2022.)**	3-10 measure achievement points based on performance compared to the benchmark	No Change
Class 2	Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark; and (2) Meets case minimum.	3 points	No change
Class 3	Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum.	MIPS eligible clinicians other than small practices will receive zero points for this measure. Small practices will continue to receive 3 points.	No change
New Measures: Class 4	Measures that are in their first two performance periods in the MIPS program that meet the data completeness requirement, but (1) May lack a benchmark (2) May not meet case minimum	No Policy	(a) For measures that can be reliably scored against a benchmark: 7-10 measure achievement points for measures in their first year 5-10 measure achievement points for measures in their second year (b) For measures that cannot be reliably scored against a benchmark because they lack a benchmark or do not meet case minimum: 7 points in their first year. 5 points in their second year

*The Class 2 and 3 measure scoring policies are not applicable to Web Interface and administrative claims-based measures.

**We refer readers to § 414.1335(a)(3) for our policy on data completeness.

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(iv) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2018 Quality Payment Program final rule (82 FR 53732), we finalized that, beginning with the 2019 performance period/2021 MIPS payment year, we will validate the availability and applicability of quality measures only with respect to the collection type that a MIPS eligible clinician utilizes for the quality performance category for a performance period, and only if a MIPS eligible clinician collects via claims only, MIPS CQMs only, or a combination of MIPS CQMs and claims collection types. We will not apply the validation process to any data collection type that the MIPS eligible clinician does not utilize for the quality performance category for the performance period. We sought comment on how to modify the validation process for the 2019 performance period/2021 MIPS payment year when clinicians may submit measures collected via multiple collection types.

In the CY 2019 PFS final rule (83 FR 59847), we finalized a proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen. For example, this policy will not apply to eCQMs even if they are submitted by a registry. We noted that a MIPS eligible clinician may not have available and applicable quality measures. If we are unable to score the quality performance category, then we may reweight the clinician's score according to the reweighting policies.

In this year's rule, we proposed to modify our validation process to provide that it only applies to MIPS CQMs or the Part B claims collection type, but it will not apply in instances when a MIPS eligible clinician submits for both collection types. Currently, very few reporters report for a combination of Part B claims and MIPS CQMs. In CY 2020, of submissions with less than 6

measures, only 0.08 percent of individual submissions and 0.3 percent of group submissions included a combination of Part B claims and other submission types. In CY 2019, of submissions with less than 6 measures, only 0.094 percent of individual submissions and 0.07 percent of group submissions included a combination of Part B claims and other submission types. We see that reporting using both collection types is an option very few clinicians have chosen to utilize, and consequently believe that the associated costs for validation of a combination of the both the Part B claims based and MIPS CQM collection types is too great in these instances. To align with this reality that very few clinicians submit data in this manner, we proposed to update our policy.

We invited public comments to modify our validation process to provide that it only applies to MIPS CQMs or the claims collection type and not a combination of the two.

We did not receive public comments on this provision, and therefore, are finalizing as proposed.

(v) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to § 414.1380(b)(1)(iv) for our previously finalized policies regarding the identification of topped out measures and § 414.1380(b)(1)(iv)(B) for our finalized policies regarding the scoring of topped out measures. Under § 414.1380(b)(1)(iv), we identify topped out measures in the benchmarks published for each Quality Payment Program year. Under § 414.1380(b)(1)(iv)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727).

We noted in the CY 2021 PFS proposed rule (85 FR 50307) that we intended to use performance period benchmarks for the 2021 performance period/2021 MIPS payment year, which would mean we will not be able to publish measures that are topped out prior to the 2021 MIPS performance period. As discussed in that proposed rule (85 FR 50309), this also means we would not be able to identify those that have been topped-out for 2 or more consecutive years for purposes of the topped out scoring of 7 measure achievement points. As we were intending to use performance period benchmarks again for the 2022 performance period/2024 MIPS payment year, these problems would occur again. We believed it is still important to retain a topped-out scoring cap of 7 measure achievement points so that clinicians have incentives to pick alternate measures that are not topped out. We also believed that if a measure were not topped out in the 2022 performance period benchmark, then it should have the ability to achieve up to 10 measure achievement points.

In the CY 2022 PFS proposed rule, we proposed to use performance period benchmarks again and subsequently needed to adjust the topped-out measure lifecycle to account for this. Therefore, we proposed as an exception to the general rule at § 414.1380(b)(1)(iv)(B) at paragraph (b)(1)(iv)(B)(1) that, for the CY 2022 MIPS performance period/2024 MIPS payment year, MIPS eligible clinicians would receive no more than 7 measure achievement points for each measure (except for measures in the CMS Web Interface) for which the applicable benchmark were identified as topped out for 2 or more consecutive years based on the historical benchmarks published for the CY 2021 MIPS performance period and continues to be identified as topped out based on the performance period benchmarks published for the CY 2022 MIPS performance period/2024 MIPS payment year.

We believe these two criteria collectively would provide clinicians the information to know prior to the CY 2022 performance period/2024 MIPS payment year which measures would have the topped-out scoring applied but will also account for the scenario where a measure is no longer topped out. We would not limit the number of measure achievement points for measures that have not been topped out for at least 2 years as published in the 2021 MIPS performance period/2023 MIPS payment year historical benchmarks.

We invited public comments on our proposal to apply the 7-measures achievement point cap to measures that meet the two criteria.

We received public comments on the assigning measure achievement points for topped out measures. The following is a summary of the comments we received and our responses.

Comment: One commenter noted that clinicians want to know which measures are topped out before the performance period begins.

Response: We will continue to provide notice of topped out measures according to our standard policy. We are not finalizing our proposal to use performance period benchmarks, and therefore, will communicate topped out measures before the performance period begins as is customary.

Comment: One commenter supported the policy to provide clinicians with additional information to determine which measures are topped out prior to the performance period and noted that the policy will ensure that clinicians can select meaningful measures and earn maximum points on quality measures due to the extraordinary circumstances of the COVID–19 pandemic

Response: We appreciate the commenters for their support for this policy based on the intended use of the performance period benchmarks, but note that as we are not finalizing the use of performance period benchmarks as discussed in section IV.A.3.e.(1)(c)(ii) of this final rule. We are not finalizing this proposal.

Comment: A few commenters requested that the 7-point scoring cap on topped out measures be waived for specific measure sets that only have topped out measures from which to select. One commenter requested that the topped-out scoring cap be suspended as topped out performance may not be accurate due to shifting program requirements and COVID–19 related disruptions in care.

Response: As MIPS is a performance-based program, we do not believe that MIPS eligible clinicians electing to report topped out measures should be able to receive the same maximum score as other measures that demonstrate variation in performance and room for improvement. Therefore, we continue to believe it necessary to maintain the 7-point cap for measures identified as topped out, including those belonging to measure sets. Additionally, please refer to *qpp.cms.gov/about/covid19* our national PHE for COVID–19 response and flexibilities provided within QPP.

After consideration of public comments, we are not finalizing our proposal to revise paragraph (b)(1)(iv)(B)(1). We will instead continue our policy that the 7-point cap will be applied to measures (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years, beginning in the second year the measure is identified to be topped out.

(vi) Minimum Case Requirements

We refer readers to § 414.1380(b)(1)(iii) for our previous finalized policies regarding case minimum requirements for the quality performance category, which establishes the case minimum requirement

threshold at 20 cases for quality measures, with the exception of administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1). As more measures are introduced under MIPS, there may be measures, similar to the administrative claims-based measures, that warrant a different case minimum requirement from the other quality measures. In Table Group A of Appendix 1 of the proposed rule, we proposed to add the following quality measure starting with the 2022 MIPS performance period: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO–PM), which uses a comprehensive and parsimonious set of 11 patient-reported items to assess the broad scope of primary care (86 FR 39435 and 39436).

In order to achieve the appropriate reliability of the measure—the survey results (adequate number of surveys to provide an accurate representation of the MIPS eligible clinician, group, subgroup, virtual group, and APM Entity), for each MIPS eligible clinician, group, subgroup, virtual group, and APM Entity, a minimum of 30 PCPCM PROM instruments per clinician are needed for submission of this measure. For MIPS eligible groups, subgroups, virtual groups, and APM Entities with 5 or more clinicians, a minimum of 150 PCPCM PROM instruments per TIN for each site/location associated with the clinicians' part of the group, subgroups, virtual groups, and APM Entities are needed for submission of this measure. For TINs with a composition of multiple specialty practices at one site/location, a minimum of 150 PCPCM PROM instruments per specialty practice within a TIN are needed for submission of this measure. If the MIPS eligible group, subgroup, virtual group, and APM Entity with 5 or more clinicians encompasses multiple sites/locations, each site/location will need to meet the PCPCM PROM instruments requirements as noted above. To allow for the reliable implementation of PCPCM PRO–PM under MIPS, such measure requires a case minimum that exceeds 20 cases.With more measures being introduced under MIPS that warrant differing case minimum requirements (other than administrative claims-based measures), we proposed to modify our minimum case requirements policy to broaden the type of measures (to not only include administrative claims-based measures) that would have an exception to the minimum case requirement threshold of 20 cases and to provide a measure-specific case minimum requirement for measures identified and determined on a case-by-case basis by CMS. For each measure with a measure-specific case minimum, the minimum case requirement is specified in the annual list of MIPS measures. Specifically, we proposed to amend § 414.1380(b)(1)(iii) to reflect that, except as otherwise specified in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

We invited public comment on our proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported including flexibility to enable larger case minimum requirements on a measure-by-measure basis to ensure measures are reliable and valid, as adequate reliability may not always be achieved using a case minimum of 20 patients.

Response: We are committed to assure reliable and valid quality measurement under the MIPS program and will assess our measures and policy to assure we are meeting this goal.

Comment: A few commenters stated that CMS must ensure that the data produced yields scores that accurately and consistently represent the quality of care provided by an individual clinician and practice and believed that the current average reliability threshold of 0.4 is too low and the minimum sample size should be increased to a higher number to produce a minimum reliability threshold of sufficient magnitude (0.7). One commenter cautioned that having too many case minimum requirements will add to the complexity and burden and a few commenters asked CMS to monitor whether there are increasing numbers of existing measures requiring measure specific case minimums and the impact on burden.

Response: We will continue to review measures to ensure they meet the reliability threshold of 0.4 as previously establish (81 FR 77287). We believe that measures with a reliability of 0.4 with a minimum attributed case size of 20 meet the standards for being included as quality measures within the MIPS program. We aim to measure quality performance for as many clinicians as possible, and limiting measures to reliability of 0.7 would result in fewer individual clinicians with quality performance category measures. In addition, a 0.4 reliability threshold ensures moderate reliability for most MIPS eligible clinicians or group practices that are being measured on quality. We acknowledge that inclusion of too many case minimum requirements may add complexity. However, we believe that the benefit to the program from adding measures that require additional case minimum standards for effective implementation justifies the burden created by the additional complexity. We will continue to listen to stakeholder feedback and monitor the effects of this policy on burden.

After consideration of public comments, we are finalizing our amendment at § 414.1380(b)(1)(iii) to reflect that, except as otherwise specified in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

(vii) Incentives to Report High-Priority Measures

We refer readers to current § 414.1380(b)(1)(v)(A) for our previously finalized policies regarding incentives to report high priority measures. In the CY 2017 Quality Payment Program final rule (81 FR 77293), we established the scoring policies for high priority measure bonus points to encourage the selection of additional high-priority and outcome measures that impact beneficiaries and were closely aligned to our measurement goals. In the CY 2019 PFS final rule (83 FR 59850), we discontinued awarding measure bonus points to CMS Web Interface reporters for reporting high priority measures since CMS Web Interface reporters have no choice in measures.

We stated in the CY 2019 PFS proposed and final rules (83 FR 35950 and 59851) that as part of our move towards fully implementing high value measures, we believe that bonus points for high priority measures for all collection types may no longer be needed. We noted in the CY 2019 PFS final rule (83 FR 59851) that measure bonus points were created as transition policies which were not meant to continue through the life of the program. We believe with the finalized framework for transforming MIPS through MVPs (84 FR 62948), we will find ways in the future to emphasize high priority measures without needing to incentivize with bonus points.

In the CY 2022 PFS proposed rule, we proposed to end the high-priority measure bonus points. As we move to MVPs we are simplifying our scoring by ending transition policies that were established in the initial years of the program. We have signaled for many years now that this policy was temporary and would be removed from the program. As we transition to a new State, we anticipate that there will no longer be a need to incentivize high-

priority measures by usage of bonus points in MIPS and MVPs as we increase the share of high-priority measures in the program.

We proposed to end measure points for reporting high priority measures beginning the 2022 performance period/2024 MIPS payment year. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(A) to provide that for the 2017 through 2021 performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus points.

We invited public comments on our proposal to end measure bonus points for reporting high priority measures beginning the 2022 performance period/2024 MIPS payment year.

The following is a summary of the comments we received and our responses.

Comment: Several commenters asked to delay the removal of the high-priority bonus by at least one year, until the CY 2023 performance period, due to the COVID–19 pandemic impacts and since the performance threshold is also increasing this year. Many commenters suggested keeping the bonus in place until final MVP measure sets are available as this would be less disruptive to eligible clinicians with few quality performance measures and who depend on bonus points to successfully participate in the MIPS program. One commenter noted that the pandemic took clinician focus off of the mechanics of MIPS and few clinicians will be prepared for the removal of the high priority bonus. One commenter suggested that a delay in removal of the bonus would ensure a less disruptive transition to a higher performance threshold. Another commenter suggested that CMS do a phased-out removal of these bonuses in consideration of the performance threshold.

Response: We agree that the national PHE of COVID–19 has resulted in a reduced focus by clinicians from the mechanics of MIPS to providing effective care in response to the PHE. We also understand that clinicians are worried about their performance in the program as a result of the proposal to increase the performance threshold. We remain committed to addressing stakeholder feedback, while working towards the goals of the program.

As previously noted in section IV.A.3.e.(1)(c)(iii). of this final rule, we have decided to delay the removal of the 3-point floor until the CY 2023 performance period/2025 MIPS payment year, but will move forward with the removal of the bonuses in the quality performance category. We believe that this provides a phased approach to removing the transition policies to which clinicians have become accustomed, while also moving towards the program goal of reducing sources of scoring inflation and being able to score based on meaningful distinctions in performance on quality measures. We will not maintain bonuses until MVP measures set are available. MVP measure sets are in development and will be introduced overtime. We are aiming to simplify MIPS scoring ahead of MVPs so as to develop scoring s provide incentives to report MVPs as discussed in section IV.A.3.b.(5)(a) of this final rule. We cannot continue to support reporting strategies that rely on bonus points awarded for reporting. We note that we have signaled for years that the measure bonus and scoring floor policies were intended to support the transition to MIPS and would be removed (86 FR 39436). In order to be responsive to the challenges of the COVID–19 PHE, we are maintaining the policies related to the scoring floors, but will continue through future rulemaking to remove these transition policies and the scoring inflation they introduce.

Comment: Many commenters opposed the removal of the high-priority bonus. A few commenters noted that the bonus serves as an incentive to report important measures, recognizes clinicians for their efforts to meet CMS' priorities, and provides clinicians extra help in meeting the increased performance threshold. One commenter stated that the bonus helps make up for what is lost based on limited measure selection if a clinician only has topped out measures from which to choose. One commenter noted that small practices are reliant on the bonus points and are otherwise not able to have scores that reflect the quality care small practices provide. One commenter requested the bonuses remain in place for small practices given the continued inequities between small and large practices and to help level the playing field and to encourage continued small practice participation. A few commenters noted that given the impacts of the COVID–19 pandemic the bonuses should remain in place to provide additional assistance. One commenter noted that as the program gets harder, clinicians need more assistance in achieving the threshold to avoid a penalty.

Response: We understand that receiving bonus points for submitting high-priority measures has eased clinicians' participation in the program and supported their adoption of high priority measures. That was the intent of offering bonus points at the start of the program (81 FR 77292). Now that it has been several years, we believe clinicians should be familiar with the areas that CMS considers high priority and familiar with reporting them. Ultimately, these bonuses have fulfilled their purpose and a high proportion of clinicians and groups report on high-priority measures. CMS wishes to measure performance on clinical quality measures and some types of bonus points can mask performance, and therefore, we want to use them judiciously such as to provide a scoring floor for new measures and incentivize reporting in MVPs. As the program transitions to MVPs, we will focus on providing incentives to report through MVPs. Reporting strategies that solely use bonus points for reporting to offset lower performance or topped out measure selection are not compatible with the intent of a performance-based program. We understand that with the removal of the quality performance category level bonus points and increase in the performance threshold, clinicians are concerned about receiving negative payments. We ultimately believe these scoring changes will enable fairer scoring that will benefit many clinicians, including those in small practices. Additionally, we believe the impact of this policy is partially mitigated by the maintenance of small practice bonus points within the quality performance category, as well as the Complex Patient Bonus for all MIPS eligible clinicians. To ease the transition to the new policies and to be responsive to hardships caused by the COVID–19 PHE, we are maintaining the 3-point scoring floor until CY 2023, but we are removing the high priority measure bonus points. We believe this decision will lead to fairer and simpler scoring that clinicians will ultimately benefit from.

Comment: One commenter requested feedback reports that include detailed information about which and how many bonus points were earned as a result of high priority measures.

Response: We currently provide information about the total number of bonus points added to the quality performance category score as part of

the final feedback reports that are available to all MIPS eligible clinicians.

Comment: One commenter suggested CMS finalize greater accommodations for small practices, such as applying a separate small practice bonus to the MIPS final score rather than limit the small practice bonus to the quality performance category or increasing the size of the existing small practice bonus. Commenters also recommended that CMS allow small practices to continue to receive bonus points for reporting high priority measures or reporting measures using end-to-end electronic reporting.

Response: We are committed to ensuring the small practices are able to fairly participate in MIPS. As the commenter noted, we currently offer measure bonus points for small practices at quality performance category score level (83 FR 59847). For the reasons stated in the CY 2019 PFS final rule, we believe a small practice bonus specific to the quality performance category is preferable for the CY 2019 performance period/2021 MIPS payment year and future years (83 FR 59847). Data analytics suggest that the removal of the high priority and end-to-end electronic reporting measure bonus points for all practices would help small practices by reducing scoring inflation at the quality performance category level by reducing the over-utilization of these measure bonus points by larger practices that have the resources to report additional measures. A greater proportion of larger practices receive high priority measure bonus points and reach the measure bonus point cap when compared with practices of all other sizes and solo and small practitioners utilize these points and reach the measure bonus point cap the least. We will continue to monitor the performance of small practices in MIPS and make the appropriate interventions, as well as develop MVPs to facilitate the meaningful participation of small practices in MVPs which may include increasing the size of the existing small practice bonus.

Comment: One commenter noted that without the high priority bonus, clinicians may opt to submit data for fewer measures leading to smaller datasets for benchmarking and public reporting. The commenter requested that CMS add a new opportunity for clinicians to earn points to encourage such reporting, such as higher bonuses for performance improvement or incentives for reporting extra measures.

Response: We understand that clinicians may submit data for fewer measures as a result of this policy and that this may affect datasets available for benchmarking and public reporting, but do not believe these changes will be significant. We will monitor the effect that this has on benchmarking however, we will not be instituting new bonuses in MIPS. As we move to MVPs we are moving to simplify scoring in MIPS and focus on incentives for reporting through MVPS.

After consideration of public comments, we are finalizing our proposal as proposed.

(viii) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT and qualified clinical data registries. Section 1848(q)(5)(B)(ii)(II) of the Act requires that the Secretary shall treat such clinicians as satisfying the clinical quality measures reporting requirement described in section 1848(o)(2)(A)(iii) of the Act if they report such measures through the use of such EHR technology for a given performance period. In the CY 2017 Quality Payment Program final rule (81 FR 77297), we established the measure bonus point and bonus cap for using CEHRT for end-to-end electronic reporting. We refer readers to § 414.1380(b)(1)(v)(B) for our previously finalized policies regarding measure bonus points for end-to-end electronic reporting. We believe that with the framework for transforming MIPS through MVPs discussed in the CY 2020 PFS proposed rule (84 FR 40739) and the CY 2021 PFS proposed rule (85 FR 50279 through 50285), we will find ways to encourage the use of CEHRT for reporting quality measures without needing to incentivize the use of CEHRT for end-to-end electronic reporting with bonus points. In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged stakeholders to consider electronically specifying their quality measures as eCQMs, to encourage clinicians and groups to move towards the utilization of electronic reporting. As noted in the CY 2019 PFS final rule (83 FR 59851), bonus points were created as transition policies which were not meant to continue through the life of the program.

In the CY 2022 PFS proposed rule, we proposed to end measure bonus points for end-to-end electronic reporting. We noted that as we move to MVPs we are simplifying scoring by removing many of the transition policies that we established in the early years of the program. We believe it is imperative to remove transition policies in order to develop a stronger MVP program and promote alignment between MIPS and MVPs. As stated in previous rulemaking, we are working to develop ways to encourage the use of CEHRT for electronic reporting without offering measure bonus points. Measure bonus points introduce scoring inflation into the program and preclude our ability to accurately compare clinicians' clinical quality. As the program works to focus on the quality of care provided to beneficiaries, we intend to score for performance on measures and not for reporting. Additionally, we believed that we can fulfill the statutory requirement at sections 1848(q)(5)(B)(ii)(I) of the Act to encourage the usage of CEHRT, through other means. As a program and across the Department of Health and Human Services, we are working towards the goal of all measures within MIPS being digital by 2025 through a movement towards the inclusion of more digital quality measures (dQMs), emphasizing approaches to electronic data sharing that utilize the FHIR standard. As part of these approaches we intended to further leverage the use of electronic reporting from CEHRT for all quality measurement completed in the MIPS program including measurement and reporting facilitated by third party intermediaries such as QCDRs and plan to further address this issue through rulemaking in future years. We are also giving preference to dQMs including eCQMs in our annual call for measures. More information on dQMs and the FHIR standard is available in section IV.A.1.c. of this final rule, information on the call for measures and CMS measurement needs and priorities is available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1313/2021%20Call%20for%20Measures%20and%20Activities%20Toolkit.zip,* and *https://www.cms.gov/files/document/cms-measurement-priorities-and-needs.pdf,* respectively. Furthermore, over the past few years, we have reduced the availability and limited who can submit data for the Medicare Part B claims collection type to only small practices. We note that the Medicare Part B claims collection type is not an electronic means of submission. We solicited comments on other methods that we could use to encourage the use of CEHRT for electronic reporting (86 FR 39436 and 39437).

Accordingly, we proposed at § 414.1380(b)(1)(v)(B) that for the 2017 through 2021 performance period/2019 through 2023 MIPS payment years,

MIPS eligible clinicians would receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus points for submitting using end-to-end electronic reporting.

We invited public comments on our proposal to end measure bonus points for end-to-end electronic reporting beginning in the 2022 performance period/2024 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: Many commenters opposed the removal of the end-to-end reporting bonus as electronic reporting remains a priority for CMS; bonus points provide an incentive to report through end-to-end reporting, which is often costly; and bonus points help the clinicians reach the increasing performance threshold. A few commenters noted that practices should be awarded for going above and beyond in their quality reporting. A few commenters opposed the removal of these bonus achievement points considering the COVID–19 PHE, MVP reporting beginning in performance year 2023, and the move to digital quality measurement by 2025. Many commenters believed that an incentive is still required to encourage the use of CEHRT for electronic reporting. One commenter noted that the bonus should be maintained during the transition to dQMs. One commenter stated that many hospitals and some entities are still not providing clinicians with access to medical record information and some EMR vendors are still not in compliance with the ability to provide adequate clinical data. One commenter stated that the bonus furthers the goal of the program and provides more useable real-world data while encouraging clinicians to sign up with QCDRs. One commenter suggested that CMS apply bonus points at the composite score level providing some consistency to providers. One commenter noted that maintaining the bonus would help combat problems obtaining appropriate differentiation among practice performance due to clinical quality measure selection bias. A few commenters expressed concern with the removal of the bonus negatively impacting specialists' scores given that the diminished scoring opportunities are not due to changes in performance. One commenter requested that all electronic measures be eligible for end-to-end reporting bonus points, even if there is an eCQM equivalent.

Response: As MIPS transitions to MVPs, our priority is to simplify scoring and score for performance rather than for reporting. We believe that the use of CEHRT adds value for clinicians and will work to develop other ways that encourage its use as we move to MVPs and digital quality measurement. We recognize concern about the effects of the PHE and increase in the performance threshold, and therefore, are maintaining our 3-point scoring floor policy to ease clinicians' transition to simplified scoring as we move towards MVPs. We do not believe that using CEHRT for electronic reporting is going above and beyond as the commenter suggests, nor do we believe that reporting via end-to-end electronic reporting still requires awarding bonus points. Rather we believe it is important to facilitate high quality clinical care and the ability to participate in this program meaningfully as such will no longer provide incentives for reporting in MIPS as we transition to MVPs. We understand the commenter's concerns about data blocking and/or hospitals not sharing data with Third Party Intermediaries and will continue to work with partners across HHS to explore ways to address this issue. The end-to-end electronic reporting bonus has been active throughout the last few years of MIPS. While we intended it to encouraged some clinicians to transition to an electronic data submission mechanism, our assumption was that the applicable clinicians would have transitioned by now. Additionally, we believe that clinicians who have made the transition to an electronic data submission mechanism likely will not make the decision to revert back to a manual/claims-based option. Furthermore, we do not believe it is necessary or appropriate to apply this bonus at the final score level. As mentioned in the previous section of this final rule, reporting strategies that solely use bonus points for reporting to offset lower performance or topped out measure selection are not compatible with the intent of a performance-based program. We will continue to try and find other solutions to the diminished scoring opportunities for specialists through MVPs.

After consideration of public comments, we are finalizing our proposal as proposed.

(ix) Improvement Scoring for the MIPS Quality Performance Category Score

We refer readers to § 414.1380(b)(1)(vi)(C)(4) for more on our current for the 2020 through 2023 MIPS payment years, which provides for the purpose of improvement scoring that we will assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

In the CY 2022 PFS proposed rule, we proposed to continue our previously established policy for improvement scoring for the 2022 performance period/2024 MIPS payment year and to revise § 414.1380(b)(1)(vi)(C)(4) to remove the phrase ''2020 through 2023 MIPS payment years'' and adding in its place the phrase ''beginning the 2018 performance period/2020 MIPS payment year'' to indicate that for each MIPS payment year after 2020, we would assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. Specifically, for the 2022 performance period/2024 MIPS payment year, we would compare the MIPS eligible clinician's quality performance category achievement percent score for the 2022 performance period/2024 MIPS payment year to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance score less than or equal to 30 percent for the 2021 performance period/2023 MIPS payment year.

We did not receive public comments on this proposal, and we are finalizing as proposed.

(d) Cost Performance Category

(i) Scoring Flexibility for Changes That Impact Cost Measures During the Performance Period

We refer readers to § 414.1380(b)(2) for our policies regarding scoring for the cost performance category and to previous rules where these policies were finalized, including the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311), the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), the CY 2019 PFS final rule (83 FR 59856), and the CY 2021 PFS final rule (85 FR 84877 through 84880). In § 414.1380(b)(2)(v), we finalized that a cost performance category score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a

benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

We have identified that there is a need for additional flexibility in calculating the scores for cost measures to account for the impact of changing conditions that are beyond the control of MIPS eligible clinicians and groups. This flexibility would allow us to ensure that clinicians are not impacted negatively when performance is affected not due to the care provided, but due to external factors. Thus, beginning with the 2022 MIPS performance period/2024 MIPS payment year, we proposed a policy to provide scoring flexibility in instances where changes during a performance period impede the effective measurement of resource use. We stated that we believe that there may be instances when there are rapid or unprecedented changes to the delivery of healthcare services that are reflected in administrative claims data used to calculate cost measures. In the CY 2022 PFS proposed rule (86 FR 39437), we provided the example of the COVID–19 PHE and referred readers to section IV.A.3.e.(2)(b)(ii)(A) of the proposed rule, where we summarized our assessment of the impact of COVID–19 on the calculation of cost measure scores for the 2020 performance period. In this discussion, we concluded that due to the unique and rapid changes to healthcare in the COVID–19 pandemic, which significantly affected service utilization and the underlying data used to calculate cost measures, we could not reliably calculate scores for the cost measures that adequately capture and reflect clinician performance for 2020. This example demonstrated that the assessment of costs could be impeded by substantial changes to clinical practice and service utilization, and result in misleading or inaccurate results.

We noted (86 FR 39438) that we would determine whether such external changes impede the effective measurement of resource use by considering factors including: The extent and duration of the changes, and the conceptual and empirically tested relationship between the changes and each measure's ability to accurately capture clinician cost performance. Empirical testing could include assessing whether there are rapid or unprecedented changes to patient case volume or case mix, and the extent to which this could lead to misleading or inaccurate results. We noted that substantial changes in service utilization may not impede our ability to accurately calculate a cost measure score. Consider for example the case of a hypothetical measure that includes the cost of a series of procedures to treat the condition being measured. Due to advances in clinical knowledge, the procedures are declared to no longer be appropriate to treat the condition during a performance period. This would hypothetically lead to rapid and substantial changes in the services captured in the measure in that performance period; however, these changes will not necessarily lead to misleading or inaccurate results as the measure will be appropriately capturing the costs of care for that condition and appropriately reflecting changes in clinician practice. We stated that we would assess this empirically for each measure, as we believe that even widespread external changes to service utilization could have a range of different impacts across measures as they focus on diverse types of care. For example, a hypothetical national shortage of blood products may lead to the suspension of elective surgeries. This may not affect the care patterns for a particular outpatient screening or preventative care procedure, meaning that a hypothetical cost measure focused on that outpatient procedure would still accurately reflect clinician cost performance.

While we can monitor the impact of these changes during the performance period, we noted (86 FR 39438) that there is an inherent delay between the time we can identify trends in administrative claims data and when we can test for potential impact on the cost measures, due to the claims run-out period necessary to ensure that data included in our analyses reflect final claims for all services in episodes. To ensure sufficient case volume, we expected that we would not be able to properly test the full impact of external changes on the cost measures until after the end of the performance period in which the changes occurred. Thus, we would not be able to determine whether a cost measure should be suppressed due to changes in the performance period until after the completion of the performance period. To allow sufficient time for claims data query and investigatory work to test for potential impacts on cost measure calculations, we expected that we would reach a conclusion as to whether a cost measure should be suppressed and notify clinicians affected by the suppression no later than when performance feedback is issued for the performance period. We believed this will not put undue burden on clinicians since cost measures are calculated by CMS using administrative claims data without any additional data submission by clinicians.

Accordingly, we proposed to add § 414.1380(b)(2)(v)(A) to provide that beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure were impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure would be excluded from the MIPS eligible clinician's or group's cost performance category score. We proposed that, for the purposes of this paragraph (b)(2)(v)(A), ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. Significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

We solicited comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the addition of the policy to suppress a cost measure for a MIPS eligible clinician or group in instances where changes during a performance period impede the effective measurement of resource use. One commenter stated that the unpredictability of the pandemic makes it difficult to understand the impact on cost. The commenter stated that CMS should assess whether clinicians can reasonably be scored on the cost performance category. Another commenter suggested that CMS consider national disasters, such as wildfires and hurricanes, as significant changes warranting measure suppression. One commenter stated that CMS should evaluate scoring variation year-to-year to determine if it can be attributed to changes in performance and investigate whether a measure should be suppressed due to factors outside of the control of the physician.

Response: We recognize the impact that the pandemic has on clinicians and continue to monitor its effects on cost measures to ensure that clinicians' performance is being fairly assessed. In addition, we conduct regular monitoring of cost measures, to assess year-to-year changes in patterns of care and analyze whether certain circumstances or events impact clinicians' performance on

measures. These monitoring efforts can help to inform whether a future event, such as a natural disaster, could warrant measure suppression.

Comment: One commenter urged CMS to delay the application of any new episode-based measures to a TIN's final MIPS score for the first 2 years of applicability. The believe applying these measures without adequate prior information or data on an ongoing basis furthers the burden on clinicians and TIN's.

Response: We disagree with the commenter that delaying the application of new episode-based measures for 2 additional years after their incorporation into the MIPS cost performance category would reduce the burden on clinicians (TIN–NPIs) or clinician groups (TINs). We note that the episode-based measures are claims-based, so there is no submission burden for MIPS eligible clinicians, groups, and virtual groups. Additionally, the measure specifications that describe the steps for constructing the measures and contain the medical codes used in that methodology are publicly available during the measure development and notice-and-comment rulemaking processes. Thus, MIPS eligible clinicians, groups, and virtual groups have the opportunity to understand the measure specifications, including what costs are included in each episode, prior to the implementation of such measures in MIPS.

We further believe that newly developed measures generally would be ready for implementation in MIPS beginning with the performance period following the publication of the final rule in which they are adopted for the cost performance category. The episode-based measures are developed with extensive involvement of clinician experts, including clinicians from the attributed specialties, as well as other clinicians involved in the relevant care continuum for each measure, who make informed recommendations based on empirical data. Throughout the measure development and implementation processes, we work to help clinicians get familiar with the new measures through ample education and outreach activities, and also encourage them to provide feedback on the measure specifications (we refer readers to 86 FR 39396 and 39397 for more information on the development process for new episode-based measures). For example, for the 5 new episode-based measures that we proposed for inclusion in MIPS in the CY 2022 PFS proposed rule, stakeholders had an opportunity to observe all clinical expert workgroup meetings via a listen-only line, as well as participate in the national field-testing activities on the measures in the summer of 2020. Additionally, the measures were published in the Measures Under Consideration (MUC) list in December 2020, and the measure specifications and testing results were later available for public comments during the NQF's pre-rulemaking process and as part of the CY 2022 PFS proposed rule (86 FR 39397 through 39401). Given that the 5 new episode-based measures are ready for implementation in MIPS and that these measures play an important role in expanding the MIPS cost measure inventory, we believe that a delay in the application of those measures is not appropriate and would only prevent the performance of a MIPS eligible clinician, group, and virtual group from being assessed.

After consideration of public comments received, we are finalizing this policy as proposed.

(e) Promoting Interoperability Performance Category

For our previously established policies regarding scoring the Promoting Interoperability performance category, we refer readers to § 414.1380(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77216 through 77227), the CY 2018 Quality Payment Program final rule (82 FR 53663 through 53670), the CY 2019 PFS final rule (83 FR 59785 through 59796), the CY 2020 PFS final rule (84 FR 63020) and the CY 2021 PFS final rule (85 FR 84893 through 84894). We also refer readers to § 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), the CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), the CY 2019 PFS final rule (83 FR 59785 through 59820), and the CY 2021 PFS final rule (85 FR 84886 through 84895 for our previously established policies regarding the Promoting Interoperability (formerly the advancing care information) performance category generally.

In the CY 2019 PFS final rule, we established a new performance-based scoring methodology for the Promoting Interoperability performance category that applies beginning with the 2019 performance period/2021 MIPS payment year (83 FR 59787 through 59796). The scoring methodology is codified at § 414.1380(b)(4)(ii); however, the regulation text refers only to the 2021 and 2022 MIPS payment years, and does not mention subsequent years. We proposed to revise § 414.1380(b)(4)(ii) for consistency with the previously established policy, by indicating that the methodology applies beginning with the 2019 MIPS performance period/2021 MIPS payment year and continuing to subsequent years. We proposed to revise § 414.1380(b)(4)(ii) to remove ''for the 2021 and 2022 payment years'' and add in its place ''beginning with the 2019 performance period/2021 MIPS payment year'' and remove the word ''six'' to provide that beginning with the 2019 performance period/2021 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required measures and any applicable bonus scores, not to exceed 100 points.

In addition, for the 2020 performance period/2022 MIPS payment year, each optional measure in the Promoting Interoperability performance category was worth five bonus points (84 FR 63003), and for the 2021 performance period/2023 MIPS payment year, each optional measure was worth ten bonus points (85 FR 84894). In the proposed rule, we proposed that the Query of Prescription Drug Monitoring Program measure would be worth 10 bonus points; we also proposed that submission of a ''yes'' for the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure would be worth 5 bonus points (86 FR 39438). To reflect these policies, we proposed a change to § 414.1380(b)(4)(ii)(C) to reflect that the optional measures are worth five or ten bonus points, as specified by CMS.

We solicited comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal to revise the language to reflect that optional measures are worth 5 or 10 bonus points.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposal as proposed.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for each MIPS eligible clinician, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, and CY 2021 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917, respectively) on final score calculations, performance category

weights, reweighting the performance categories, and the complex patient bonus.

As described in more detail in the following sections, we:

- Proposed to continue doubling the complex patient bonus for the CY 2021 performance period/2023 MIPS payment year, as was previously finalized with a cap of 10 bonus points for the CY 2020 performance period/2022 MIPS payment year (86 FR 39439 through 39440).
- Proposed to revise the complex patient bonus formula, which currently provides a bonus to all MIPS eligible clinicians, groups, virtual groups, and APM entities who submit data for at least one MIPS performance category, so that beginning with the CY 2022 performance period/2024 MIPS payment year the complex patient bonus better targets clinicians who treat a higher caseload of more complex and high-risk patients (86 FR 39442 through 39446).
- Solicited comments on potential circumstances where we may not be able to reliably calculate a score for any of the cost measures as described under § 414.1380(c)(2)(i)(A)(*2*). Additionally, we note that we are reweighting the cost performance category for the CY 2020 performance period/2022 MIPS payment year because we have concluded there are not sufficient measures and activities applicable and available for us to score any clinicians on performance due to the national PHE for COVID–19 (86 FR 39446 through 39448).
- Proposed to continue performance category weight redistribution policies finalized for the CY 2022 performance period/2024 MIPS payment year (86 FR 39448).
- Proposed policies for redistributing the weight of the performance categories for small practices (86 FR 39448 through 39449).
- Clarify how our application-based and automatic extreme and uncontrollable circumstances policies intersect (86 FR 39450).
- Proposed a new policy to determine the MIPS final score for clinicians and groups who are eligible for facility-based measurement (86 FR 39450 through 39452).

(a) Complex Patient Bonus

(i) Background

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our MIPS scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS; and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we established at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). In subsequent rulemaking, we continued the complex patient bonus at § 414.1380(c)(3) for the 2021, 2022, and 2023 MIPS payment years (83 FR 59870, 84 FR 63023, and 85 FR 84910, respectively). Additionally, we finalized for the 2022 MIPS payment year at § 414.1380(c)(3)(iv) that the complex patient bonus will be calculated under the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value will then be multiplied by 2 (85 FR 84911 through 84913). We refer readers to these final rules for additional details on the background, statutory authority, policy rationale, and previously finalized calculation of the complex patient bonus.

We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. The overall goal, when considering a bonus for complex patients, is two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We used the term ''patient complexity'' to consider a multitude of factors that describe and have an impact on patient health outcomes; such factors include the health status and medical conditions of patients, and social risk factors. We believe as the number and intensity of these factors increase for a single patient, the patient may require more services, more clinician focus, and more resources to achieve health outcomes similar to those who have fewer factors. In developing the policy for the complex patient bonus, we assessed whether there was a MIPS performance discrepancy by patient complexity using two well-established indicators in the Medicare program: Medical risk as measured through Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients that is dually eligible for Medicare and Medicaid (82 FR 53771 through 53776).

(ii) Complex Patient Bonus for the CY 2021 Performance Period/2023 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39439 through 39440), we proposed to modify the complex patient bonus for the CY 2021 performance period/2023 MIPS payment year in response to the PHE for COVID–19. In the CY 2020 PFS final rule, we finalized a policy to continue the complex patient bonus for the CY 2020 performance period/2022 MIPS payment year (84 FR 63021 through 63023). However, due to the national PHE for COVID–19 during performance period 2020, we noted in the CY 2021 PFS proposed rule that we need to re-evaluate the previously established policy for the complex patient bonus for the CY 2020 performance period/2022 MIPS payment year (85 FR 50311). We refer readers to the CY 2021 PFS proposed rule (85 FR 50311 through 50313) for further details on how the PHE for COVID–19 impacts care delivery both directly and indirectly. We acknowledged there are direct effects of COVID–19 for those patients who tested positive for SARS–CoV–2 and indirect effects of COVID–19 for other patients whose care was impacted because of the PHE, including increased complexity and barriers such as postponing care, accessing care in a different way (for example, via telecommunications), and disruptions to lab results and medications, which are not accounted for in our existing final score calculations using these complexity indicators.

Considering both these direct and indirect effects, we finalized § 414.1380(c)(3)(iv) (85 FR 84913), under which the complex patient bonus is calculated for the CY 2022 MIPS payment year pursuant to the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value is then multiplied by 2 but cannot exceed 10.0. The doubled numerical value

(subject to the 10-point cap) is added to the final score.

We noted we had made significant progress against COVID–19. While we are encouraged by the progress, we believed that there may be some direct and indirect effects from the PHE that could affect the CY 2021 performance period/2023 MIPS payment year. In particular, through the third quarter of CY 2021, we had high COVID cases in multiple regions.[254] Additionally, we cannot quantify the effect of beneficiaries who delayed care because of the PHE and are now seeking care.

Because of the concerns of the direct and indirect effects of the COVID–19 PHE, we proposed to continue doubling the complex patient bonus as described at § 414.1380(c)(3)(iv) for the CY 2023 MIPS payment year, and we proposed corresponding revisions to the regulation text at § 414.1380(c)(3)(iv). The doubled numerical value (subject to the 10-point cap) will be added to the final score. Since the COVID–19 cases and deaths have decreased throughout the year, we considered applying a smaller multiplier (like 1.5 for a cap of up to 7.5 points) or to not apply a multiplier at all. However, we believe doubling the complex patient bonus is appropriate given the continuation of the national PHE for COVID–19 into the 2021 MIPS performance period, the potential direct and indirect effects of COVID–19 on care delivery and care postponement, and additional uncertainties. We solicited comments on this proposal and whether a different multiplier should be applied as we plan to consider the options based on public comment.

We received public comments on the doubling of the complex patient bonus for the CY 2021 performance period/2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the doubling of the complex patient bonus for CY 2021 performance period/2023 MIPS payment year due to the impacts of the ongoing national PHE for COVID–19. A few commenters suggested that CMS continue to double the complex patient bonus in CY 2022 given the continuation of the national PHE for COVID–19.

Response: We appreciate commenters' support of this proposal. As noted in section IV.A.3.e.(2)(a)(iii)(B) of this final rule, we have revised the formula for CY 2022 performance period/2024 MIPS payment year in efforts to better acknowledge complex patients treated by MIPS eligible clinicians.

Comment: One commenter opposed CMS' proposal to continue doubling the complex patient bonus for the CY 2021 performance period/2023 MIPS payment year saying that MIPS eligible clinicians have had over a year to adapt to the changes caused by the national PHE for COVID–19.

Response: While we are encouraged by the progress made against COVID–19, we believe that there continues to be direct and indirect effects from the PHE that could affect the CY 2021 performance period/2023 MIPS payment year for reasons stated in the CY 2021 PFS final rule (85 FR 84913).

After consideration of public comments, we are finalizing the proposal to continue doubling the complex patient bonus as described at § 414.1380(c)(3)(iv) for the CY 2021 performance period/2023 MIPS payment year, and the corresponding revisions to the regulation text at § 414.1380(c)(3)(iv). The doubled numerical value (subject to the 10-point cap) will be added to the final score.

(iii) Complex Patient Bonus Beginning With the CY 2022 Performance Period/2024 MIPS Payment Year

(A) Complex Patient Bonus Background and Analysis

As discussed in the CY 2021 PFS final rule (85 FR 84908), we intended the complex patient bonus as a short-term solution to address the impact patient complexity may have on MIPS scoring. However, during the development of the CY 2021 PFS final rule, we did not have sufficient information available to develop a long-term solution to account for patient risk factors in MIPS that we could include as a finalized policy for the CY 2021 performance period/2023 MIPS payment year. In the CY 2020 PFS proposed and final rules, we considered whether newly available data from the Quality Payment Program still supported the complex patient bonus at the final score level (84 FR 40793 through 40795). More specifically, within the data analysis, we did not observe a consistent linear relationship for any reporting type or complexity measure, HCC risk score or dual proportion (84 FR 63021 through 63023). However, we only had a few years of data and believed more recent data may bring different results than the findings we explained in detail in the CY 2020 PFS final rule. We refer readers to the CY 2020 PFS final rule for further details on the methodology and findings (84 FR 63021 through 63023).

Further, section 1848(q)(1)(G) of the Act requires us to consider the relevant studies conducted under section 2(d) of the IMPACT Act and, as appropriate, other information, including information collected before completion of such studies and recommendations. We refer readers to section IV.A.3.e.(2)(a)(iii)(A) of the CY 2022 PFS proposed rule (86 FR 39440 through 39441) for discussion on HHS Assistant Secretary for Planning and Evaluation's (ASPE) first report (released in December 2016) and ASPE's second report (released in June 2020). Further, we noted in the CY 2021 PFS final rule (85 FR 84909) that as we continue to review the findings from the report, we intend to consider its recommendations, along with any updated data that would become available, for future rulemaking. In the CY 2021 PFS final rule (85 FR 84909), we also noted we plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify longer term policy solutions that achieve the goals of attaining health equity for all beneficiaries, and minimizing unintended consequences, and would propose modifications to the complex patient bonus in future rulemaking as appropriate.

Under § 414.1380(c)(3), the complex patient bonus is calculated as follows. For MIPS eligible clinicians and groups: [The average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5]. For APM entities and virtual groups: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively, × 5].

For the CY 2022 PFS proposed rule, we explored alternative calculation methodologies to modify the complex patient bonus formula based on several factors including stakeholder feedback, updated data analysis, and implications from ASPE reports to Congress. We also reviewed a series of literature recently published utilizing the 2017 MIPS performance period data. We refer readers to section IV.A.3.e.(2)(a)(iii)(A) of the CY 2022 PFS proposed rule (86

[254] *https://www.nytimes.com/interactive/2021/us/covid-cases.html.*

FR 39441) for the detailed discussion on the Johnston KJ, Hockenberry JM et al. article [255] which found that the current complex patient bonus formula appears unlikely to mitigate the most regressive effects of MIPS. Further details in section IV.A.3.e.(2)(a)(iii)(A) (86 FR 39441) of the CY 2022 PFS proposed rule also highlighted the two other research studies we considered related to how risk scores, specifically related to HCCs, differ between both rural and urban areas.

While ASPE's reports to Congress support the use of a complex patient bonus at the final score level, we also acknowledge the findings reported in the published literature by identifying ways to make the complex patient bonus more targeted for clinicians caring for high risk and complex patients and to mitigate differences in resources that affect MIPS scores. Once it became available, we reviewed the 2018 MIPS actual data to see if we could replicate the findings and identified some structural issues within the current complex patient bonus formula. We refer readers to section IV.A.3.e.(2)(a)(iii)(A) of the CY 2022 PFS proposed rule (86 FR 39441 through 39442) for the details on the updated analysis.

In summary, our updated analyses using actual 2018 MIPS scored data found that clinicians who have a higher share of complex patients have lower final scores, on average, prior to the assignment of the complex patient bonus than other clinicians. Additionally, our analyses showed that there is little evidence of association between the complex patient risk indicators (HCC and dual proportion) and MIPS final scores among the clinicians with a lower share of complex patients. We also noted, based on the above analysis using actual 2018 MIPS scored data for clinicians scored as individuals and groups examined separately, the median raw final scores for engaged clinicians in the calculated top complex patient bonus quintile were more than 10 points less than the median raw final score of those in the bottom complex patient bonus quintile. Specifically, the median raw final scores for engaged clinicians in the top complex patient bonus quintile were 82.33 for groups and 60.76 for individuals compared to median raw scores of 94.36 for groups and 81.28 for individuals in the lowest quintile. Additionally, when we compared the median raw final scores for engaged clinicians in the calculated middle complex patient bonus quintile to the highest quintile, we still observed a difference in median raw final scores of greater than 10 points for both individuals and groups. Table 61 shows 2018 median MIPS raw final scores for the engaged individuals and groups within the lowest, middle and highest complex patient bonus (CPB) quintiles.

TABLE 61: 2018 Median MIPS Raw Final Scores for Engaged Individuals and Groups by Complex Patient Bonus Quintile

	Lowest CPB Quintile	Middle CPB Quintile	Highest CPB Quintile
Median MIPS Final Score (Individual)	81.28	77.44	60.76
Median MIPS Final Score (Group)	94.36	94.38	82.33

We found while the two risk indictors, dual proportion and HCC risk score, were correlated substantially, each has a different scale. For example, the dual proportion has a natural upper bound of 1 whereas the HCC risk score does not. The distribution of each risk indicator around its mean and median is also different. Given these findings, we have identified areas within the complex patient bonus that can be improved. Most importantly, the complex patient bonus formula used through the CY 2021 performance period/2023 payment year gave bonus points to clinicians not adversely affected by social risk and medical risk of their patients and does not sufficiently account for clinicians who treat patients who are high-risk and/or medically complex.

(B) Updates to the Complex Patient Bonus Beginning With the CY 2022 Performance Period/2024 MIPS Payment Year

Based on the ASPE report and our analyses, we proposed to revise the complex patient bonus by—(1) limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual proportion); (2) standardizing the distribution of the two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients; and (3) providing one overall complex patient bonus cap at 10 bonus points. To accomplish this, we included five separate proposals to update our complex patient bonus for the CY 2022 performance period/2024 MIPS payment years and future performance periods/MIPS payment years. We note that in section IV.A.3.e.(2)(a)(iii)(B) of this final rule, we use the term ''clinician(s)'' to generally refer to those individuals and entities that these proposals apply to, including MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups. First, we proposed to add to § 414.1380(c)(3) that, similar to our current policy, beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraph (c)(3)(v) through (c)(3)(viii). Second, we proposed at § 414.1380(c)(3)(v) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment years, the

[255] Johnston KJ, Hockenberry JM et al. (Sept 2020) ''Clinicians With High Socially At-Risk Caseloads Received Reduced Merit-Based Incentive Payment System Scores'' HEALTH AFFAIRS 39, NO. 9 (2020): 1504–1512.

Khullar D, Schpero WL, et al. (Sept 2020) ''Association between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System'' JAMA. 2020; 324 (10):975–983.

complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. Third, we proposed the revised formulas at § 414.1380(c)(3)(vi). For MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation. Fourth, we proposed the revised formulas at § 414.1380(c)(3)(vii). For APM entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation. Finally, we proposed at § 414.1380(c)(3)(viii) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment years, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

(aa) Continuing the Requirement To Submit Data and To Use the Same Risk Indicators

Under the first proposal, beginning with the CY 2022 performance period/2024 MIPS payment years, we proposed at § 414.1380(c)(3) to continue the requirement to submit data for at least one MIPS performance category for the applicable performance period for the MIPS payment year for a MIPS eligible clinician, group, subgroup, virtual group or APM entity to receive a complex patient bonus added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii).

As discussed below in section IV.A.3.e.(2)(a)(iii)(B)(cc) of this final rule, the proposals at § 414.1380(c)(3)(vi) and (vii) include complex patient bonus components within the formulas proposed beginning with the CY 2022 performance period/2024 MIPS payment year to account for social and medical risk, while still using our current established risk indicators of dual proportion and HCC risk scores, respectively. We also continue to believe that applying this bonus at the final score is appropriate because caring for complex and vulnerable patients can affect all aspects of a practice and not just specific performance categories.

We requested public comments on the proposal to continue the requirement that a MIPS eligible clinician, group, subgroup, virtual group or APM entity must submit data for at least one MIPS performance category for the applicable performance period for the MIPS payment year to receive a complex patient bonus added to the final score for the MIPS payment year, if applicable.

However, we did not receive public comments on this proposal, and we are finalizing as proposed.

(bb) Cutoff at the Median for Complex Patient Bonus Beginning With the CY 2022 Performance Period/2024 MIPS Payment Year

Beginning with the CY 2018 performance period/2020 MIPS payment year, a complex patient bonus was added to the final score for the MIPS payment year for all MIPS eligible clinicians, groups, virtual groups and APM entities if they submitted data for at least one MIPS performance category for the applicable performance period for the MIPS payment year (§ 414.1380(c)(3)). We did not include any requirement that clinicians had to attain a certain threshold to receive the complex patient bonus. Under the second proposal, we proposed at § 414.1380(c)(3)(v), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment, the complex patient bonus would be limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. This proposal limits the component for social risk to clinicians with a dual proportion value at or above the median dual proportion, and it limits the component for medical risk to clinicians with an HCC score value at or above the median HCC score. Those at or above the median for a risk indicator will get complex bonus points for that risk indicator component. To ensure the points are impactful and provided specifically to clinicians treating higher numbers of medically and socially complex patients, we proposed to provide bonus points beginning at the respective calculated medians.

Both medical and social factors within the newly proposed methodology, discussed in section IV.A.3.e.(2)(a)(iii)(B)(bb) of this final rule, will have separate medians and distributions calculated to provide more transparent bonuses to directly target those clinicians who treat a higher caseload of high-risk and complex patients. Both the dual proportion and the HCC risk indicators attributed to each clinician will be calculated in the same manner as under our current policy (for more information about the current policy, see the CY 2018 Quality Payment Program final rule (82 FR 30135)).

To determine the median for the respective risk indicator (HCC and dual proportion), we proposed to use the risk indicators associated with the final score assigned to a clinician from the prior performance period for all engaged MIPS clinicians, which we stated means those who have submitted data for at least one MIPS performance category or are facility-based. We inadvertently did not include this proposal in regulatory text in the CY 2022 PFS proposed rule (86 FR 39443), but for clarity, we are adding the following text to § 414.1380(c)(3)(v) in this final rule: To determine the median for the respective risk indicator (HCC and dual proportion), risk indicators associated with the final score assigned to a clinician from the most recent prior performance period, for all those who have submitted data for at least one MIPS performance category or are facility-based, are used. For example, the medians from the CY 2021

performance period, calculated using the associated risk indicators from the CY 2021 performance period, would be compared to the CY 2022 MIPS performance period risk indicator values to determine who would be eligible for a CY 2022 performance period/2024 MIPS payment year complex patient bonus. We stated that we would also use this same final score distribution to determine the standardized score discussed in the proposed rule (86 FR 39444). These statistics would be applied to the applicable performance period values of the risk indicators for each clinician to calculate the social and medical risk component scores for the MIPS performance period. We stated that we believe we need a prospective determination of the median, and standardized score from a prior performance period where the final scores are already resolved.

In our proposal, only those clinicians with risk indicator scores at or above the median for either one or both risk indicators will receive complex patient bonus points. Based on this final rule regulatory impact analysis (see section VI.F.18. of this final rule), we estimate 64 percent of clinicians will receive a complex patient bonus because there is not 100 percent overlap in the clinicians that are at or above the median for both risk indicators. Approximately 36.3 percent of engaged clinicians will not receive any complex patient bonus points, as they are below the median for both the HCC risk score and the dual proportion. We believe this number is appropriate as we will be targeting the complex patient bonus points to clinicians treating a higher caseload of highly complex patients.

Additionally, the complex patient bonus points will be more impactful as the difference in awarded bonus points between those with high caseloads of complex patients and those with low caseloads, will be greater. We believe establishing a cutoff point at the median, as opposed to the mean, is appropriate given the median is less impacted by outlier cases since the median is simply the middle value. We considered whether to use the mean, instead of the proposed median, but estimated that will result in about 50 percent of clinicians no longer receiving any complex patient bonus points because outliers could increase the mean.

In the CY 2022 PFS proposed rule (86 FR 39443), we acknowledged that alternate approaches could be used to target the bonus at clinicians with higher caseloads of complex patients. For example, we considered using a different distribution of risk indicator scores, such as one from an earlier performance period, so clinicians could know their scores in advance, or through using a distribution that includes individual clinician scores and counts group scores, APM Entity scores, virtual group scores, and, starting in the CY 2023 MIPS performance period/2025 MIPS payment year, subgroup scores only once, so the group, APM Entity, virtual group, or subgroup score is not weighted by the number of clinicians in the group, APM Entity, virtual group, or subgroup. We also considered building risk benchmarks based on our current quality measure benchmark methodology (81 FR 77282 and 82 FR 53718) to determine the number of complex patient bonus points. Under that methodology, risk indicator scores higher than the decile in which the median risk factor lies would receive complex patient bonus points and all of the clinicians in the top decile would receive 5 points for each risk indicator. We solicited comments on alternate approaches for calculating the complex patient bonus.

We received public comments on our proposal to limit the complex patient bonus to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median beginning in the CY 2022 MIPS performance period/2024 MIPS payment. The following is a summary of the comments we received and our responses.

Comment: A few commenters support CMS' proposal to set the cutoff at the median for complex patient bonus points.

Response: We thank the commenters for their feedback and support.

Comment: Several commenters opposed CMS' proposal to use the cutoff at the median for the individual risk indicators. A few commenters were concerned that the proposed methodology would disadvantage rural practices. One of the commenters was specifically concerned about rural areas having lower HCC due to coding differences and recommended that CMS utilize the median HCC risk indicator at both the national and regional levels and determine eligibility using the lower of the two scores. A few commenters noted that utilizing the median as a cutoff may introduce a ''cliff'' in which practices with small differences in risk factor scores could experience very different complex patient bonuses. Other commenters suggested that having the cutoff below the median would result in unintended consequences and discourage clinicians from treating complex patients.

Several commenters advised that CMS proceed very cautiously before eliminating the bonus for those clinicians who have relatively few complex patients versus those clinicians who have a larger number of such patients. Finally, one commenter suggested that CMS continue the already established complex patient bonus formula and provide complex patient bonus points to all clinicians.

Response: We believe the structure of the formula prevents a major cliff from occurring at the median as those right below the median and those right above median do not experience very different complex patient bonuses. Within the formula, the standardized score is based on the mean, which, at this time, is higher than the median. The additive component of 1.5 allows clinicians with standardized scores between the median and the mean to receive between zero and 1.5 points for each risk indicator, thus slowly increasing the number of bonus points as clinicians' standardized scores increase. For example, if the dual proportion risk indicator median is 0.2 and the dual proportion risk indicator mean is 0.23, a clinician with an associated standardized score of -0.25 (0.25 standard deviations below the mean, but still above the median), the clinician will receive a complex patient bonus equal to $1.5 + 4 * (-0.25)$ which equals 0.5 for the dual proportion component. We note that CMS will continue to monitor the impact of our policy for those clinicians who will no longer receive the complex patient bonus under the revised formula, but at this time, we continue to support targeting the bonus to make the points more impactful. We believe that generating a risk score at a regional or State level may be beneficial, however, there are complexities and technicalities that would need to be addressed such as defining the appropriate region, addressing circumstances when groups or individuals practice across multiple regions or States, and assessing how much of the score is national versus regional. Additionally, our analysis regarding the impact of the revised formula on rural areas showed that while there is no significant difference between rural and non-rural TIN/NPIs at the payment adjustment level, we do see differences in HCC scores that align with the literature findings discussed at section IV.A.3.e.(2)(a)(iii)(A) of the CY 2022 PFS proposed rule (86 FR 33441). As this topic is complex, we will monitor and consider changes in the future, if necessary, based on available data. Further, we disagree having the

cutoff at the median would discourage clinicians from treating complex patients because they have always treated those patients even prior to CMS establishing the complex patient bonus. We continue to believe the goal of the bonus for complex patients is two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. Finally, we do not believe that we should continue to use the previous formula given that the revised formula more precisely targets clinicians caring for high risk and complex patients and better mitigates differences in resources that affect MIPS scores.

After consideration of public comments, we are finalizing at § 414.1380(c)(3)(v), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. To determine the median for the respective risk indicator (HCC and dual proportion), risk indicators associated with the final score assigned to a clinician from the most recent prior performance period, for all those who have submitted data for at least one MIPS performance category or are facility-based, are used.

(cc) Revised Complex Patient Bonus Formulas Beginning With the CY 2022 Performance Period/2024 MIPS Payment Year

Under the third proposal, we proposed at § 414.1380(c)(3)(vi) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment, for MIPS eligible clinicians, groups, and subgroups, that the complex patient bonus components would be calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation. For example, we will use the mean and standard deviation from the CY 2021 MIPS performance period and the indicator assigned in the CY 2022 MIPS performance period to determine the clinician's standard score for the CY 2022 performance period/2024 MIPS payment year.

Under the fourth proposal, we also proposed at § 414.1380(c)(3)(vii), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment years, for APM entities and virtual groups, that the complex patient bonus components would be calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

The mean and standard deviation statistics will be used along with the performance period values of the risk indicators for each clinician to calculate the standardized score used to calculate the social and medical risk component scores for the MIPS payment year. For example, if the raw dual proportion score calculated for a clinician is 0.25, the dual proportion mean (from the prior performance period) is 0.23, and the dual proportion standard deviation (from the prior performance period) is 0.15, the clinician's standardized score will be (0.25 − 0.23)/0.15 = 0.13. We believe that the standardized score calculation is appropriate as it is typically used to understand how far the raw risk indicator scores fall from the mean. We noted that those with a mean score will have a standardized score of zero, and those with a standardized score of 1 are one standard deviation above the mean. Those below the mean will have a negative standardized score. The proposed formulas will also provide bonus points to clinicians who have a negative risk indicator standardized score and fall between the calculated median and mean for the respective risk indicator and to those who fall at or above the mean and thus have a positive risk indicator standardized score. As noted in section IV.A.3.e.(2)(a)(iii)(B)(bb) of the final rule, at § 414.1380(c)(3)(vi) and (vii), the new bonus components will use respective means to calculate standardized scores to then calculate and provide bonus points for clinicians with risk indicators, HCC and dual proportion, at or above the median, to capture medical and social risk, separately. For each of the two component calculations, higher standardized scores above the mean would be associated with more bonus points. For example, a clinician with a standardized score of zero (the mean value) for each risk indicator, HCC and dual proportion, will receive bonus points for each component that is equivalent to the constant, additive factor within the new formula, 1.5. The proposed formulas acknowledged complexity without creating a large cliff between those who are just below the median and those who have a marginally higher caseload of complex patients. The bonus, as proposed, would increase proportionally with the increased number of complex patients a clinician is treating and/or the degree of patient complexity. For example, we did not want to provide those who fall at the mean 1.5 bonus points, and then provide 10 bonus points to those who only have only a slightly higher caseload. Hence, we intended to incorporate a standardized score multiplied by 4 to ensure the score got proportionally higher as complexity increases.

The additive factor of 1.5 ensures that all clinicians at or above the mean for the social complex patient bonus calculation, based on dual proportion, will receive at least 1.5 complex patient bonus points and all clinicians at or above the mean for the medical complex patient bonus calculation, based on HCC risk score, will receive at least 1.5 complex patient bonus points. Further, the additive factor of 1.5 will allow clinicians between the median and mean to still receive complex patient bonus points. For example, if the dual proportion risk indicator median is 0.2

and the dual proportion risk indicator mean is 0.23, a clinician with an associated standardized score of −0.1 (0.1 standard deviations below the mean, but still above the median), the clinician will receive a complex patient bonus equal to 1.5 + 4 * (−0.1) which equals 1.1 for the dual proportion component. If the dual proportion risk indicator calculated for a clinician falls below the median, they will receive zero complex patient bonus points for the dual proportion component. Based on the standardized score calculation, if the dual proportion risk indicator calculated for a clinician falls above the mean, they will receive complex patient bonus component points greater than the additive factor of 1.5 for the dual proportion component.

We believe this formula avoids a major complex patient bonus points cliff that could be created by providing the clinicians right *above* the cutoff point significant bonus points compared to the clinicians right *below* the cutoff point (who do not receive any complex patient bonus points). We acknowledge those who fall below the median will no longer receive any complex patient bonus points, per proposal at § 414.1380(c)(3)(v) that for the CY 2022 performance period/2024 MIPS payment years and future MIPS performance periods/MIPS payment years, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median.

We received public comments on our proposal to revise the complex patient bonus formula. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to revise the complex patient bonus formula for the CY 2022 performance period/2024 MIPS and future payment years to better account for care delivered to highly complex patients.

Response: We thank the commenters for their support and feedback.

Comment: A few commenters suggested some modifications to revise the proposed formulas. One commenter suggested that the proposed methodology for standardizing the scores for risk indicators is overly sensitive to outliers. Rather, they suggested that CMS standardize risk indicators using the median instead of the mean. The commenter also suggested that we use a more robust measure of variation than the standard deviation. Another commenter suggested that CMS standardize the dual eligible ratio using the median value in each State, rather than the median or mean at a national level. More specifically, the commenter suggested this given that the dual eligible ratio for a clinician varies depending on the number of Medicaid-eligible beneficiaries attributed to clinician which may be lower if a State has not expanded Medicaid. Finally, another commenter suggested that CMS increase the average HCC score for clinician based on the proportion of patients living in rural areas.

Response: We acknowledge that Medicaid eligibility criteria vary across States, and this could impact the number of dual-eligible patients attributed to a clinician. We also understand that there may be advantages to having an average HCC score for clinicians based on the proportion of patients living in rural areas. More specifically due to the potential coding differences between rural and non-rural areas as noted in the Tyler Malone, Denise Kirk et al. study [256] which indicated that Medicare beneficiaries in rural counties have lower average CMS–HCC risk scores compared to urban counties despite previous research suggesting that rural populations are sicker than urban populations. However, it may be misleading to create a median value for a State when a clinician or group may practice in multiple locations across different State lines. More specifically, we note that clinicians providing patient care as part of a clinical team may practice in different locations under the same group (TIN) which would make it difficult for us to assign a State-based dual eligible ratio. Additionally, dually-eligible patients may seek care across State lines, adding to the complexity. We are interested in exploring these suggestions further through future rulemaking but would need to do extensive modeling to rule out unintended consequences, identify appropriate data sources, and assess whether the advantages outweigh the additional complexity. We will continue to evaluate dual proportion to see if any additional modifications are needed. We would also be interested in hearing from stakeholders the best way to resolve these challenges in the future.

Further, the proposed policy standardizes each risk indicator (HCC risk score and dual proportion) using the mean and standard deviation. Specifically, the proposed policy used the standardized score formula of (risk indicator − mean of risk indicator)/standard deviation of risk indicator. We conducted a preliminary analysis that uses the median instead of the mean and the median absolute deviation (MAD) instead of the standard deviation for each risk indicator (HCC risk score and dual proportion) to create the standardized score. We used Year 5 final RIA data to calculate the values of the median and the MAD. The MAD first takes the absolute difference between a risk indicator value and the median of the risk indicator and then takes the median of the absolute differences. In other words, MAD = median (absolute difference (risk factor − median of the risk factor)) and the standardized score would be calculated using (risk indicator-median of risk indictor)/MAD of risk indicator.

Based on the analysis, we observed that the MAD is smaller than the standard deviation, used in our proposed rule's analysis, for each risk indicator. More specifically, using the median and MAD, the standard score is, on average, more than twice the value when compared to using the mean and standard deviation. Given that the standardized scores would be larger using the median and MAD to standardize, we recalibrated the multiplier as the initial multiplier was 4 but would effectively become 8 or more with the larger standardized scores. Additionally, if we use the median to standardize, clinicians at the risk indicator median would receive, at minimum, the initial constant (1.5 in the proposed formula). Because of these two reasons, when conducting our analysis, the proposed formula for the complex patient bonus (which is currently 1.5 + 4 * standardized score) needed to be recalibrated for our analysis to avoid unintended consequences.

We conducted our analysis using the median and the MAD to standardize and we used the formula 0.25 + 2 * standardized score for each risk indicator. We used 0.25 as the additive component to provide those at the median for each risk indicator with a non-zero amount of bonus points that would also not create a cliff. We used 2 as the multiplicative component to provide a bonus that gets proportionally higher as complexity increases while also accounting for the larger size of the standardized score. Using this formula, the number of clinicians receiving complex patient bonus points decreases slightly due to changes in entity type and clinicians would receive slightly fewer complex patient bonus points compared to the proposed formula.

[256] UNC Rural Health Research Program, ''CMS Hierarchical Condition Category (HCC) 2014 Risk Scores Are Lower for Rural Medicare Beneficiaries than for Urban Beneficiaries,'' December 2020.

However, the adjusted standardization method using the median and the MAD and associated formula did not have any major impact on the overall distribution and no impact of outliers was detected.

Comment: One commenter supported CMS' proposal to use the current risk indicators including HCC and dual eligibility. A few commenters requested that CMS look at additional risk indicators to account for additional complexities within the complex patient bonus formula. Specifically, a few commenters suggested that CMS consider clinical data to capture comorbidities and alternatives to dual eligibility to capture social risk. A few commenters suggested that CMS consider using other data such as Z-codes and indices (for example, Social Vulnerability Index, Community Needs Index, etc.).

Response: We thank the commenters for their support and suggestions and will take them into consideration as we continue updating the complex patient bonus in future years. We note that, although the ASPE report [257] found dual eligibility to be a reliable indicator of social risk, we understand there may be some limitations. However, we are not aware of data sources and/or methodologies to account for other social indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient's complexity. Further, we continue to believe that average HCC risk scores are a valid proxy for medical complexity that are also used by other CMS programs. Therefore, we have decided to continue to pair the HCC risk score with the proportion of dually eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We will evaluate additional, more comprehensive options, such as Z-codes and indices, in future years based on any updated data or additional information, including to better account for social risk factors while minimizing unintended consequences and consider these as we move forward.

After consideration of public comments, we finalize the proposal at § 414.1380(c)(3)(vi) that beginning with the CY 2022 performance period/CY 2024 MIPS payment, for MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

We also finalize the proposal at § 414.1380(c)(3)(vii), beginning with the CY 2022 performance period/2024 MIPS payment years, for APM entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(dd) Cap for the Complex Patient Bonus Beginning With the CY 2022 Performance Period/2024 MIPS Payment Year

When we originally established the complex patient bonus policy in the CY 2018 Quality Payment Program final rule (82 FR 53774), we finalized at § 414.1380(c)(3)(iii) that the complex patient bonus cannot exceed 5.0. At that time, our data analysis estimated a decrease in simulated scores of 5.4 points (for individuals who report 6 or more quality measures) and 4.5 points (for groups) from the top quartile to the bottom quartile for the average patient HCC risk scores and 4.8 points (for individuals who report 6 or more quality measures) and 4.5 points (for groups) from the top quartile to the bottom quartile for the dual proportion. Therefore, we believed a cap for the complex patient bonus of 5 points was supported by the data and was sufficient to compensate for the estimated differences in performance based on HCC risk scores and dual proportion (82 FR 53773). In CY 2019, CY 2020, and CY 2021 PFS final rules, we continued to believe that the 5-point cap was appropriate given that we had not updated our prior analyses (83 FR 58769 through 59870, 84 FR 63021 through 63023, 85 FR 84908 through 84913, respectively). However, based on our updated analyses using actual 2018 MIPS scored data, described above, about 5 percent of clinicians scored as group or individual had a complex patient bonus that would have been more than 5-points had the cap not been in place. The complex patient bonus cap of 5-points (82 FR 53773 through 53776) affects clinicians who are most likely carrying higher caseloads for patient complexity, which is inconsistent with the intent of the policy, and we no longer believe we should maintain the overall cap of 5-points. As discussed in section IV.A.3.e.(2)(a)(iii)(A) of this final rule, our updated analyses using actual 2018 MIPS scored data also found that clinicians with a higher caseload of complex patients have lower final scores, by more than 10 points on average, prior to the assignment of the complex patient bonus than clinicians with lower caseloads of complex patients. We believe, with a cap of 10 bonus points, we are targeting the bonus to address the differences in final scores these clinicians face more appropriately without capping at a larger number, such as 15 or 20 bonus points, which could result in inappropriate score inflation and masking of poor performance. A cap of fewer than 10 bonus points would not address the differences in the observed raw final scores and would not adequately address the need to provide more equity within our scoring system for those clinicians treating higher caseloads of socially and/or medically complex patients. We did consider lower caps, such as 5 or 7 bonus points, or higher caps, such as 20 bonus points, but for the reasons described above, we proposed the cap of 10 bonus points. However, if future analyses and more recent data show differences in raw

[257] ASPE. Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 29, 2020. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

final scores that differ from our previous findings, we would consider proposing in future rulemaking the use of a cap that aligns with new findings.

As discussed in section IV.A.3.e.(2)(a)(iii)(B)(cc) of this final rule, we proposed the formulas as: Risk indicator complex patient bonus component = 1.5 + 4 * associated risk indicator standardized score. The formula, as proposed, has a multiplier of 4. We also considered a multiplier of 2 with a cap of 5 bonus points which results in a lower final score mean and median but does not change the number of clinicians receiving a complex patient bonus when compared to the proposed policy. We do not believe that this alternate approach would produce a bonus impactful enough to overcome the differences seen at the final score level when comparing complex patient bonus quintiles. We solicited feedback on this alternate approach and additional alternate approaches we should consider.

Under the fifth proposal, we proposed at § 414.1380(c)(3)(viii) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0. Based on the proposed formulas at § 414.1380(c)(3)(vi) and (vii), the social complex patient bonus component (using dual proportion standardized score) and the medical complex patient bonus component (using HCC risk score standardized score) will be added together to calculate one overall complex patient bonus. Then, based on the proposal at § 414.1380(c)(3)(viii) the complex patient bonus will then be capped at the 10 points overall.

For example, if a clinician's dual proportion standardized score is 1.5, their complex patient bonus social risk component is 1.5 + 4 * 1.25 = 6.5. If their HCC risk score standardized score is 0.25, their complex patient bonus medical risk component is 1.5 + 4 * 0.25 = 2.5. The two complex patient bonus components are then added together to total 9 complex patient bonus points for this clinician. Had the total been above 10 bonus points, the 10-point cap would have applied and the clinician would have received 10 complex patient bonus points added to their final MIPS score.

We solicited feedback on whether we should use the multiplier of 4 and cap of 10 bonus points as proposed, a multiplier of 2 and cap of 5 bonus points as discussed as an alternative, or if we should consider additional options and rationale for the complex patient bonus formula and bonus cap, such as a cap of 7 or 20 bonus points.

We received public comments on the cap for the complex patient bonus. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to place the complex patient bonus cap at 10 points, similarly to how it was capped for the previous 2 years due to the policy to double the previously established 5-point cap in response to the impacts of the national PHE.

Response: We thank the commenters for their support and feedback.

Comment: A few commenters suggested that CMS increase the complex patient bonus cap from 10 points to 20 points. One commenter specifically suggested that CMS scale the formula so that individual clinicians in the upper quintile can receive at least 15 complex patient bonus points.

Response: At this time, we do not believe we need to increase the complex patient bonus cap from 10 points to 20 points or provide at least 15 complex patient bonus points to the upper quintile. We believe, with a cap of 10 bonus points, we are appropriately targeting the bonus to address the differences in final scores these clinicians face without capping at a larger number. Fifteen bonus points would contribute to the final score the same amount of points as the entire Improvement Activities performance category. However, if future analyses and more recent data show differences in raw final scores that differ from our previous findings, we would consider proposing in future rulemaking the use of a cap that aligns with new findings.

After consideration of public comments, we finalize the proposal at § 414.1380(c)(3)(viii) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

In summary, we finalized the five separate proposals for the CY 2022 performance period/2024 MIPS payment year and future MIPS performance periods/MIPS payment years as follows:

- Finalized as proposed at § 414.1380(c)(3), by adding, beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii).
- At § 414.1380(c)(3)(v), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, we finalized as proposed the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. To determine the median for the respective risk indicator (HCC and dual proportion), risk indicators associated with the final score assigned to a clinician from the most recent prior performance period, for all those who have submitted data for at least one MIPS performance category or are facility-based, are used.
- At § 414.1380(c)(3)(vi), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, we finalized as proposed for MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroups; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.
- At § 414.1380(c)(3)(vii), we finalized as proposed that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for APM entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or

virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

- At § 414.1380(c)(3)(viii), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, we finalized as proposed the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

In addition to the proposals we made, we also considered the alternative of continuing the use of the complex patient bonus formulas, as previously finalized at § 414.1380(c)(3)(i) and (ii), along with the 5.0 point cap as previously finalized at § 414.1380(c)(3)(iii) for the CY 2022 MIPS performance period/CY 2024 MIPS payment year. We solicited comment on that alternative and have addressed the comments we received above under section (IV.A.3.e.(2)(a)(iii)(B)(bb)) of this final rule.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2021 PFS final rules (81 FR 77320 through 77329, 82 FR 53779 through 53785, 83 FR 59870 through 59878, and 84 FR 62950 through 62959, 85 FR 84898 through 84908, respectively). Table 62 summarizes the weights established in prior rulemaking (85 FR 84913) for each performance category for the CY 2022 performance period/2024 MIPS payment year and each subsequent MIPS payment year.

TABLE 62: Weights by MIPS Performance Category for the CY 2022 Performance Period/2024 and each Subsequent MIPS Payment Year

Performance Category	2024 and Future MIPS Payment Years
Quality	30%
Cost	30%
Improvement Activities	15%
Promoting Interoperability	25%

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved.

Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician generally would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Under certain circumstances, however, a MIPS eligible clinician who fails to report could be eligible for an assigned scoring weight of zero percent and a redistribution of the performance category weights. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2021 PFS final rule (85 FR 84914 through 84916).

(A) Reweighting the Cost Performance Category

Under § 414.1380(c)(2)(i)(A), we will assign a different weight to a performance category and redistribute its prescribed weight to another performance category or categories in certain circumstances where we determine there are not sufficient measures and activities applicable and available under section 1848(q)(5)(F) of the Act. For the cost performance category, this includes circumstances where we cannot reliably calculate a score for the cost measures which adequately captures and reflects the performance of a MIPS eligible clinician (*see* § 414.1380(c)(2)(i)(A)(*2*)). In the CY 2018 Quality Payment Program final rule (82 FR 53780), for the cost performance category, we noted in the proposed rule we had stated that we continue to believe having sufficient measures applicable and available means that we can reliably calculate a score for the cost measures which adequately captures and reflects the performance of a MIPS eligible clinician, and that MIPS eligible clinicians who are not attributed enough cases to be reliably measured should not be scored for the cost performance category. We noted (82 FR 53780) we had established a policy in the CY 2017 Quality Payment Program final rule that if a MIPS eligible clinician is not attributed enough cases for a measure (in other words, has not met the required case minimum for the measure), or if a measure does not have a benchmark, then the measure will not be scored for that clinician (81 FR 77323). We stated (82 FR 53780) if we do not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score. In the CY 2022 PFS proposed rule (86 FR 39446 through 39448), we solicited comments on potential circumstances where we may not be able to reliably calculate a score for any of the cost measures which adequately captures and reflects the performance of a MIPS eligible clinician, and may assign a different

weight to the cost performance category and redistribute its prescribed weight to another performance category or categories. We stated that we are interested in comments on circumstances that could affect all MIPS eligible clinicians, as well as those that could affect a subset of MIPS eligible clinicians or individual MIPS eligible clinicians. We noted the cost performance category reweighting provision at § 414.1380(c)(2)(i)(A)(*2*) is distinct from the measure suppression policy proposed in section IV.A.3.e.(1)(d)(i) of the proposed rule, as it applies to the performance category as a whole and not on a measure-by-measure basis.

In the CY 2022 PFS proposed rule (86 FR 39447), we discussed our responses to commenters' concerns in the CY 2021 PFS final rule regarding the potential for COVID–19 to impact cost measures and our analyses of whether we could reliably calculate scores for the cost measures for the 2020 performance period. We noted that because we determined we cannot reliably calculate scores for the cost measures that adequately capture and reflect the performance of MIPS eligible clinicians, we announced via email communication (subject: *CMS Reweighting 2020 MIPS Cost Performance Category*) on May 20, 2021, in accordance with § 414.1380(c)(2)(i)(A)(*2*), we will assign a weight of 0 percent to the cost performance category for the CY 2020 performance period/2022 payment year and redistribute the prescribed weight of 15 percent to another performance category or categories, as established at § 414.1380(c)(2)(ii)(D). We noted as with all measures, we continue to monitor the evolving impact of COVID–19.

We stated in the CY 2022 PFS proposed rule (86 FR 39447) that we recognize there may be additional circumstances where we may not be able to reliably calculate a score for any of the cost measures within the cost performance category that adequately captures and reflects the performance of a MIPS eligible clinician, which could include external factors beyond the control of clinicians. Similar to the Measure Suppression Factors proposed and subsequently finalized in the FY 2022 IPPS/LTCH PPS rulemaking (86 FR 25473, 45301), we stated that such external factors may include significant national shortages or rapid or unprecedented changes in: (1) Healthcare personnel; (2) medical supplies, equipment, or diagnostic tools or materials; or (3) patient case volumes or patient case mix.

We solicited comments on whether these external factors should inform our future decision-making on whether to reweight the cost performance category under § 414.1380(c)(2)(i)(A)(*2*). We also solicited comments on whether there are other external factors we should consider, or other circumstances in general that could affect our ability to reliably calculate a score for the cost performance category as described under § 414.1380(c)(2)(i)(A)(*2*). We received public comments on these external factors. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS considering additional external factors in future decision-making on whether to reweight the cost performance category under § 414.1380(c)(2)(i)(A)(2).

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS specifically consider whether events will impact multiple performance periods and whether medical guidelines (such as the changing COVID–19 vaccination schedule) are being updated. One commenter recommended CMS consider small practices and practices with low volume when determining whether to reweight the cost performance category. A few commenters recommended reweighting decisions be based, in part, on an assessment of whether an external event impacts patterns of care or a clinician's ability to control complications, admissions, and readmissions.

Response: We appreciate the commenters' suggestions for external factors or other circumstances we should consider. We recognize that certain circumstances can affect clinicians and clinician groups across multiple performance periods, and we intend to assess each performance period to determine whether clinicians' performance has been affected by external factors that are not within their control. We also agree about the importance of monitoring potential impacts for small practices and practices with low volume of cases and note that setting a case minimum for a measure helps to ensure that practices have a sufficient case volume to be reliably scored on a measure. We continue to apply the appropriate case minimum for each measure as part of monitoring and testing for the impact of external events. Additionally, to address a stakeholder's comment on the importance of assessing whether external events impact patterns of care or a clinician's ability to control complications, admissions, and readmissions, we note that as part of our regular monitoring of the cost measures, we run empirical analyses to assess changes in patterns of care and evaluate whether certain circumstances or events impact clinicians' performance on measures. This assessment would help us to determine if these circumstance or events warrant cost performance category reweighting. This monitoring would include empirical analyses to compare cost performance across years. Depending on the specific measure, this may include the cost of complications, admissions, and readmissions.

After consideration of the public comments we received, we intend to consider the following three factors, in addition to any other factors that may be relevant in the future, when we make a determination as to whether we can reliably calculate a score for the cost performance category that adequately captures and reflects the performance of a MIPS eligible clinician, as described under § 414.1380(c)(2)(i)(A)(2): Significant national shortages or rapid or unprecedented changes in: (1) Healthcare personnel; (2) medical supplies, equipment, or diagnostic tools or materials; or (3) patient case volumes or patient case mix. We offer the following examples to illustrate each of these three factors.

- Factor 1: A significant national shortage or rapid or unprecedented change in healthcare personnel could mean that there is a systematic decrease in medical services being provided and similar impacts on data availability.
- Factor 2: A rapid and unprecedented national change in medical supplies, equipment, or diagnostic tools or materials could mean a rapid and systematic change in the way medical care is provided, which might result in distortions to resource use measurement.
- Factor 3: A rapid and unprecedented national change in the number and case mix of patients receiving medical services could mean that the measure cannot be reliably calculated due to systemic decreases in case counts and data available for risk adjustment.

(iii) Redistributing Performance Category Weights

In the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2021 PFS final rules (81 FR 77325 through 77329, 82 FR 53783 through 53785, 83 FR 59876 through 59878, 84 FR 63027 through 63031, and 85 FR 84914 through 84916), and at § 414.1380(c)(2)(ii), we established policies for redistributing

the weights of the performance categories in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories.

In CY 2021 PFS final rule, we finalized a policy for redistributing the performance category weights for the CY 2022 performance period/2024 MIPS payment year and noted that we planned to revisit our redistribution policies in future rulemaking and may consider redistributing more weight to the cost performance category after clinicians have more experience with cost being weighted at 30 percent (85 FR 84914). While we still intend to redistribute more weight to the cost performance category in future years, we believe it will be beneficial to establish the redistribution policies for the CY 2023 performance period/2025 MIPS payment year and future years to provide as much notice as possible to clinicians and other stakeholders. Hence, we proposed to apply the redistribution policy finalized for the CY 2022 performance period/2024 MIPS payment year at § 414.1380(c)(2)(ii)(F) to the 2025 MIPS payment year and each subsequent MIPS payment year, and we proposed corresponding revisions to § 414.1380(c)(2)(ii)(F). We still plan to revisit our redistribution policies in future rulemaking after clinicians have more experience with cost being weighted at 30 percent and gain more experience with our newly proposed MVPs.

We solicited public comments on this proposal.

We received public comments on the redistribution policy. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' proposal to continue the redistribution policies for future MIPS performance periods/MIPS payment years.

Response: We thank the commenters for their support and feedback.

After consideration of public comments, we finalize our proposal to apply the redistribution policy finalized for the CY 2022 performance period/2024 MIPS payment year at § 414.1380(c)(2)(ii)(F) to the 2025 MIPS payment year and each subsequent MIPS payment year, and we finalize the proposed corresponding revisions to § 414.1380(c)(2)(ii)(F).

TABLE 63: Performance Category Redistribution Policies Finalized for the CY 2022 Performance Period/2024 MIPS Payment Year and for Future MIPS Performance Periods/MIPS Payment Years

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	55%	30%	15%	0%
-No Quality	0%	30%	15%	55%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

Our finalized redistribution policies for the CY 2025 MIPS payment year and each subsequent MIPS payment year are included in Table 63. We note that not all the redistribution scenarios described in Table 63 will apply to MIPS eligible clinicians in small practices. Please refer to Table 64 for the redistribution policy for small practices.

(A) Redistributing Performance Category Weight for Small Practices

Clinicians and groups who work in small practices are a crucial part of the health care system. The Quality Payment Program provides options designed to make it easier for these clinicians and groups to report on performance and quality and participate in advanced alternative payment models for incentives. We have heard directly from clinicians in small practices that they face unique challenges related to financial and other resources, environmental factors, and access to health information technology. We heard from many commenters that the Quality Payment Program gives an advantage to large organizations because such organizations have more resources invested in the infrastructure required to track and report measures to MIPS (82 FR 53776). In response to the feedback on the potential burden on small practices, we have established special policies available for small practices including the small practice bonus and special scoring policies. For example, in the CY 2018 QPP final rule (82 FR 53682 through 53683), we established a significant hardship exception for small practices for the Promoting Interoperability performance category.

In this section of the rule, we discuss how we would redistribute the Promoting Interoperability performance category weight for small practices. Within the reweighting policy for the CY 2022 performance period/2024 MIPS payment year, the Promoting Interoperability performance category weight is redistributed fully to the quality performance category, unless the

quality performance category is weighted at zero percent. In general, our reweighting policies have emphasized the quality performance category over the improvement activities performance category. We have noted it is important to prioritize performance on measures that show a variation in performance such as quality measures, rather than the activities under the improvement activities performance category, which are based on attestation of completion (85 FR 84914). We believe this helps reduce incentives to not report measures for the quality performance category in circumstances when a clinician may be able to report but chooses not to do so. However, given stakeholder input and recently published literature, we believe there could be other reasons why a small practice would not report quality measures. One recent article [258] stated that physicians in larger group practices, multispecialty practices, or participating through alternative payment models had higher MIPS scores, possibly reflecting such practices' greater infrastructure and resources to collect, analyze, and report measures to CMS. We have also heard directly from clinicians in small practices that they face unique challenges related to financial and other resources and access to health information technology. Many commenters have shared their belief that the Quality Payment Program gives an advantage to large organizations because such organizations have more resources invested in the infrastructure required to track and report measures to MIPS (82 FR 53776). Indeed, 85 percent of clinicians who are not engaged with MIPS (who do not submit data) are clinicians in small practices (85 FR 85018), which we believe may be due to their limited resources. Given infrastructure and resource limitations within small practices, we believe it is appropriate to place more emphasis on a performance category that poses a reduced reporting burden such as the improvement activities performance category. We proposed that for small practices, as defined at § 414.1305, when the Promoting Interoperability performance category is reweighted, the quality performance category will be weighted at 40 percent, the cost performance category will be weighted at 30 percent, and the improvement activities performance category will be weighted at 30 percent. When both the cost performance category and the Promoting Interoperability performance category are reweighted, the quality performance category will be weighted at 50 percent and the improvement activities performance category will be weighted at 50 percent. We plan to revisit this redistribution policy in future rulemaking and may consider redistributing more weight to the cost performance category after clinicians have more experience with cost being weighted at 30 percent.

We anticipate that our proposal noted in the two rows in Table 64 will greatly assist small practices by providing further flexibilities to help with our goal of increasing engagement across the MIPS program and to be able to meet the MIPS requirements. Beginning with the CY 2022 performance period/2024 MIPS payment year, we proposed at § 414.1380(c)(2)(ii)(G) redistribution policies for small practices, as shown in Table 64.

We solicited public comments on this proposal.

We received public comments on the redistribution of performance category weights for small practices. The following is a summary of the comments we received and our responses.

Comment: Many commenters support CMS' proposal to redistribute the Promoting Interoperability weight in efforts to reduce burden on small practices.

Response: We thank the commenters for their support and feedback.

Comment: A few commenters supported CMS' proposal to redistribute the Promoting Interoperability weight for small practices but provided additional comments. A few commenters suggested that CMS apply this redistribution matrix to all practices particularly given that the performance threshold is increasing. A few commenters suggested that CMS allow for small practices to choose between reweighting of the quality performance category and improvement activities categories to 50 percent each and the standard reweighting option of quality performance category and improvement activities performance category. Another commenter suggests that CMS score small practices using both redistribution scenarios and apply the higher of the two scores to the final score. Finally, one commenter recommended that CMS distribute the weight more evenly across the MIPS performance categories.

Response: We continue to believe that it is appropriate to redistribute the Promoting Interoperability performance category weight across the quality and improvement activities performance categories as proposed for small practices. More specifically, we believe this is appropriate, given the infrastructure and resource limitations within small practices, to place more emphasis on a performance category that poses a reduced reporting burden such as the improvement activities performance category. We do not believe it necessary to provide small practice clinicians with a choice of which redistribution matrix they would like applied since we believe this would add burden by requiring small practices to inform CMS as how they would like to be scored—contradicting our reasoning for establishing this policy. Given the additional burden and resource limitations known to impact small practices to an extent greater than non-small practice clinicians, we, at this time, continue to believe this policy should remain limited to small practices. We also choose not to take the higher of the two scores for small practices as this may create an unfair advantage across MIPS eligible clinicians and we will continue to monitor this policy to ensure that there are no inadvertent impacts.

After consideration of public comments, we finalize the proposed redistribution policies for small practices at § 414.1380(c)(2)(ii)(G), as shown in Table 64, beginning with the CY 2022 performance period/2024 MIPS payment year.

[258] Johnston KJ, Wiemken TL et al. (Sept 2020) ''Association of Clinician Health System Affiliation with Outpatient Performance Ratings in the Medicare Merit-based Incentive Payment System'' JAMA. 2020; 324(10):984–992.



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Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements; Final Rule

TABLE 64: Performance Category Redistribution Policies for Small Practices for the CY 2022 Performance Period/2024 MIPS Payment Year and Future MIPS Performance Periods/MIPS Payment Years

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability*	40%	30%	30%	0%
-No Quality	0%	30%	15%	55%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability*	50%	0%	50%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

*The finalized redistribution policy specifically for MIPS eligible clinicians in small practices.

(iv) MIPS Reweighting Based on Extreme and Uncontrollable Circumstances

(A) MIPS Applications for Reweighting for the CY 2021 Performance Period/ 2023 MIPS Payment Year Based on Extreme and Uncontrollable Circumstances

We anticipate that the national PHE for COVID–19 will continue through CY 2021. Therefore, we remind clinicians that the application-based extreme and uncontrollable circumstances policy, as described in § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*), will be available for the CY 2021 performance period/2023 MIPS payment year (85 FR 84916 through 84917). Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for details. The application allows clinicians, groups, and virtual groups significantly impacted by the PHE for COVID–19 to request reweighting for any or all MIPS performance categories. Under this policy, if a clinician, group, or virtual group submits a reweighting application and also submits data for a performance category for which an application was submitted, the data submission will override the application, and the clinician, group, or virtual group will be scored on the data submitted.

Additionally, if an application is submitted for one performance category only, and data is submitted for the other 2 performance categories, only the performance category for which the application was submitted will be reweighted and the other performance categories will be scored. We believe this approach maintains a balance of encouraging participation in the Quality Payment Program while still providing for flexibility in weighting the performance categories for those who have been affected by the national PHE for COVID–19. Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for more information.

(B) MIPS Reweighting Based on Extreme and Uncontrollable Circumstances; Automatic and Application-Based Policies Clarification

Under the application-based extreme and uncontrollable circumstances policy codified at § 414.1380(c)(2)(i)(A)(*6*) for the quality, cost, and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(*2*) for the promoting interoperability performance category, clinicians who are subject to extreme and uncontrollable circumstances may submit an application to CMS to request reweighting of a performance category or categories. We also established an automatic extreme and uncontrollable circumstances policy at § 414.1380(c)(2)(i)(A)(*8*) for the quality, cost, and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(*3*) for the promoting interoperability performance category, under which we automatically reweight the performance categories for clinicians who are located in an area affected by extreme and uncontrollable circumstances as identified by us.

Based on stakeholder inquiries, we recognize not all stakeholders understand how individual MIPS eligible clinicians who are eligible for reweighting under the automatic extreme and uncontrollable circumstances policy and who also submit an application for reweighting based on extreme and uncontrollable circumstances are affected by the intersection of these policies. Currently, under both the application-based and automatic extreme and uncontrollable circumstances policies, if a MIPS eligible clinician who is located in an area affected by extreme and uncontrollable circumstances as identified by CMS submits data for any of the MIPS performance categories by the applicable submission deadline for the MIPS performance period, they will be scored on each performance category for which they submit data, and the performance category will not be reweighted to zero percent in the final score. Under the automatic extreme and uncontrollable circumstances policy, the other performance categories for which data was not submitted will remain reweighted to zero percent (82 FR 53898, 83 FR 59874). Additionally, as described in the CY 2019 PFS final rule (83 FR 59874), under the automatic extreme and uncontrollable circumstances policy, a MIPS eligible clinician who is located in an area affected by extreme and uncontrollable circumstances as identified by CMS will

not be scored on the cost performance category. As we stated in the CY 2019 PFS final rule (83 FR 59874), if a MIPS eligible clinician is located in an affected area, we would assume the clinician does not have sufficient cost measures applicable to him or her and assign a weight of zero percent to that category in the final score, even if we receive administrative claims data that will enable us to calculate the cost measures for that clinician.

The following example is intended to illustrate the intersection of the automatic and application-based extreme and uncontrollable circumstances policies. A MIPS eligible clinician who is located in an area affected by extreme and uncontrollable circumstances as identified by CMS and eligible for the automatic extreme and uncontrollable circumstances policy submits an application for reweighting based on extreme and uncontrollable circumstances. The application requests reweighting for the Promoting Interoperability performance category, and the clinician submits data for the quality and improvement activities performance categories. The clinician will be scored on the quality and improvement activities performance categories because they submitted data for those categories; the cost performance category is reweighted to zero percent under the automatic extreme and uncontrollable circumstances policy, as discussed above; and the Promoting Interoperability performance category is also reweighted to zero percent under the automatic extreme and uncontrollable circumstances policy. The application for reweighting was not needed in this example to reweight the Promoting Interoperability performance category.

Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for more information.

(v) Redistributing Performance Category Weights for Facility-Based Measurement

(A) Background

In the CY 2018 Quality Payment Program final rule, we established facility-based measurement under section 1848(q)(2)(C)(ii) of the Act which provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories (82 FR 53752 through 53767). Scoring under facility-based measurement was available for clinicians beginning with the CY 2019 performance period/2021 MIPS payment year. We established facility-based measurement to better align incentives between facilities and the MIPS eligible clinicians who provide services there (82 FR 53753). For more background on facility-based measurement, we refer readers to both the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767) and the CY 2019 PFS final rule (83 FR 59856 through 59867).

(B) Redistribution of Performance Category Weights Under Facility-Based Measurement

In the CY 2019 PFS final rule, we established that clinicians and groups would not need to elect or opt-in to facility-based measurement, but instead we would automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score (83 FR 59863). In this same final rule, we finalized policies for redistributing weight among the performance categories for the CY 2019 performance period/2021 MIPS payment year under § 414.1380(c)(2)(ii)(C). Under those redistribution policies, if the cost performance category is reweighted to zero percent of the final score, its weight is redistributed entirely to the quality performance category, unless the quality performance category is reweighted to zero percent, in which case the quality and cost performance category weights would be redistributed to the improvement activities and Promoting Interoperability performance categories. A clinician or group could have the weight of the cost performance category redistributed because they did not meet the case minimum for any of the measures in the cost performance category. Because facility-based measurement always includes both the quality and cost performance categories, it is possible a clinician or group would be scored on the cost performance category under facility-based measurement but not outside of facility-based measurement. There are two common scenarios for a facility-based clinician or group which could occur in the CY 2019 performance period/2021 MIPS payment year. In the first scenario, a facility-based clinician or group meets the case minimum for at least one cost performance category measure and receives a cost performance category percent score as defined at § 414.1380(b)(2). The respective quality and cost scores will be multiplied by the available points in the quality performance category (45 points) and the available points in the cost performance category (15 points) to determine the combined contribution of the quality performance category and the cost performance category to the final score out of the available 60 points. In the second scenario, a facility-based clinician or group does not meet the case minimum for any cost performance category measure and the cost performance category weight is redistributed to the quality performance category so the quality performance category score alone determines the score out of the available 60 points. Table 65 shows these two scenarios.

TABLE 65: Two Scenarios for a Facility-based Clinician or Group Which Could Occur Under Current Policy

Quality Performance Category Percent Score	Cost Performance Category Percent Score	Combined Quality and Cost Performance Category Scores (out of 60 available points)
75%	50%	(45 points x 0.75) + (15 points x 0.5) = 41.25
75%	N/A (no cost measures met case minimum)	(60 points x 0.75) = 45

In the CY 2020 PFS final rule, we established a redistribution policy for the CY 2020 performance period/2022 MIPS payment year at § 414.1380(c)(2)(ii)(D), for scenarios when the cost performance category weight is redistributed to the Promoting Interoperability performance category, as well as to the quality performance category (84 FR 63028). Under this policy, the weights of the combined quality and cost performance categories could be different for a clinician or group under facility-based measurement and outside of facility-based measurement in circumstances in which the clinician or group was not scored on the cost performance category outside of facility-based measurement but was scored on all other performance categories. Table 66 shows the scenario in which the combined weights of the quality and cost performance categories differ if cost is included, which occurs when the cost performance category is redistributed, and all other categories are scored.

TABLE 66: Scenario in which the Combined Weights of the Quality and Cost Performance Categories Differ if Cost is Included

Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability	Combined Quality and Cost
Scores for all four performance categories	45	15	15	25	60
No cost	55	0	15	30	55

We established similar redistribution policies for CY 2021 performance period/2023 MIPS payment year and CY 2022 performance period/2024 MIPS payment year at § 414.1380(c)(2)(ii)(E) and (F) in that same rule (84 FR 63029 through 63031), which also described situations where the combined weight of the cost and quality performance categories was not always consistent. For more on the background and proposed policies related to redistribution of performance categories, please see section IV.A.3.e.(2)(b)(iii) of this final rule.

Based on inquires we received from clinicians who were eligible for facility-based measurement, we believe our policy for determining the combined quality and cost performance category scores via facility-based measurement and outside of facility-based measurement is not ideal because it could result in a facility-based clinician or group receiving a lower final score than they would otherwise receive outside of facility-based measurement. We considered whether this more complex consideration of the scores and the weights in the performance categories necessitated a reconsideration of an opt-in requirement for facility-based measurement. However, we believe that establishing such a requirement would create administrative burden for clinicians and groups.

Instead of adding an opt-in requirement, we proposed a new policy to determine the MIPS final score for clinicians and groups who are eligible for facility-based measurement. We proposed at § 414.1380(e)(6)(vi)(B) that beginning with the CY 2022 performance period/2024 MIPS payment year, the MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission. Under this proposed policy, we will calculate two final scores for clinicians and groups who are facility-based. One score will be based on the clinician or group's performance and the weights of the performance categories if facility-based measurement did not apply, and the other will be based on the application of facility-based measurement. The example below shows how this proposed policy will apply for a facility-based group that did not meet the case minimum for any of the cost measures but was scored on all other performance categories.

TABLE 67: Application of Policy for a Facility-based Group that Did Not Meet the Case Minimum for any of the Cost Measures but was Scored on All Other Performance Categories

Scenario	Quality Points/available points	Cost points/available points	Improvement Activities points/available points	Promoting Interoperability points/ available points	Final Score
Facility-based	26/30	27/30	15/15	20/25	88/100
Not facility-based	52/55	0/0	15/15	24/30	91/100

As a result of this policy, the group in this example will receive a final score on the basis of their performance outside of facility-based measurement because they have obtained a higher final score through the combination of their submitted quality measures, submitted improvement activities and submitted promoting interoperability measures.

We solicited comments on this proposal.

We received public comments on the redistribution of performance category weights under facility-based measurement. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' proposal to take the higher of the two scores when

determining the final score for facility-based eligible clinicians and groups. One commenter suggested that CMS adopt this policy starting from CY 2021 performance period/2023 MIPS payment year.

Response: We thank the commenters for their support and feedback and note that, as mentioned in the 2021 Facility-Based Measurement Quick Start Guide, because the FY 2022 total performance score from the Hospital Value-Based Purchasing Program will be unavailable, we will not be able to calculate MIPS facility-based scores for the CY 2021 MIPS performance period/2023 MIPS payment year.[259] Please refer to *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1293/2021%20MIPS%20Facility%20Based%20Quick%20Start%20Guide.pdf* for more information.

After consideration of public comments, we finalize the proposal at § 414.1380(e)(6)(vi)(B) that beginning with the CY 2022 performance period/2024 MIPS payment year, the MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission.

f. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score used to determine MIPS payment adjustments we refer readers to the CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799) and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343). In the CY 2022 PFS proposed rule (86 FR 39453 through 39458), we proposed: (1) To select the mean as our methodology for calculating the performance threshold; (2) to establish the performance threshold for the 2024 MIPS payment year using 2019 MIPS payment year data; (3) to establish the additional performance threshold for exceptional performance for the 2024 MIPS payment year; and (4) to update the scoring hierarchy to include subgroups. In addition, we are including information about our timing for providing MIPS performance feedback to clinicians for the performance period in 2020.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

We have applied these special rules for the past 5 years to provide for a gradual and incremental transition to the year 6 performance threshold. For further information on established performance threshold policies we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program (82 FR 53787 through 53794), CY 2019 PFS final rule (83 FR 59880 through 59883), the CY 2020 PFS final rule (84 FR 63031 through 63037), and the CY 2021 PFS final rule (85 FR 84919 through 84923). We codified the performance thresholds for each of the first 5 years of MIPS at § 414.1405(b)(4), (5), (6), (7), and (8) as presented in Table 68.

[259] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1293/2021%20MIPS%20Facility%20Based%20Quick%20Start%20Guide.pdf.*

TABLE 68: Performance Thresholds for the 2019 MIPS Payment Year through 2023 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year
	Year 1	Year 2	Year 3	Year 4	Year 5
Performance Threshold	3 points	15 points	30 points	45 points	60 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	15 points	15 points

In the CY 2020 PFS final rule (84 FR 63031 through 63037) at § 414.1405(b)(7) and (8), we finalized the performance thresholds for the 2022 and 2023 MIPS payment years at 45 and 60 points, respectively, an increase of 15 points each year until the 2024 MIPS payment year, for which we estimated that the performance threshold would be 74.01 points. We believe that this approach effectively provided for a gradual and incremental transition to the performance threshold we had estimated for the 2024 MIPS payment year, as required by the statute.

Beginning with the 2024 MIPS payment year, section 1848(q)(6)(D)(i) of the Act requires the performance threshold to be the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. That section also provides that the Secretary may reassess the selection of the mean or median every 3 years. Thus, we considered whether to use the mean or median as the methodology for determining the performance threshold. We will use this methodology to determine a performance threshold for each of the following 3 years: The 2024 MIPS payment year, 2025 MIPS payment year, and 2026 MIPS payment year. We would then reassess and establish the methodology (mean or median) that we will use for each of the next 3 years (2027 MIPS payment year, 2028 MIPS payment year, and 2029 MIPS payment year). At the time of drafting of this final rule, we have final score data from the CY 2017 performance period/2019 MIPS payment year through the CY 2020 performance period/2022 MIPS payment year available to use in our assessment of whether to use the mean or median as our methodology for the next 3 years. At this time, however, the targeted review process (see § 414.1385) for the CY 2020 performance period/2022 MIPS payment year has not yet concluded, and the data for the CY 2020 performance period/2022 MIPS payment year may be subject to change as a result of targeted review which began on August 2, 2021, and will conclude on November 29, 2021, at 8:00 p.m., eastern standard time. For more information on the targeted review process, see our announcement sent to our list serve on September 27th, 2021 available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1631/2020%20Scoring%20Updates_EUC%20Reweighting%20Requests%20Extension_Listserv.pdf.*

We do not believe it would be appropriate to consider mean and median final scores from the CY 2020 performance period/2022 MIPS payment year for purposes of establishing the performance threshold for the 2024 MIPS payment year in this final rule when those scores may be subject to change as a result of the targeted review process. Furthermore, we are not utilizing final scores from the CY 2020 performance period/2022 MIPS payment for the creation of our regulatory impact analysis model. For a detailed discussion of the RIA methodology, including the basis of our decision to not use CY 2020 performance period/2022 MIPS payment year data, please see section VI.F.18.a of this final rule.

From our review of the data available to us, we have identified the mean and median final scores for each of the 2019 through 2021 MIPS payment years, as shown in Table 69. These six values represent the prior year mean and median final scores that we considered for the 2024 MIPS payment year performance threshold.

TABLE 69: Possible Values for the 2024 MIPS Payment Year Performance Threshold

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year
Mean	74.65 Points	87 Points	85.61 Points
Median	89.71 Points	99.63 Points	92.30 Points

As shown in Table 69, using the median final score gives a possible range of performance thresholds from 89.71 points to 99.63 points. Given our performance threshold of 60 points in year 5, these values would result in an increase of 29.71 points to 39.63 points for year 6. Selecting the median of final scores as our methodology would, at a minimum, nearly double the annual increase in the performance threshold of 15 points that we had from year 2 to year 5 of the program. Section 1848(q)(6)(D)(iv) of the Act required that we increase the performance threshold for each of the third, fourth, and fifth years of MIPS to ensure a gradual and incremental transition to the performance threshold we estimated with respect to the sixth year of MIPS. In prior rules we estimated the year six

performance threshold to be 74.01 points and used this estimate to determine how to gradually raise the performance threshold (83 FR 59881, 84 FR 63032, 84 FR 40802). Although section 1848(q)(6)(D)(iv) of the Act does not require this approach for the sixth year and subsequent years of MIPS, we believe that it is appropriate to set the performance threshold at a level that is in line with our previous estimates for year 6. We believe that continuing the gradual and incremental increase into year 6 would provide consistency to our stakeholders. After evaluating the possible values shown in Table 69, we believe that using the mean as our methodology would continue this approach.

Using the mean final score as the methodology would yield a possible range of performance thresholds from 74.65 points to 85.61 points (rounded to 75 points and 86 points respectively). Given our performance threshold of 60 points in year 5, these values would result in an increase of 15 points to 26 points for year 6. Given these values and our annual performance threshold increases of 15 points for years 2 to 5 of the program, 75 is the value that is most consistent with the gradual and incremental approach that we have elected to continue. Therefore, we proposed at § 414.1405(g) that for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under § 414.1405(b). This methodology will be used for MIPS payment years 2024 through 2026 of the program after which we will reassess the methodology for MIPS payment years 2027 through 2029.

In addition to selecting the methodology (mean or median), section 1848(q)(6)(D)(i) of the Act also requires us to specify a prior period from which we will use the final scores for all MIPS eligible clinicians to calculate the mean or median. As shown in Table 69, the mean final scores are 74.65, 87, and 85.61 points for MIPS payment years 2019 through 2021 respectively. In previous rules (83 FR 59881, 84 FR 63032), we used the MIPS payment year 2019 mean final score to estimate a performance threshold of 74.01 points for year 6 of the program. Our data have been updated to reflect completed targeted reviews since the time we made this estimate, and the mean final score for the 2019 MIPS payment year is now 74.65 points (see Table 69). This value would be an increase of almost exactly 15 points from the MIPS payment year 2023 performance threshold of 60 points, which is identical to the increases of the previous 3 years and consistent with our intention to continue the gradual and incremental approach that has been utilized in prior years. After reviewing the available final score data, we proposed at § 414.1405(b)(9) to use the MIPS payment year 2019 as the prior period and the rounded mean final score of 75 points as the year 6 performance threshold. When we establish the performance threshold for future MIPS payment years in future rulemaking, we will reassess using the mean final score for MIPS payment year 2019 as mean final scores for subsequent years become available.

We solicited comments on these proposals, as well as the alternative methodology of the median that we considered but did not propose. Additionally, we solicited comments on calculating the performance threshold using an alternative year's final scores that we considered but did not propose.

We received public comments on establishing the performance threshold. The following is a summary of the comments we received and our responses.

Comment: One commenter requested that CMS not roll back or reduce the performance threshold from its current value with the transition to MVPs in future years. The commenter believes that the extended phase in of the performance threshold under traditional MIPS was not necessary and had the unintended consequence of clinicians not taking MIPS as seriously as they should have. The commenter also stated that any phase-in does not advance the goals of transitioning to value-based care.

Response: In future years of the program we will evaluate the data available to us and select a performance threshold in accordance with the requirements of the statute. The gradual and incremental increase in the performance threshold gave clinicians time to anticipate the transition to the statutorily mandated methodology for the performance threshold beginning in year six. The CY 2022 performance period/2024 MIPS payment year is the first year of the program where CMS does not have additional flexibilities and must set the performance threshold at the mean or median of a prior year's final scores, thus ending the performance threshold transition period. While we agree with the commenter that further phase in of the performance threshold is not needed, it is possible the performance threshold numerical value for a future year could be lower than the numerical value for the CY 2022 performance period/2024 MIPS payment year, depending on the final score data available.

Comment: One commenter believes that data from the CY 2019 performance period/2021 MIPS payment year is a better basis for creating performance thresholds than the CY 2017 performance period/2019 MIPS payment year. The commenter believes that the entire structure of the program as far as scoring was very different in 2017 and that 2019 offers a more accurate picture compared to 2017.

Response: We understand that the program has undergone modifications since the CY 2017 performance period/2019 MIPS payment year. However, we have previously stated our intent to use a gradual and incremental approach to raising the performance threshold. For reference, the mean and median final scores for CY 2019 performance period/2021 MIPS payment year are 85.61 and 92.30 respectively and would represent an increase in the performance threshold of 25.61 or 32.3 points. We raised the performance threshold 12 points from CY 2017 performance period/2019 MIPS payment year to CY 2018 performance period/2020 MIPS payment year and raised the performance threshold 15 points in each subsequent year. We believe that raising the performance threshold 15 points in CY 2022 performance period/2024 MIPS payment year is consistent with our gradual and incremental approach. We recognize that clinicians are facing ongoing difficulties due to the PHE, and we believe that choosing the lowest performance threshold value available to us would gradually increase the performance threshold while minimizing disruption to clinicians during this emergency.

Comment: Several commenters supported setting the performance threshold at 75 and using the mean from a prior performance period. Some commenters stated the 15-point increase aligns with the gradual increase over the last 4 years. One commenter stated it was an attainable goal. A few commenters stated this meant having a larger budget neutral pool to redistribute funds, but one commenter requested more information about impact to their specialty. One commenter supported that it was the lowest of the possible options.

Response: We thank the commenters for their support for setting the performance threshold for the CY 2022 performance period/2024 MIPS payment year at 75 points, for noting that the 15-point increase is the same magnitude as the change in prior years, and for noting that the performance threshold selected was the lowest of the

possible options. Overall information on prior year's final scores can be found in the corresponding Quality Payment Program Experience Report and specialty specific information can be found in the Public Use File in the QPP resource library (*https://qpp.cms.gov/resources/resource-library*).

Comment: A few commenters expressed concern with the proposed performance threshold, specifically for small practices. A few commenters requested setting a separate performance threshold for small practices at a value such as 60, or setting the performance threshold for other practices higher at 85 points.

Response: We appreciate this feedback from commenters. However, as we previously discussed, the statute requires us to set the performance threshold at the mean or median of a prior period's final scores, and we do not have the statutory authority to establish a separate performance threshold for small practices. We also note that CMS does not have the authority to waive the statutory requirements for setting the performance threshold using our extreme and uncontrollable circumstances policies or section 1135 of the Act. We encourage the commenters to look at our estimates of how our proposed policies will affect the payment adjustments, broken down by practice size, for the MIPS 2024 payment year in our regulatory impact analysis (see section VI.F.18.e of this final rule). As shown in the impact analysis, we project the discrepancy in payment adjustments between large and small practices to shrink as a cumulative result of our policies, including raising the performance threshold.

Comment: Many commenters opposed the proposed performance threshold and recommended that CMS lower the performance threshold. Most of these commenters requested that CMS explore ways to use its authority to adjust the performance threshold beginning with the CY 2022 performance period/2024 MIPS payment year. Commenters specifically requested that CMS consider emergency authorities under the PHE such as the section 1135 waiver authority or its Extreme and Uncontrollable Circumstances policy. Commenters noted the stress of the continuing pandemic on practices; that the proposed performance threshold of 75 points represents a significant increase from the 30 points in 2019 or 45 points for 2020. A few commenters acknowledged that CMS has chosen the lowest value possible (75 points), but the commenters believe that positive payment adjustments will become more difficult to obtain, especially as the COVID–19 pandemic continues. One commenter expressed concern that clinicians may become frustrated and lose motivation to engage with the MIPS program. Another commenter stated that the steep increases in the performance threshold assumes that practices will not only perform, as well as they did before COVID–19 but that they will be able to perform better than before. Some commenters stated that CMS should establish a transitional policy that recognizes the impact of the COVID–19 PHE. One commenter appreciated the flexibilities that CMS has put in place during the pandemic and urges CMS not to flip a switch in 2022 as if the past 3 years have been business as usual. A few commenters suggested lower performance threshold levels, including 60, 50 and 45. One commenter requested that CMS delay the increase to the performance threshold until the implementation of MVPs.

Response: We understand the commenters concern about the stress the PHE is putting on practices. However, we do not have the authority to set the performance threshold for MIPS payment year 2024 at a value other than the mean or median of the final scores with respect to a prior period, as required by section 1848(q)(6)(D)(i) of the Act. We agree that positive payment adjustments could be more difficult to obtain with a higher performance threshold and are actively working to keep clinicians engaged with the introduction of MVPs which provide a streamlined way for clinicians to participate in the program with a set of measures that are relevant to their practice. We understand that the performance threshold of 75 represents a steep increase from the pre-pandemic performance threshold of 45 points, which was applicable for the CY 2019 performance period/2021 MIPS payment year. For the past 4 years we have finalized increases of 15 points. We increased the performance threshold from 15 to 30 between the CY 2018 and 2019 performance periods/2020 and 2021 MIPS payment years, from 30 to 45 between the CY 2019 and 2020 performance periods/2021 and 2022 MIPS payment years, and from 45 to 60 between the CY 2020 and 2021 performance periods/2022 and 2023 MIPS payment years. We acknowledge the commenter's concern that this increase assumes that clinicians will not only perform, as well as they did before COVID–19 but that they will be able to perform better than before. We note that the proposed increase of 15 points is the same as the increase in the previous 3 years and was based on a gradual and incremental approach to setting the performance threshold. As discussed previously, we are statutorily required to set the performance threshold for the 2024 MIPS payment year at the mean or median of the final scores with respect to a prior period, and we do not have the flexibility to choose other values. We appreciate the commenter's suggestion to adopt a transitional policy for the performance threshold due to the PHE but reiterate that we do not have the flexibility to do so due to the statutory requirements discussed previously. We also note that CMS does not have the authority to waive the statutory requirements for setting the performance threshold under section 1135 of the Act.

Comment: A few commenters opposed the proposed performance threshold for specialty related or practice related reasons. A few commenters were specifically concerned about groups or specialties that can only be measured on two performance categories. One commenter expressed their opinion that setting the performance threshold at the mean or median of prior final scores of all MIPS eligible clinicians in a prior period was an unfair standard for their specialty because they are limited in their ability to report under the Promoting Interoperability performance category. They stated this limitation gives them fewer opportunities to amass points. Another commenter stated that their group was unable to report Promoting Interoperability performance category measures and would be reweighted in a manner that would increase their cost category weight. A different commenter stated that they have a limited number of quality measures that they can report. As a result, they stated that for groups such as theirs that have limited measures and a high-weighted quality category, CMS now requires 100 percent quality to meet the performance threshold or otherwise they would receive a negative MIPS payment adjustment.

One commenter expressed concern that CRNAs cannot report 6 of the measures in the MIPS Anesthesia Measure set because they do not provide relevant services. The commenter suggested CMS should address how specialties such as anesthesia can meet the performance threshold, perhaps through the use of CAHPS data or by allowing them to report additional Improvement Activities.

Response: We understand that different specialties sometimes face challenges with not being able to report

measures and activities for every performance category. We agree that the final scores of these clinicians may be based on fewer categories than they would be for a clinician reporting all 4 performance categories. However, we remind clinicians that even if their final score is based on fewer than 4 performance categories they still have the ability to score anywhere from 0 to 100 points for their final score, just as a clinician reporting all 4 performance categories would. In this way, we do not believe that a performance threshold of 75 points is disadvantageous to clinicians reporting fewer than 4 performance categories. As stated below, we also encourage clinicians that do not have enough quality measures relevant to their scope of practice to work with their specialty societies to provide recommendations during the specialty measure set solicitation process and to consider reporting a relevant MVP when one becomes available.

We note, for the commenter who stated that not being able to report Promoting Interoperability would cause their group to be reweighted in a manner that would increase their cost category weight, that the cost category weight would only increase if a group was reweighted for the Promoting Interoperability and Quality performance categories. If a group is reweighted for the Promoting Interoperability performance category only, the cost category weight remains at 30 percent. We believe the commenter who stated that they have a limited number of quality measures that they can report is referring to the possibility that if the weight of other performance categories is redistributed to the quality category, a clinician may need to achieve a high score in quality in order to exceed the proposed performance threshold of 75 points. We understand that some clinicians may not have 6 measures in the Quality performance category that are relevant to their practice. To address this, we have our eligible measure applicability policy within the quality performance category to reduce the denominator of required measures for the MIPS CQM and Medicare Part B claims collection types, in the event that a clinician has less than 6 applicable measures to report. In this way, clinicians can be scored on the quality measures that are relevant to their scope of practice. For more information on the eligible measure applicability policy please see the CY 2017 through CY 2019 PFS final rules (81 FR 77290 through 77291, 82 FR 53750 through 53732).

For the commenter's concerns on the specialty measures available, we solicit stakeholder recommendations for new specialty measure sets and revisions to existing specialty sets on an annual basis. We urge stakeholders to work with their specialty societies to provide recommendations during the specialty measure set solicitation process (for more information please see the QPP resource library at *http://www.qpp.cms.gov*). We are also developing MIPS Value Pathways (MVPs) to provide clinicians with a simplified method to report measures that are relevant to their practice and we encourage them to report an MVP when one that is relevant to their scope of practice is available. We thank the commenter for their suggestion to expand the use of CAHPS or to allow clinicians to report additional improvement activities if they cannot report 6 quality measures.

Comment: Many commenters expressed concern that the proposal to increase the performance threshold to 75 points would increase the number of clinicians receiving a negative payment adjustment and decrease the number of clinicians with positive or neutral adjustments. Many commenters also stated their concern that the increase in the performance threshold comes with several proposed policies to remove bonuses and floors for quality measures and proposals to change quality data completeness which may lower the MIPS final score. A few commenters requested that CMS reconsider the reporting and scoring policies, delay the scoring policies, or gradually phase in the scoring changes, especially if CMS finalized the proposed performance threshold. One commenter specifically requested continuing current scoring for an additional year. A few commenters noted the difficulty of achieving the performance threshold now compared to a few years ago because of the scoring changes. A few commenters noted the cost of participating in MIPS versus the potential incentive. One commenter cited a study on the cost to participate in MIPS and expressed concern that clinicians would still get negative MIPS payment adjustment after these costs due to a premature increase in the performance threshold following 3 years of flexibilities due to the COVID–19 PHE.

Response: We acknowledge the commenters concerns regarding the increased burden on clinicians due to the COVID–19 PHE and agree that the statutory formula for determining the performance threshold beginning with the 2024 MIPS payment year could lead to additional clinicians receiving a negative payment adjustment. The MIPS is a budget neutral program and is designed in the statute to balance the positive payment adjustments of clinicians who score above the performance threshold against the negative payment adjustments of clinicians whose scores are below the performance threshold. We encourage the commenter to look at our estimates of how our proposed policies will affect the payment adjustments for the MIPS 2024 payment year in our regulatory impact analysis (see section VI.F.18.e of this final rule). In light of the continuing burden of the PHE we are making changes to some scoring flexibility proposals including postponing the removal of the 3-point scoring floor on quality measures and keeping the data completeness threshold at 70 percent (see section IV.A.3.e.(1)(c)(iii)(B) of this final rule). We are also introducing some new flexibilities including a 7-point floor for scoring new measures in their first year and a 5-point floor in their second year (see section IV.A.3.e.(1)(c)(iii)(B) of this final rule).

Comment: A few commenters discussed refinements for the performance threshold methodology. One commenter suggested CMS determine what the mean or median of ''raw'' or ''achievement'' final performance scores would be and use that figure to set the 2022 threshold. The commenter stated that CMS only uses the base quality measure score, absent any bonus points, to determine improvement scoring in the Quality category. Therefore, the commenter stated that method could be used in setting the performance threshold as well. Another commenter recommended that CMS evaluate balancing the reported data from 2019, 2020, and 2021 to control for self-selection bias since the commenter believed MIPS reporting has been fundamentally voluntary for these performance periods. One commenter asked what the agency's intent is with respect to performance thresholds and quality benchmark data going forward given that CY 2022 performance period/2024 MIPS payment year benchmarks will be based on CY 2022 performance period data while CY 2024 performance period/2026 MIPS payment year benchmarks appear to revert to performance period 2017 data. The commenter noted the performance threshold is based on CY 2017 performance period data while benchmarks are proposed to be based on CY 2022 performance period data.

Response: We appreciate the commenter's suggestion to use a ''raw'' or ''achievement'' score to set the performance threshold; we interpret the

suggestion of ''raw'' or ''achievement'' scores to mean removing any performance category bonuses, final score bonuses or improvement scoring. We note section 1848(q)(6)(D)(i) of the Act requires us to set the performance threshold using composite performance scores, which we refer to as the final score as defined under § 414.1305 (81 FR 77319 through 77320). We do not believe that the statute allows us to use ''raw'' or ''achievement'' scores when setting the performance threshold. We thank the commenter for the suggestion of balancing the scores from 2019, 2020, and 2021 but reiterate that the statute requires us to choose the mean or median from a prior period and does not allow us to balance scores from multiple years.

We refer the commenter to section IV.A.3.e(1)(c)(ii) of this final rule, where we are not finalizing our proposal to use performance period benchmarks and instead we will continue to use historic quality benchmarks for the CY 2022 performance period/2024 MIPS payment year will be based on CY 2020 performance period data. In regards to the comment on using 2017 data for purposes of the CY 2024 performance period/2026 MIPS payment year benchmarks, we note that we have not yet made any proposals on quality benchmarks for the CY 2024 performance period/2026 MIPS payment year.

Comment: One commenter supported the larger size of positive payment adjustments that a higher performance threshold would cause due to a greater quantity of money being redistributed through BN, but requested more information on the impact to specialties and practices. The commenter stated that this information will give societies a stronger argument for their membership as to why clinicians should continue to participate in MIPS.

Response: We encourage the commenter to read our projections of the impact of the Quality Payment Program Finalized policies on payment adjustments for MIPS payment year 2024 in our Regulatory Impact Analysis (see section VI.F.18.e of this final rule). We also note that CMS publishes a Quality Payment Program Experience Report and Public Use File at *https://qpp.cms.gov/resources/resource-library.* A detailed breakdown of a prior year's scores can be found in the QPP Experience Report and specialty specific information can be found in the Public Use File.

After consideration of public comments, we are finalizing our proposal at § 414.1405(g) that for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under § 414.1405(b). We are also finalizing our proposal at § 414.1405(b)(9) to use the MIPS payment year 2019 as the prior period and the rounded mean final score of 75 points as the year 6 performance threshold.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS (beginning with the 2019 MIPS payment year and ending with the 2024 MIPS payment year), an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to the prior period described in section 1848(q)(6)(D)(i) of the Act. Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500 million of funding available for the year under section 1848(q)(6)(F)(iv) of the Act. We note that under section 1848(q)(6)(F)(iv) of the Act, funding is available for additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act only through the 2024 MIPS payment year, which is the sixth year of the MIPS program.

In the CY 2020 PFS final rule (84 FR 63037 through 63040), we used the special rule under section 1848(q)(6)(D)(iii) of the Act to set the additional performance threshold at 85 points for the 2022 and 2023 MIPS payment years. We note that the special rule under section 1848(q)(6)(D)(iii) of the Act applies only to the initial 5 years of MIPS, so we cannot use that rule to establish the additional performance threshold for the 2024 MIPS payment year. As noted above, under section 1848(q)(6)(D)(ii) of the Act, we may set the additional performance threshold at either: (1) The 25th percentile of the range of possible final scores above the performance threshold, or (2) the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to the prior period described in section 1848(q)(6)(D)(i) of the Act.

TABLE 70: Possible Values for the 2024 Payment Year Additional Performance Threshold

	2019 MIPS Payment Year Mean	2019 MIPS Payment Year Median	2020 MIPS Payment Year Mean	2020 MIPS Payment Year Median	2021 MIPS Payment Year Mean	2021 MIPS Payment Year Median
25th Percentile of Possible Scores	81.26	92.51	90.26	100	89.51	94.01
25th Percentile of Actual Scores	88.94	94.84	98.33	100.00	91.83	94.70

In the CY 2022 PFS proposed rule (86 FR 39453), for illustrative purposes, we referenced the possible additional performance thresholds shown in Table 70. Note that mean or median refers to the methodology for calculation of the performance threshold. As can be seen in Table 70, the potential values for the additional performance threshold range from a low of 81.26 to a high of 100. However, to remain consistent with our gradual and incremental approach, we proposed to use the mean as our methodology for setting the performance threshold during the next 3 years and

we proposed to use the final score data from MIPS payment year 2019. We are finalizing these proposals in section IV.A.3.f.2 of this final rule. The selection of the mean for the methodology and final score data from the 2019 MIPS payment year leaves us with the options in the first column of Table 70 for where we can set the additional performance threshold.

With a performance threshold of 75 points for the 2024 MIPS payment year based on final scores for the 2019 MIPS payment year, the calculation methods in section 1848(q)(6)(D)(ii) of the Act give us two possible options for where we can set the additional performance threshold for MIPS payment year 2024. The first calculation method (described in section 1848(q)(6)(D)(ii)(I) of the Act), using the range of possible final scores above the proposed performance threshold for the 2024 MIPS payment year, yields a value of 81.26 points (the 25th percentile of the range of 75.01 to 100). The calculation is as follows: 75.01 + [(100 − 75.01) * 0.25] = 81.26. The second calculation method (described in section 1848(q)(6)(D)(ii)(II) of the Act), the 25th percentile of the actual final scores for the 2019 MIPS payment year at or above the proposed performance threshold for the 2024 MIPS payment year, yields a value of 88.94. For the second calculation method, we will apply the 25th percentile calculation of (n+1)p/100 to the 2019 MIPS payment year final score data that are at or above 75.

We considered using each of these methods, but we do not believe that it would be appropriate to lower the additional performance threshold to 81.26 points from its present value of 85 points. Maintaining or increasing the additional performance threshold will serve as a greater incentive to clinicians to continue to improve their performance on the MIPS measures and activities and to achieve exceptional performance. We believe that an additional performance threshold of 88.94 points rounded to 89 points is appropriate. This is an increase of 4 points from the prior year, which we believe is a gradual increase. Therefore, using the second calculation method described above, we proposed at § 414.1405(d)(7) to set the additional performance threshold for the 2024 MIPS payment year at 89 points.

We solicited comments on these proposals, as well as the alternative additional performance thresholds listed that we considered but did not propose.

We received public comments on the additional performance threshold for exceptional performance. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern about the exceptional performance funding under section 1848(q)(6)(F)(iv) of the Act ending after the CY 2022 performance period/2024 MIPS payment year. One commenter believes that eliminating this funding is contradictory to the mission of the Quality Payment Program as it provides an additional incentive for improving performance. A few commenters expressed concerns about the cost of participating in MIPS and that the majority of the MIPS adjustment has been funded from the exceptional performance funding under section 1848(q)(6)(F)(iv) of the Act rather than from negative payment adjustments. Some commenters requested that CMS work with Congress to extend the funding.

Response: We acknowledge the commenters' concern about the exceptional performance funding under section 1848(q)(6)(F)(iv) of the Act ending after the CY 2022 performance period/2024 MIPS payment year. We acknowledge that in previous years the additional performance threshold has funded a large portion of positive MIPS payment adjustments. However, we point the commenter to our Regulatory Impact Analysis (see section VI.F.18.e of this final rule) where we estimate that positive MIPS payment adjustments funded by BN will be much higher than in previous years.

Comment: A few commenters suggested that CMS should consider using the section 1135 waiver authority it has under the PHE or its Extreme and Uncontrollable Circumstances policy to waive the statutory requirement to set the additional performance threshold at either: (1) The 25th percentile of the range of possible final scores above the performance threshold, or (2) the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to the prior period described in section 1848(q)(6)(D)(i) of the Act, and instead keep the additional performance threshold at 85 points in 2022.

Response: We note that CMS does not have the authority to waive the statutory requirements for setting the additional performance threshold using our extreme and uncontrollable circumstances policies or section 1135 of the Act.

Comment: One commenter acknowledged the two statutory options CMS presented for the additional performance threshold (81.26 and 88.94), but urged CMS to use PHE authorities to maintain the additional performance threshold at 85 points instead of 89 points. The commenter stated that it gives clinicians a final opportunity to qualify for this funding and takes into account the unusual operational and clinical circumstances present during the COVID–19 pandemic.

Response: We agree with the commenter that there have been unusual operational and clinical circumstances for clinicians during the COVID–19 pandemic. However, we are not aware of any PHE authorities available to CMS that would allow us to set the additional performance threshold for the 2024 MIPS payment year at any value other than those resulting from the calculation methods described in section 1848(q)(6)(D)(ii) of the Act.

Comment: A few commenters supported the additional performance threshold. One commenter stated that the increase to the additional performance threshold increases the difficulty but still makes the additional positive payment adjustment an attainable goal.

Response: We thank the commenters for their support.

Comment: A few commenters supported a lower additional performance threshold. Some commenters requested that CMS select the option of 81 points rather than the proposed 89 points to account for loss of score potential due to removal of bonus points in the quality performance category and the increased weight of the cost performance category. One commenter noted that CMS has the latitude to select 81 points as it meets the 25th percentile of possible scores and believes that the lower additional performance threshold will incentivize a greater number of clinicians. The commenter also noted that choosing a lower additional performance threshold will allow CMS to both reward top performers in MIPS and incentivize more of them by setting reasonable thresholds to reward them for their performance. Other commenters requested keeping the additional performance threshold at 85 points.

Response: We established the additional performance threshold at 85 points for the 2022 and 2023 MIPS payment years in the CY 2020 PFS final rule (84 FR 63037 through 63040). We do not believe that it is appropriate to set the additional performance threshold at a lower value (81 points) than it was set at for the CY 2020 performance period/2022 MIPS payment year nor do we have the authority to keep the additional

performance threshold at 85 points as was requested by the commenter. We believe that 89 points is an appropriate value to incentivize the highest performing clinicians, given that the threshold has been 85 points for the past 2 years.

After consideration of public comments, we are finalizing the proposal at § 414.1405(d)(7) to set the additional performance threshold for the 2024 MIPS payment year at 89 points.

(4) Example of Adjustment Factors

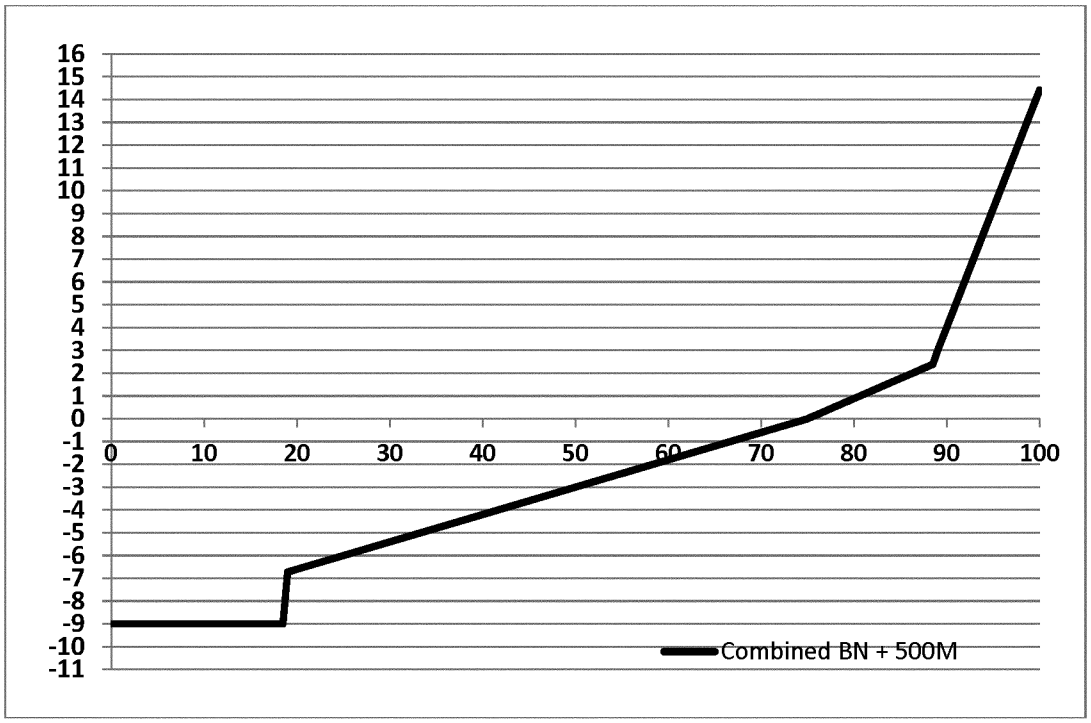
Figure A provides an illustrative example of how various final scores will be converted to a MIPS payment adjustment factor and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our finalized policies for the 2024 MIPS payment year. In Figure A, the performance threshold is set at 75 points. The applicable percentage is 9 percent for the 2024 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the 2024 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the performance threshold of 75 points for the 2024 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive the lowest negative applicable percentage (negative 9 percent for the 2024 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent. If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 75 points (which is the finalized performance threshold) will receive a neutral MIPS payment adjustment. Because the performance threshold is 75 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor will be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points will be less than 9 percent.

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Figure A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2024 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustartive. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is inteded to ensure BN, but cannot be higher than 3.0. MIPS eligible clinicians with a final score of at least 89 points will also receive an additional adjustment factor for expectional performance. The additional adjustment factor starts at 0.5 percent, cannot exceed 10 percent, and is also mulitiplied by a scaling factor that is greather than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustartive as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 71 illustrates the changes in payment adjustment based on the final policies from the CY 2021 PFS final rule (85 FR 84923 through 84925) for the 2023 MIPS payment year and the final policies for the 2024 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 71: Illustration of Point System and Associated Adjustments Comparison between the Finalized 2023 MIPS Payment Year and the 2024 MIPS Payment Year

2023 MIPS Payment Year		2024 MIPS Payment Year	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-15.0	Negative 9%	0.0-18.75	Negative 9%
15.01-59.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
60.0	0% adjustment	75.0	0% adjustment
60.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	75.01-88.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance	89.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 89.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance

(5) Final Score Hierarchy Used in Payment Adjustment Calculation

In the CY 2021 PFS final rule (85 FR 84917 through 84919), we modified the final score hierarchy that applies when more than one final score is associated with a TIN/NPI, as displayed in Table 72. Beginning with the CY 2021 performance period/2023 MIPS payment year, if a TIN/NPI has a virtual group final score associated with it, we use the virtual group final score to determine the MIPS payment adjustment. If a TIN/NPI does not have a virtual group final score associated with it, we use the highest available final score associated with the TIN/NPI to determine the MIPS payment adjustment.

TABLE 72: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, an APP final score, a group final score, and/or an individual final score.	Virtual group final score.
TIN/NPI has an APM Entity final score, an APP final score, a group final score, and/or an individual final score, but is not in a virtual group.	The highest of the available final scores.

In the CY 2022 PFS proposed rule (86 FR 39457), we proposed policies applicable to subgroups, including a definition of a subgroup at § 414.1305 as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI. Each clinician in a subgroup would be identifiable by a unique TIN/NPI combination just as in any MIPS group or APM Entity. In addition, a clinician, group, subgroup, or APM Entity could choose more than one MIPS reporting option for a performance period. A clinician, group, subgroup, or APM Entity could choose to report through MVPs, traditional MIPS, and/or the APP (assuming they are eligible for each of these reporting options) for a performance period. As a result, there could be more than one final score for a clinician, group, subgroup, or APM Entity for a performance period from MVPs, traditional MIPS, and/or the APP. Therefore, we proposed to update the scoring hierarchy to include subgroups and to specify that the scoring hierarchy would apply with respect to any available final score that is associated with a TIN/NPI from MVPs, traditional MIPS, and/or the APP. The proposed updated scoring hierarchy can be seen in Table 73. We solicited comments on this proposal.

TABLE 73: Proposed Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, a group final score, a subgroup final score, and/or an individual final score, from MVPs, traditional MIPS, and/or the APP.	Virtual group final score.
TIN/NPI has an APM Entity final score, a group final score, a subgroup final score, and/or an individual final score, from MVPs, traditional MIPS, and/or the APP. The TIN/NPI is not in a virtual group.	The highest of the available final scores.

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We received public comments on the proposed updated scoring hierarchy. The following is a summary of the comments we received and our responses.

Comment: A few commenters requested clarification on the scoring hierarchy. One commenter expressed concerns with the modified hierarchy, citing the complexity of adding subgroups to MIPS and concerns about allowing ACO clinicians to report outside the ACO. The commenter recommended that to reduce complexity, ACO performance should be evaluated at the ACO level for MIPS evaluations. Another commenter noted confusion about how payment adjustments would be calculated and applied for clinicians reporting an MVP as part of a subgroup.

Response: We acknowledge the commenters concern about the complexity of the scoring hierarchy for ACO reporters. However, we disagree with the recommendation that ACOs only be evaluated at the ACO level. CMS is introducing subgroups to collect data at a more granular level that will be more useful for beneficiaries to use to make informed healthcare decisions. Having data at the subgroup level will allow beneficiaries to evaluate performance data, especially performance data about specialists, that is more closely related to the actual clinicians the beneficiaries may see for their medical care. We also note that subgroup scores will not be rolled up to the ACO level. If a TIN reports as a subgroup, the subgroup score would only be applicable to the NPIs in the subgroup.

Comment: A few commenters supported the proposed scoring hierarchy. Commenters appreciated CMS' intent to select the highest final score achieved for a TIN/NPI across the QPP pathways for individual, group subgroup or APM entity.

Response: We thank the commenter for their support.

Comment: One commenter asked CMS to confirm that a MIPS eligible clinician that participates in MVPs via multiple subgroups would receive the highest final score that can be attributed to their TIN/NPI combination from any reporting option (traditional MIPS, APP reporting, or any MVP subgroup reporting) and participation option (as an individual, group, subgroup, or APM Entity (with the exception of virtual groups).

Response: The commenter is correct that, with the exception of virtual groups, a MIPS eligible clinician will receive the highest final score that can be attributed to their TIN/NPI combination from the listed reporting options (traditional MIPS, APP, or MVPs) and participation options (individual, group, subgroup, or APM entity).

After consideration of public comments, we are finalizing the proposed updated scoring hierarchy as proposed.

g. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

On July 1, 2018, we provided the first performance feedback for the Quality Payment Program. The second performance feedback was provided on July 1, 2019. In the CY 2021 PFS proposed rule (85 FR 50321), we noted that we aim to provide performance feedback on or around July 1 of each year, but due to the PHE and COVID–19, we estimated that we would provide performance feedback for the performance period in 2019 in late July

or early August of 2020. The third performance feedback (for the CY 2019 performance period) was provided on August 5, 2020. In the proposed rule, we noted that similar to the CY 2019 performance period, due to the PHE for COVID–19, we may provide performance feedback for the CY 2020 performance period after July 1, 2021. Although we aim to provide performance feedback on or around July 1 of each year, it is possible that the release date could be later than July 1 depending on the circumstances. We provided performance feedback for the CY 2020 performance period on August 2 and September 27, 2021. We direct readers to *qpp.cms.gov* for more information.

h. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (85 FR 84926 through 84947) for our previously established policies regarding third party intermediaries.

As discussed in the CY 2022 PFS proposed rule (86 FR 39458), we proposed to make several changes: (1) Reorganization and consolidation of § 414.1400 generally; (2) new third party intermediaries general requirements; (3) new requirements specific to both QCDRs and qualified registries; (4) new requirements specific to only QCDRs; and (5) remedial action and termination of third parties.

(1) Reorganization and Consolidation of § 414.1400 Generally

We recognize that many of our policies for third party intermediaries are similar or verbatim, and yet in prior rules, we have described them separately. To minimize the lengthiness and burden of reading our policies, we proposed to consolidate our regulatory text under § 414.1400. To be clear, our proposed updates would not change previously finalized requirements for third party intermediaries, but would bring more clarity and simplicity to the regulatory text. These changes are discussed by topic in more detail below. We also note that in several places at § 414.1400 the regulation text was only updated to reflect both the applicable MIPS performance period/MIPS payment year.

(a) Reorganization for Requirements Related to MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We previously established in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), further revised in the Quality Payment Program provisions in the CY 2019 and CY 2020 PFS final rules ((83 FR 60088 and 84 FR 63049 through 63052, respectively), and further clarified our requirements for QCDRs, qualified registries, and health IT vendors with regards to submitting data for the purposes of the MIPS program in the Quality Payment Program provisions in the CY 2021 PFS final rule. Our current policy, codified at § 414.1400(a)(2), states that, beginning with the CY 2021 performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories, and Health IT vendors must be able to submit data for at least one of the following MIPS performance categories: Except as provided under paragraph (a)(2)(ii), QCDRs, qualified registries, and health IT vendors must be able to submit data for all of the following MIPS performance categories:

- Quality, except:

++ The CAHPS for MIPS survey; and

++ For qualified registries and Health IT vendors, QCDR measures;

- Improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(9)).

++ Health IT vendors that do not support MIPS Value Pathways must be able to submit data for at least one of the MIPS performance categories described in paragraphs (a)(2)(i)(A) through (C) of this section.

++ Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*)).

In an effort to simplify, we proposed reorganizing the existing language at § 414.1400(a)(2). Specifically, we proposed providing updates to separately identify and provide clarity to data submission requirements since data requirements vary based on third party intermediary type and to provide clarification to exceptions to Promoting Interoperability for virtual groups and subgroups. We proposed the following updates:

- To revise and redesignate existing paragraph at § 414.1400(a)(2) through (a)(2)(i) to proposed paragraphs § 414.1400(b)(1)(i) and (c)(1) through (c)(1)(i) to state the following:
- To state at proposed § 414.1400(b)(1)(i), beginning with the CY 2021 performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories:
- Quality, except:

++ The CAHPS for MIPS survey; and

++ For qualified registries, QCDR measures.

- Improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

++ The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*)).

- To state at proposed § 414.1400(c)(1), beginning with the CY 2021 performance period/2023 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:
- To state at proposed § 414.1400(c)(1)(i) through (c)(1)(i)(B), health IT vendors that support MVPs must be able to submit data for all of the MIPS performance categories:
- Quality, except:

++ The CAHPS for MIPS survey; and

++ QCDR measures;

- Improvement activities; and
- To revise and redesignate existing paragraph at § 414.1400(a)(2)(iii) to proposed paragraph § 414.1400(c)(1)(i)(C) state, Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

++ The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

- To revise and redesignate existing paragraph at § 414.1400(a)(2)(ii) to proposed paragraph § 414.1400(c)(1)(ii) to state, health IT vendors that do not support MVPs must be able to submit data for at least one of the MIPS

performance categories described in paragraphs (c)(1)(i) through (iii) of this section.

- We proposed to create a new requirement at § 414.1400(c)(1)(iii) for health IT vendors to support MVPs. For more information on this proposal, please refer to section ''proposed new requirement for third party intermediaries to support MVPs and the APP'' at section IV.A.3.h.(2)(b)(i) of this final rule.
- To move the current Health IT vendor requirements from paragraphs §§ 414.1400(a)(2)(ii) through (iii) and (d) to a new paragraph applicable to Health IT vendor requirements at § 414.1400(c). This will separately identify and provide clarity to data submission requirements specific to Health IT vendors.
- To move the current CMS-approved survey vendor requirements from paragraphs (a)(3) and (e) to a new paragraph applicable to CMS-approved survey vendor requirements at § 414.1400(d). We proposed to the redesignate paragraph (a)(3) current requirements to paragraph (d)(1) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category. For the current requirements at paragraph (e), we proposed to move up those requirements to paragraph (d)(2).
- To redesignate paragraph (a)(4) as paragraph (a)(2).
- To redesignate paragraph (a)(5) as paragraph (a)(3).

We solicited public comments on our proposals.

We did not receive public comments on these proposals, and therefore, we are finalizing them as proposed.

(b) Reorganization for Requirements Related QCDR and Qualified Registries Self-Nomination

We proposed to consolidate and redesignate the existing language at § 414.1400(b)(1) and (c)(1) to proposed § 414.1400(b)(2) to reference both QCDR and qualified registries. We proposed this consolidation to provide clarity and alignment with the aforementioned proposals and consolidate the duplicative criteria of QCDRs and qualified registries. As discussed below, we also proposed to consolidate and redesignate the performance feedback requirements previously at existing § 414.1400(b)(1) and (c)(1) to § 414.1400(b)(3)(iii). We proposed to state at § 414.1400(b)(2), Self-nomination. For the CY 2018 and 2019 performance periods/2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR or qualified registry must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the CY 2020 performance period/2022 MIPS payment year and future years, entities seeking to qualify as a QCDR or qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR or qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the CY 2019 performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

We also proposed removing the last two sentences of existing § 414.1400(b)(1), which are duplicative with existing § 414.1400(b)(3)(iii). We proposed consolidating this language with existing paragraph (b)(3)(iii). We solicited public comments on our proposals.

The following is a summary of the comments we received and our responses.

Comment: One commenter suggested that we refine the QCDR option under MIPS to streamline the self-nomination process, and to provide better incentives for organizations, including medical associations, to continue to invest in their QCDRs and develop new, meaningful measures for specialists to use for MIPS reporting and other clinical and research purposes.

Response: We thank the commenter for their suggestion. We may consider it for future rulemaking.

Comment: One commenter expressed support for the updates that CMS has made to the QCDR and qualified registry self-nomination process, including the development of the measure submission portal at *QualityPaymentProgram.cms.gov.*

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing these policies as proposed.

(c) Reorganization for Requirements Related to QCDR and Qualified Registries Conditions for Approval

We refer readers to existing § 414.1400(b)(2) for QCDR conditions for approval and existing § 414.1400(c)(2) for qualified registries conditions for approval. In this final rule, we proposed the following in order to better organize, consolidate the duplicative criteria of QCDRs and qualified registries, and refer to both ''QCDR and qualified registry'' instead of one or the other:

- We proposed to redesignate existing paragraph (b)(2) to proposed paragraph (b)(3) and to revise the paragraph heading as, *Conditions for approval.*
- We also proposed to update the reference to both QCDR and qualified registry in proposed paragraph (b)(3).
- We proposed to revise to include both QCDR and qualified registry and redesignate existing paragraph (b)(2)(i) to proposed paragraph (b)(3)(i).
- We proposed to revise and redesignate existing paragraph (b)(2)(ii) to paragraph (b)(3)(ii). We also proposed to extend our policy for collaboration. For more information on this proposal, please refer to section ''collaboration of entities to become a QCDR and proposal to extend policy for collaboration of entities to become a qualified registry'' at section IV.A.3.h.(3)(a)(ii) of this final rule.
- As discussed above, we proposed to consolidate and redesignate the performance feedback requirements previously at existing § 414.1400(b)(1) and (c)(1) to § 414.1400(b)(3)(iii). Furthermore, to consolidate similar performance feedback requirements, we also proposed to revise and redesignate existing paragraph (b)(2)(iii) to paragraph (b)(3)(iii) to state, beginning with the CY 2021 performance period/2023 MIPS payment year, require the QCDR or qualified registry must to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the reporting period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).
- We proposed to consolidate and redesignate paragraphs (b)(2)(iv) and (c)(2)(iii) in their entirety, into a new paragraph (b)(3)(v), and to correct a typographical error in which the word ''MIPS'' was omitted in the first sentence.

• We proposed to consolidate and redesignate paragraphs (b)(2)(v) and (c)(3)(iv), in their entirety, into a new paragraph (b)(3)(vi).

We solicited public comments on our proposals.

We did not receive public comments on these proposals, and therefore, we are finalizing them as proposed.

(d) Reorganization for Requirements Related to QCDR Measures

(i) Reorganization for Requirements Related to QCDR Measures for the Quality Performance Category

We refer readers to existing language at § 414.1400(b)(3) for QCDR measures for the quality performance category. We currently define ''QCDR measure'' at existing § 414.1400(b)(3). We recognize that the QCDR measure definition is referred to throughout our policies and that it is not specific to § 414.1400(b)(3) or third party intermediaries. Therefore, to provide further clarity and to better align with the current policy, we proposed moving the QCDR measure definition to the definitions section at § 414.1305. We also proposed the following revisions to better organize regulation text at § 414.1400(b)(4) and to update cross-references to correspond to the new section numbers as reflected in this final rule:

• We proposed to redesignate paragraphs (b)(3)(i), (b)(3)(i)(A), and (b)(3)(i)(B) to definitions at § 414.1305.

• We proposed to revise and redesignate existing paragraph (b)(3)(ii) to proposed paragraph (b)(4)(i) to state, for the CY 2018 performance period/2020 MIPS payment year and future years, at the time of self-nomination an entity seeking to become a QCDR must submit the following information for any measure it intends to submit for the payment year:

++ For MIPS quality measures, the entity must submit specifications including the MIPS measure IDs and specialty-specific measure sets, as applicable.

+ For QCDR measures, the entity must submit for CMS-approval measure specifications including: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS approval of any QCDR measure specifications, the entity must publicly post the measure specifications for that QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

• We also proposed adding a header to state, ''QCDR measure self-nomination requirements''. We believe adding a heading will help readers clearly distinguish QCDR measure self-nomination requirements.

• We proposed moving existing paragraph (b)(3)(iii) in its entirety to proposed paragraph (b)(4)(ii) and adding a header to state, ''QCDR measure submission requirements''. We believe adding a heading will help readers clearly distinguish QCDR measure submission requirements.

• We proposed moving existing paragraphs (b)(3)(v) through (v)(C)(*1*) in its entirety, to proposed paragraphs (b)(4)(iii) through (b)(4)(iii)(A)(*3*).

• We proposed to revise and redesignate existing paragraph at (b)(3)(v)(C)(*2*) to paragraph (b)(4)(iii)(A)(*3*)(*i*) to state, to be included in an MVP for the CY 2022 performance period/2024 MIPS payment year and future years, a QCDR measure must be fully tested.

• We proposed moving existing paragraph (b)(3)(vii) in its entirety, to paragraph (b)(4)(iv).

(ii) Reorganization for Requirements Related to QCDR Measure Approval Criteria

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) and the Quality Payment Program provisions in the CY 2020 PFS final rule (84 FR 63059), where we finalized existing § 414.1400(b)(3)(v).

At § 414.1400, we proposed to reorganize and make minor updates to the existing requirements at paragraph (b)(3)(v) to proposed paragraph (b)(4)(iii). We proposed to reorganize the existing requirements so that QCDR measure approval at paragraph (b)(3)(v) is discussed before QCDR measure considerations at paragraph (b)(3)(iv). Therefore, we proposed the following revisions:

• To revise and redesignate existing paragraph (b)(3)(v) ''QCDR measure requirement for approval include'' to proposed paragraph (b)(4)(iii) and add a heading to state, ''QCDR measure approval criteria''. We believe adding a heading will help readers clearly distinguish QCDR measure approval criteria. We also proposed to include the following updates:

++ Move existing paragraph (b)(3)(v) to proposed revised paragraph (b)(4)(iii)(A) to state, QCDR measure requirements for approval are.

++ Move existing paragraph (b)(3)(v)(A) in its entirety to proposed paragraph (b)(4)(iii)(A)(*1*).

++ Move existing paragraph (b)(3)(v)(B) in its entirety to proposed paragraph (b)(4)(iii)(A)(*2*).

++ Revise existing paragraphs (b)(3)(v)(C) and (b)(3)(v)(C)(*1*) to proposed paragraph (b)(4)(iii)(A)(*3*) to state, beginning with the CY 2022 performance period/2024 MIPS payment year, all QCDR measures must meet face validity. To be approved for the CY 2023 performance period/2025 MIPS payment year, all QCDR measures must be must meet face validity for the initial MIPS payment year for which it is approved. For subsequent years after being initially approved, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

++ Move existing paragraph (b)(3)(v)(C)(*2*) in its entirety to proposed paragraph (b)(4)(iii)(A)(*3*)(*i*).

++ Move existing paragraph (b)(3)(v)(D) in its entirety to proposed paragraph (b)(4)(iii)(A)(*4*).

++ Move existing paragraph (b)(3)(v)(E) in its entirety to proposed paragraph (b)(4)(iii)(A)(*5*).

We solicited public comment on our proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the measure requirement for face validity testing of measures and stated it should be extended for future years. One commenter noted particular concern for the face validity testing requirement, as the testing process is arduous and funding, staff, and other resources have been significantly reduced due to the PHE for COVID–19. A few commenters suggested that CMS delay the deadline for full QCDR measure testing to 2023 or later due to the impact of COVID–19 on providers and registries. Another commenter suggested that CMS limit the face validity testing requirement, stating that because the COVID–19 extreme and uncontrollable circumstances exception decreased the number of groups reporting to MIPS through QCDRs, the face validity testing requirement should be limited to the first 2 years for which measures are approved or until 2 years after the end of the COVID PHE. Several commenters expressed concerns with QCDR measure testing requirements and pointed to the significant burden of these requirements. One commenter expressed the belief that a barrier to use of QCDR measures is the requirement that they be fully tested, which is

extremely burdensome for QCDR measure owners. Another commenter asked for clarification as to what constitutes acceptable measure testing. Commenters requested that CMS develop a transparent and consistent process for evaluating QCDR testing approaches and results. Commenters noted that failure to ease the QCDR requirements may result in interested parties opting to not participate in the QCDR program.

Response: We note that we did not propose to substantively modify the measure requirement for face validity and testing in the proposed rule, such as to delay these requirements. The existing requirement (85 FR 84939) at § 414.1400(b)(3)(v)(C)(*1*) states that, for a QCDR measure to approved for the CY 2022 performance period/2024 MIPS payment year it must meet face validity. To be approved for the CY 2023 performance period/2025 MIPS payment year and for each subsequent year, a QCDR measure must meet face validity for the initial MIPS payment year for which it is approved. Separately, paragraph (b)(3)(v)(C) provides that, beginning with the CY 2022 performance period/2024 MIPS payment year, a QCDR measure must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. In addition, paragraph (b)(3)(v)(C)(*1*) requires that, for each subsequent year, for which a QCDR measure is approved, it must be fully tested. We intended our proposed reorganization of these standards at paragraph (b)(4)(B)(iii)(*3*) to track these existing requirements.

In regards to what constitutes acceptable testing and the burden associated with, and possible delay of such testing, we refer readers to our discussion of this and related issues in past rules (85 FR 27594 through 27595; 85 FR 84940; 85 FR 84926; 85 FR 84936; 84 FR 63066; 84 FR 63065 through 63067; 83 FR 59901 through 59902; 82 FR 53805 through 53806) and guidance documents, including the current CMS Measures Management System Blueprint for additional guidance in measure testing at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*.

Although we did not address any changes to the QCDR measure testing requirement at § 414.1400(b)(3)(v)(C)(*1*) in the CY 2022 PFS proposed rule, based on public comments received on our proposals, we are considering proposing in next year's rulemaking to further delay this requirement for traditional MIPS until the CY 2024 performance period/2026 MIPS payment year, instead of the CY 2023 performance period/2025 MIPS payment year as previously finalized. We clarify that this delay would not modify the existing requirement at paragraph (b)(3)(v)(C)(*2*), to be included in an MIPS Value Pathway for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested.

Comment: One commenter suggested that CMS provide more meaningful credit/incentivization for measure testing participation given the difficulty to motivate practices to engage in measure testing. The commenter suggested an improvement activity credit for measure testing given the difficulty to motivate practices to engage in measure testing.

Response: We thank the commenter for their suggestion. We may consider it for future rulemaking. We encourage the commenter to visit the 2021 Improvement Activities Inventory for additional guidance on improvement activities that focus on QCDR participation at *https://qpp-cm-prodcontent.s3.amazonaws.com/uploads/1189/2021%20Improvement%20Activities%20List.zip*.

After consideration of public comments, we are finalizing these policies as proposed.

(iii) Reorganization for Requirements Related to QCDR Measure Considerations for Approval

We refer readers to the Quality Payment Program provisions in the CY 2019 PFS final rule (84 FR 63198 through 63199), where we finalized existing § 414.1400(b)(3)(iv) ''QCDR measure considerations for approval.'' We proposed to reorganize and make minor updates to the language at existing paragraph (b)(3)(iv) to paragraph (b)(4)(iii)(B). We proposed to reorganize the existing requirements so that QCDR measure approval at paragraph (b)(3)(v) is discussed before QCDR measure considerations at paragraph (b)(3)(iv).

We also proposed to redesignate existing paragraph (b)(3)(vi) to paragraph (b)(4)(iii)(C). Specifically, we proposed the following revisions:

- To revise and redesignate existing paragraph (b)(3)(iv) ''QCDR measure considerations for approval include'' to paragraph (b)(4)(iii)(B) ''QCDR measure considerations for approval include, but are not limited to''.
- Move existing paragraphs (b)(3)(iv)(A) in its entirety to paragraph (b)(4)(iii)(B)(*1*).
- Move existing paragraph (b)(3)(iv)(B) in its entirety to paragraph (b)(4)(iii)(B)(*2*).
- Move existing paragraph (b)(3)(iv)(C) in its entirety to paragraph (b)(4)(iii)(B)(*3*).
- Move existing paragraph (b)(3)(iv)(D) in its entirety to paragraph (b)(4)(iii)(B)(*4*).
- Move existing paragraph (b)(3)(iv)(E) in its entirety to paragraph (b)(4)(iii)(B)(*5*).
- Move existing paragraph (b)(3)(iv)(F) in its entirety to paragraph (b)(4)(iii)(B)(*6*).
- Move existing paragraph (b)(3)(iv)(G) in its entirety to paragraph (b)(4)(iii)(B)(*7*).
- Revise and consolidate existing paragraph (b)(3)(iv)(G)(*1*) to paragraph (b)(4)(iii)(B)(*7*)(*i*) to state that QCDR link their QCDR measures as feasible to at least one cost measure, improvement activity, or an MVP at the time of self-nomination.
- Revise and redesignate existing paragraph (b)(3)(iv)(G)(*2*) to paragraph (b)(4)(iii)(B)(*7*)(*ii*) to state that in cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, CMS would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.
- Move existing paragraph (b)(3)(iv)(H) in its entirety to paragraph (b)(4)(iii)(B)(*8*).
- Move existing paragraph (b)(3)(iv)(I) in its entirety to paragraph (b)(4)(iii)(B)(*9*).
- Revise and redesignate existing paragraph (b)(3)(iv)(J) to paragraph (b)(4)(iii)(B)(*10*) to state beginning with the CY 2020 performance period/2022 MIPS payment year, CMS places greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.
- Move existing paragraph (b)(3)(iv)(J)(*1*) in its entirety to paragraph (b)(4)(iii)(B)(*10*)(*i*).
- Move existing paragraph (b)(3)(iv)(J)(*2*) to paragraph reserve (b)(4)(iii)(B)(*10*)(*ii*).
- Move existing paragraph (b)(3)(vi) in its entirety to paragraph (b)(4)(iii)(C).

We solicited public comments on our proposals. The following is a summary of the comments we received and our responses.

Comment: The commenter suggested that we assess whether the limit on the number of QCDR measures available (30 measures) should be revised.

Response: We thank the commenter for their suggestion. We may consider it for future rulemaking.

After consideration of public comments, we are finalizing these policies as proposed.

(iv) QCDR Measure Rejection Criteria

We refer readers to the existing requirements at § 414.1400(b)(3)(vii). We proposed reorganizing existing requirements at paragraph (b)(3)(vii) to proposed paragraph (b)(4)(iv). Therefore, we proposed the following revisions:

- To revise and redesignate existing paragraph (b)(3)(vii) ''QCDR measure rejection criteria'' to paragraph (b)(4)(iv) and add a heading to state, *QCDR measure rejection criteria.* We believe adding a heading will help readers clearly distinguish measure rejection criteria.

We also proposed to include the following updates:

- To move existing paragraph (b)(3)(vii) to proposed paragraph (b)(4)(iv) to state, *QCDR measure rejection criteria.* Beginning with the CY 2020 performance period/2022 MIPS payment year, QCDR measure rejection considerations include, but are not limited to.
- Move existing paragraphs (b)(3)(vii)(A) through (L) in their entirety to (b)(4)(iv)(A) through (L).

We solicited public comments on our proposals.

We did not receive public comments on these proposals, and therefore, we are finalizing them as proposed.

(e) Reorganization for Requirements Related to Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548), CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), and the CY 2021 PFS final rule (85 FR 84930 through 84937) for previously finalized policies for remedial action and termination of third party intermediaries. With the proposed updates being made at § 414.1400, we proposed to redesignate the following sections:

- We proposed to redesignate current paragraph (f) as paragraph (e) and to update cross-references to correspond to the new section numbers as reflected in this final rule.
- We also proposed to redesignate current paragraph (g) as paragraph (f) and to update cross-references to correspond to the new section numbers as reflected in this final rule.

We solicited public comments on these proposals.

We did not receive public comments on these proposals, and therefore, we are finalizing them as proposed.

(2) Third Party Intermediaries General Requirements

We refer readers to previously established § 414.1400(a) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), and as further revised in the CY 2019 PFS final rule (83 FR 60088), CY 2020 PFS final rule (84 FR 63049 through 63052), CY 2021 PFS final rule (85 FR 84926 through 84947) for our established policy regarding third party intermediaries general requirements.

In the CY 2022 PFS proposed rule, we proposed two changes for third party intermediaries: (1) Third party intermediary submissions for APM Entities; and (2) MIPS performance categories that must be supported by third party intermediaries. We also solicited comment on third party intermediaries that derive data from CEHRT. These proposals and the request for comments are discussed in more detail below.

(a) Third Party Intermediary Submissions for APM Entities

As finalized in the Quality Payment Program provisions in the CY 2021 PFS final rule (85 FR 84895), APM Entities now have the option of reporting to MIPS on behalf of the MIPS eligible clinicians participating in their APM Entity. They have the option of reporting to traditional MIPS or via the APP (85 FR 84859). APM Entities have historically used Third Party Intermediaries for submitting their quality measures to their APMs, rather than to MIPS, however, these third party intermediaries now have the opportunity to submit these data for purposes of MIPS.

In the CY 2022 PFS proposed rule, we proposed to add APM Entities to § 414.1400(a)(1), expanding the general participation requirements of third party intermediaries to third party intermediaries reporting to MIPS on behalf of APM Entities in order to align reporting requirements for all participants in MIPS.

We note that the Promoting Interoperability performance category is scored for APM Entities based on data submitted by the participant MIPS eligible clinicians and groups as described at § 414.1317(b)(1), and therefore, would not be required to be submitted by the third party intermediary on behalf of the APM Entity.

We solicited comments on this proposal.

We did not receive public comments on this proposal, and therefore, we are finalizing it as proposed.

(b) MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We refer readers to previously established § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), and as further revised in the CY 2019 PFS final rule (83 FR 60088), CY 2020 PFS final rule (84 FR 63049 through 63052), CY 2021 PFS final rule (85 FR 84926 through 84947) for our established policy regarding the types of MIPS data that third party intermediaries may submit.

In the CY 2022 PFS proposed rule, we proposed new requirements in alignment with our proposals in sections IV.A.3.b.(2)(c), IV.A.3.b.(4)(e) and IV.A.3.b.(3)(e) of this final rule to adopt MVPs and subgroups.

(i) New Requirement for Third Party Intermediaries To Support MVPs and the APP

As described in the Quality Payment Program provisions finalized in the CY 2021 PFS final rule (85 FR 84849), MVPs should include measures and activities from the quality, cost, improvement activities, and Promoting Interoperability performance categories. As described in section IV.A.3.b.(2)(c)(i) of this final rule, we discussed our proposals related to furthering our transition to MIPS Value Pathways (MVPs). As MVPs are implemented, proposed beginning with the CY 2023 performance period/2025 MIPS payment year, we also proposed the methods in which an MVP participant may report on an MVP or the APP. Since QCDRs, qualified registries, and health IT vendors are required under existing § 414.1400(a)(1) to submit data for quality, improvement activities, and promoting interoperability, we believe they would have the experience needed to support MVP and APP reporting.

Therefore, we proposed to create a new requirement at § 414.1400(b)(1)(ii) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. Additionally, we proposed to create a new requirement at paragraph § 414.1400(c)(1)(iii) to state that beginning with the CY 2023 performance period/2025 MIPS payment year, Health IT vendors must support MVPs that are applicable to the

MVP participants on whose behalf they submit MIPS data. Health IT vendors may also support the APP.

Based off historical participation, we are aware that some third party intermediaries (QCDRs and qualified registries) support a single specialty or subspecialty, while others support multiple specialties. Therefore, we believe that it is not appropriate to expect that all third party intermediaries are able to support all MVPs that are implemented in the program. Rather, the third party intermediaries should identify and support MVPs that are relevant to the clinicians and groups they support. We do not believe that CMS-approved survey vendors will be able to support MVP reporting, because they are historically limited, in that they only support the CAHPS for MIPS Survey Measure.

As discussed in section IV.A.3.b.(2)(c) of this final rule, MVPs will start with the CY 2023 performance period/2025 MIPS payment year. We believe this delay in implementation will allow third party intermediaries sufficient time for programming and system preparation for MVP reporting success. We solicited comments on our proposals.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported third party intermediaries only reporting on the MVPs that reflect their participant needs but suggested third-party intermediaries be able to choose which MVPs they wish to support. The commenter expressed concerns about MVPs being arbitrarily assigned to third-party intermediaries. One commenter noted that supporting an entire MVP is very different from supporting the inclusion of specific QCDR measures in an MVP and could carry much more burden for the registry and sought clarification of whether CMS will assign specific MVPs to a QCDR or qualified registry.

Response: We thank the commenter for their support. At this time, CMS does not intend on assigning specific MVPs to a third party intermediary. As described in the CY 2022 PFS proposed rule (86 FR 39462), we proposed at § 414.1400(b)(1)(ii) and (c)(1)(iii) that QCDRs, qualified registries, and Health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. We refer readers to Appendix 3 of this final rule, where discuss the MVPs being finalized beginning with the CY 2023 performance period/CY 2025 MIPS payment year, around the clinical topics of stroke care, heart disease, rheumatology, chronic conditions, emergency medicine, anesthesia, and lower extremity joint repair. QCDRs, qualified registries, and Health IT vendors that support MVP participants, who work in the aforementioned clinical areas will be required to support these MVPs, as applicable. Furthermore, we expect that QCDRs, qualified registries, and Health IT vendors who support MVPs would support all measures and activities, across the quality, PI, and improvement activities performance category that are included in the MVP (cost measures and population health measures are calculated by CMS and do not require data submission by a third party intermediary or a clinician). The expectation that the QCDR and qualified registry support measures and activities across all three performance categories is not new, as these third party intermediaries are currently required to do so. We believe allowing QCDRs to only support specific QCDR measures in an MVP creates undue burden on the MVP Participant who would need to find other means to complete MVP reporting requirements; this may deter clinicians from utilizing a third party intermediary. For the time being, CMS does not intend on assigning specific MVPs to a third party intermediary. It is required for QCDRs, qualified registries, and Health IT vendors to identify (CMS approved) MVPs that are relevant to the clinicians they support and report on those.

Comment: One commenter supported third party intermediaries supporting MVPs but requested clarification on whether a QCDR would be responsible for validating an MVP participant's performance on population health measures and/or providing ''enhanced'' performance feedback, including performance data comparing the performance of similar clinicians who report on the same MVP.

Response: Third party intermediaries will not be expected to validate the performance on the current population health measures, since they are administrative claims-based and do not require external data submission. The responsibility of identifying the population health measure that should be calculated will fall to the MVP participant to determine at the time of MVP registration. CMS calculates these measures based on administrative claims data. In the CY 2022 PFS proposed rule (86 FR 39383), we describe our proposal to include comparative performance feedback within the annual performance feedback that CMS currently provides under traditional MIPS. While CMS intends to provide this enhanced feedback through our existing performance feedback processes, QCDRs and qualified registries will still be required to provide clinicians they support with performance feedback as described at § 414.1400(b)(iii) and (c)(ii), regardless of whether the clinician chooses to report through traditional MIPS or an MVP.

Comment: One commenter suggested that CMS mandate that EHR vendors support the quality measures in MVPs, otherwise clinicians would be forced to join multiple registries with the cost exceeding the maximum penalty.

Response: To clarify, health IT vendors (such as EHRs), QCDRs, and qualified registries who support MVPs are required to support all measures and activities available in the MVP across the quality, improvement activities, and promoting interoperability performance categories. The exceptions to this requirement are the cost measures and population health measures, which do not require external data submission to be calculated. In addition, some MVPs may include QCDR measures, which are only reportable through a QCDR. In instances where QCDR measures are included in an MVP, a qualified registry or health IT vendor will be expected to support all other quality measures included within the MVP.

Comment: One commenter expressed concerns about layering another auditing requirement on QCDRs and qualified registries when MVPs are finalized as this could increase regulatory complexity and result in added work and burden without making a significant difference in the quality of data submitted. One commenter requested that CMS add more detail in future requirements for third-party intermediaries to validate data submitted by MVP participants.

Response: We disagree with the commenter. QCDRs and qualified registries are currently required to conduct data validation on data that is submitted to CMS for purposes of the MIPS program, to ensure the data is true, accurate, and complete. We refer readers to section IV.A.3.h.(3)(a)(iii) of this final rule for a detailed discussion of those requirements. The current data validation requirements that are utilized in traditional MIPS, will also be applied to MVP submissions. MVPs are considered a method of reporting under MIPS, but is nonetheless a part of the program. Therefore, the requirements and expectations remain the same—QCDRs and qualified registries must conduct data validation on data submitted to CMS for purposes of the MIPS program, regardless of whether

the data is submitted under traditional MIPS or through an MVP. In the future, data validation information that is covered in the Self-Nomination Toolkit for QCDRs and qualified registries available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1083/2021%20Self-Nomination%20Toolkit%20for%20QCDRs%20and%20Qualified%20Registries.zip* will also include MVPs.

Comment: One commenter requested clarification on whether QCDRs and qualified registries are required or permitted to support the APP, stating that the preamble states this is a requirement while the regulatory text says that QCDRs and qualified registries may support the APP. The commenter opposed a requirement for QCDRs and qualified registries to support the APP.

Response: In the CY 2021 PFS final rule (85 FR 84859), we discussed that APM Entities have the option of reporting to MIPS on behalf of the MIPS eligible clinicians participating in their APM Entity. Additionally, there is an option of reporting to traditional MIPS or via the APP. Furthermore, in the proposed rule (86 FR 39462), we proposed to add APM Entities to § 414.1400(a)(1), expanding the general participation requirements of third party intermediaries to third party intermediaries reporting to MIPS on behalf of APM Entities in order to align reporting requirements for all. We want to note that QCDRs and qualified registries would not be required to support the APP, but may do so. If QCDRs and qualified registries would like to support the APP, they would need to meet all of the other requirements of being a QCDR or qualified registry reporting to MIPS (with the exception of PI reporting, which has some exceptions) as described above.

After consideration of public comments, we are finalizing these policies as proposed.

(ii) Requirements for All Third Party Intermediaries To Support Subgroup Reporting

As proposed in section IV.A.3.b.(3) of this final rule, subgroup reporting would allow clinicians in multispecialty practices to participate in MIPS more meaningfully. Since subgroups would be implemented concurrently with MVPs, it is important that third party intermediaries have the capability to support subgroup reporting of MVPs. As described above, we believe QCDRs, qualified registries, and health IT vendors would have the capacity to support MVP and APP reporting.

In the CY 2022 PFS proposed rule, we proposed to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 performance period/2025 MIPS payment year. Therefore, we proposed to revise § 414.1400(a)(1) to state that MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup or APM Entity by any of the following third party intermediaries: QCDR; qualified registry; health IT vendor; or CMS-approved survey vendor. We believe it is imperative for all third party intermediaries to be able to support subgroup reporting as we envision that to be the future of the program.

While the CAHPS for MIPS survey vendors cannot support MVPs or the APP, we believe they can support the reporting of the CAHPS for MIPS measure within an MVP and the APP, if a subgroup decides to report on that measure. Due to the limited experience, CAHPS for MIPS survey vendors have in quality reporting, we do not believe it is feasible for them to support MVP reporting since MVP reporting would require experience with reporting across the performance categories and the use of several collection types for quality reporting. However, there may be instances where the CAHPS for MIPS survey measure may be included in an MVP. For example, in the Optimizing Chronic Conditions Management MVP, as described in Appendix 3: MVP Inventory, of this final rule. In such instances, if groups or subgroups would like to report this measure, they should be able to utilize a CAHPS for MIPS survey vendor to do so. We believe it is important that all third party intermediaries support subgroup reporting in order to support meaningful quality reporting. We understand that there may be a level of burden to third party intermediaries that are required in supporting subgroup reporting by requiring them to support another clinician type. However, we believe that requiring third party intermediaries to support subgroup reporting will allow for clinicians to participate in a manner that is more meaningful. We noted in section IV.A.3.b.(4)(f)(ii)(D) of this final rule, subgroups would have to register through the MVP participant registration process. Third party intermediaries would need to be able to track the subgroup identifiers and support the data submission process accordingly.

We solicited comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern regarding the burden for registries to identify and validate subgroup reporting.

Response: To clarify, as discussed in section IV.A.3.b.(4)(f)(ii)(D) of this final rule, subgroups must self-identify and register through a registration process in order to be considered a subgroup. The subgroup would need to register directly through the MVP registration process, that is done separately and not through a third party intermediary. Therefore, we believe there is no burden to registries to identify the subgroups. As MVP participants such as subgroups enroll to use the services of a registry, the subgroup will share with the registry their CMS-assigned identifier and a list of participants within that subgroup. The registry will need to submit the subgroup identifier information with the subgroup's data at the time of submission. We understand there may be concerns in scenarios in which subgroups inadvertently provide an incorrect subgroup identifier to the registry. We will take that into consideration for future rulemaking, as we determine whether there are additional system safeguards, such as a system rejection of an incorrect identifier can be implemented to limit the occurrence of such issues. With regards to data validation, all QCDRs and qualified registries will continue to be held to the data validation requirements that currently exist, regardless of whether a clinician or group decides to participate in MVP reporting or traditional MIPS reporting. While we understand there is a level of burden associated with data validation, we believe the benefit outweighs the burden to ensure that all data submitted to CMS is true, accurate, and complete.

Comment: One commenter suggested that CMS delay its proposal requiring third party intermediaries to support subgroup reporting to allow more time for registries to implement reporting processes. Several commenters expressed concern that subgroup reporting will impose a large increase in burden on registries, particularly with respect to how registries validate NPIs. A few commenters expressed concern that QCDRs may lack the capacity to support subgroup reporting.

Response: We disagree with the need for further delay. We intentionally proposed MVPs and subgroup reporting with a delayed implementation to account for the time that clinicians, third party intermediaries, and healthcare organizations would need to prepare to operationalize MVP and subgroup reporting. We believe the availability of subgroup reporting

should go hand-in-hand with the implementation of MVPs, and therefore, should be jointly available beginning with the CY 2023 performance period/2025 MIPS payment year. The delayed implementation should provide third party intermediaries sufficient time for system and operation preparations for subgroup reporting. In addition, we do not believe that subgroup reporting will impose a large increase in burden to registries. We refer readers to section IV.A.3.b.(3) of this final rule, for further discussion of validation requirements. Subgroups are derived from their affiliated TINs who would have otherwise reported traditional MIPS through a registry.

After consideration of public comments, we are finalizing this policy as proposed.

(c) Request for Comment on Third Party Intermediaries That Derive Data From CEHRT

For third party intermediaries that will be submitting quality measure data on behalf of MIPS eligible clinicians, we believe that EHR systems will be able to provide measure results for a set of providers that are part of a subgroup where required for subgroup reporting. We note that the existing CEHRT definition for eligible clinicians at § 414.1305 includes the 45 CFR 170.315(c)(4) ''Clinical quality measures—filter'' as an optional element. This criterion requires health IT to be able to filter CQM results at both patient and aggregate levels. Moreover, a Health IT Module must be able to filter by a single proposed data element (for example, provider type) or a combination of any of the data elements). Historically, the ''Clinical quality measures—filter'' at 45 CFR 170.315(c)(4)'' (CQM-filter) criterion has been applicable for certified health IT modules supporting quality measurement for participants in certain APMs.

We believe technology certified to this optional criterion could support subgroup reporting via third party intermediaries that derive data from CEHRT by ensuring that an EHR can produce CQM results filtered for a specific group of provider NPIs that are part of a subgroup. These filtered CQM results could then be shared with a third party intermediary, which provides this data for reporting to CMS. However, we also believe health IT developers are offering non-certified functionality that can effectively support reporting of measure results for a subgroup. As a result, we did not propose any changes at this time to the language in the CEHRT definition for eligible clinicians regarding the ''optional'' status of technology certified to the CQM-filter criterion.

We are interested in general feedback from stakeholders on the current capabilities of third party intermediaries that derive data from CEHRT to successfully receive and transmit data to CMS for CQMs based on subgroups; capabilities of EHR systems to support subgroup reporting, including reporting facilitated by third party intermediaries, and whether requiring the adoption of technology certified to the CQM-filter criterion would help to support subgroup reporting; and challenges which entities may face in meeting requirements to report on subgroups when deriving data from CEHRT. We solicited feedback on this topic.

Comment: A few commenters responded to CMS' request for information regarding CEHRT and third party intermediaries. One commenter urged CMS to establish clear expectations and guidelines to ensure data security and to define roles and responsibilities for data validation and data cleaning. Another commenter recommended that CMS consider making the CQM filter criterion mandatory for CEHRT because, otherwise, organizations would likely be required to contract with qualified registries/QCDRs to submit MIPS data. Another commenter disagreed, stating that as a developer of CEHRT that provides CQM functionality, they do not believe that the CQM-filer criterion is necessary.

Response: We thank commenters for the feedback received through this request for information. We may consider this information to inform future rulemaking.

(3) New Requirements for Both Qualified Clinical Data Registries (QCDRs) and Qualified Registries

(a) Background

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (85 FR 84926 through 84947) for our previously established policies regarding QCDRs and qualified registries.

In the CY 2022 PFS proposed rule, we proposed several changes for both QCDRs and qualified registries: (1) New requirement for approved QCDRs and qualified registries that have not submitted performance data; (2) collaboration of entities to become a QCDR and qualified registry; and (3) data validation audit and targeted audit requirements. These proposals are discussed in more detail below.

(i) New Requirement for Approved QCDRs and Qualified Registries That Have Not Submitted Performance Data

We require that both QCDRs and qualified registries must have a minimum of 25 participants signed up by the prior performance period at existing § 414.1400(b)(2) and (c)(2). We refer readers to CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (85 FR 84926 through 84947). We identified a number of QCDRs and qualified registries that have continued to self-nominate to become a third party intermediary for the MIPS program, but have not submitted clinician, group or virtual group data to CMS. As the MIPS program continues to mature, we wish to reduce the number of vendors that self-nominate to become a qualified vendor, but do not actively participate in the MIPS program. We believe that maintaining these vendors who do not actively participate does not provide a benefit to the MIPS program, rather it creates stakeholder confusion by including these vendors in our qualified postings.

We proposed a two-tiered approach to solve this issue. First, we proposed to create a new requirement at § 414.1400(b)(3)(vii) to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 performance period/2019 MIPS payment year) through the CY 2020 performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023. Exceptions to this requirement may occur if data is received for the CY 2021 performance period/2023 MIPS payment year. Under this scenario, QCDRs and qualified registries would not need to submit a participation plan for CY 2023 of the self-nomination period. If they do not submit data, their participation plan must be submitted as part of self-nomination for CY 2023 and must be accepted by CMS to continue to be an approved QCDR or qualified registry.

Secondly, we proposed to codify a new requirement at paragraph (b)(3)(viii) to state, beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. For example, for the CY 2024 performance period/2026 MIPS payment year, vendors will be required to have submitted performance data for the CY 2021 and 2022 performance periods/2023 and 2024 MIPS payment years. Under this proposal, the participation plan must explain the QCDR's or qualified registry's detailed plans about how the vendor intends to encourage clinicians to submit MIPS data to CMS through the third party intermediary on behalf of clinicians or groups. The vendor must also explain why they should still be allowed to participate as a qualified vendor. We note that this proposed participation plan was modeled off of the current requirement for QCDR measure participation at existing § 414.1400(b)(3)(iv)(J)(*1*) (redesignated to proposed paragraph (b)(4)(iii)(B)(10)(*i*)). We solicited comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with the proposal to require a participation plan for approved QCDRs that did not submit data for 2 years preceding the applicable self-nomination period. One commenter stated that the COVID PHE reduced reporting by eligible clinicians to QCDRs.

Response: While we are sympathetic and acknowledge that the impact the PHE may have had on reduced reporting, we note that we are proposing an incremental approach to assess QCDR data reporting. This includes the first proposal which would apply to any QCDR or qualified registry that has not submitted data to CMS since the inception of MIPS (CY 2017). We believe a QCDR should have been able to report data to CMS for years preceding CY 2021. Specifically, we believe a QCDR should have been able to report data to CMS for CY 2019. If a QCDR was new in CY 2020 and did not submit data to CMS, the QCDR still has CY 2021 to report for clinicians which in turn, satisfies this requirement. Furthermore, the proposal provides QCDRs and qualified registries the opportunity to submit participation plans, which could support the decision to allow a QCDR or qualified registry to continue their MIPS participation. This plan would outline possible reasons for low/no reporting to CMS and the efforts the QCDR plans to take to further encourage their clinicians to submit data to CMS. Some examples include but are not limited to: A reduction in associated fees, improvement of an EHR interface to reduce data extraction burden, expansion of the numbers/types of measures the QCDR chooses to report, etc. As such, this proposal would not immediately remove a QCDR or qualified registry from participating as a third party intermediary. As discussed above, we want to reduce the number of vendors that self-nominate to become a qualified vendor, but do not actively participate in the MIPS program. We believe that maintaining these vendors who do not actively participate does not provide a benefit to the MIPS program. We note that our goal is to decrease the operational burden on CMS and those vendors who do not submit MIPS data to CMS. CMS would decrease its operational burden by not having to go through the vetting process of these entities or monitor program compliance during the year. Additionally, we believe that we can better utilize the resources used for vendors that do not submit MIPS data elsewhere to improve the MIPS program. Furthermore, vendors who choose not to submit MIPS data to CMS are depriving CMS of data that would benefit the MIPS program. Lastly, vendors who do not submit data will decrease their burden in the long-term by not self-nominating year after year.

Comment: One commenter disagreed with the proposal for QCDRs and qualified registries who do not submit data 2 years preceding the applicable self-nomination period to submit a participation plan at the time of self-nomination. The commenter noted that CMS would also require the participation plan to include moving users over to submit their MIPS data through the qualified registry. The commenter expressed concern that this policy would create significant demand on QCDRs specifically, due to the already cumbersome Eligible Measure Applicability (EMA) process required for qualified registries. The commenter currently uses both the qualified registry and QCDR to collect data, however, the commenter only submits the data to CMS through the QCDR.

Response: We disagree with the commenter's interpretation of this policy. The intention of the participation plan requirement is to explain the QCDR's or qualified registry's detailed plans about how the vendor intends to encourage clinicians to submit MIPS data to CMS through the third party intermediary on behalf of clinicians or group and to explain why they should still be allowed to participate as a qualified vendor. The participation plan will not require moving users over to submit their MIPS data through the qualified registry and that this policy would create significant demand on QCDRs. We note that during the CY 2019 MIPS performance period, the Eligible Measure Applicability (EMA) process was updated to be applicable to collection types (that is, EMA applies to Part B Claims measures and MIPS clinical quality measures (CQMs) but does not apply to electronic clinical quality measures (eCQMs), QCDR measures, or Web Interface) rather than third party intermediaries. As such, EMA does not apply to QCDRs and qualified registries as an entity, rather it could apply to MIPS CQMs that the QCDR or qualified registry is approved to support. We encourage third party intermediaries to participate as a QCDR if they intend to self-nominate their own QCDR measures or use another QCDR's measures (with permission from the QCDR who owns the measure) or as a qualified registry if they plan to support their clients through the reporting of CQMs or eCQMs only.

After consideration of public comments, we are finalizing these policies as proposed.

(ii) Collaboration of Entities To Become a QCDR and Proposal To Extend Policy for Collaboration of Entities To Become a Qualified Registry

(A) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77377), we finalized to allow collaboration of entities to become a QCDR based on our experience with the qualifying entities wishing to become QCDRs for performance periods. We stated that we believed our previously finalized policy supporting entity collaboration should be continued under MIPS. Therefore, we discussed that an entity that may not meet the criteria of a QCDR solely on its own, but could do so in conjunction with another entity and would be eligible for qualification through collaboration with another entity. Additionally, we finalized at § 414.1400(b)(2)(ii), specifically for QCDRs, that if the entity uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the

responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

For example, an entity, such as a specialty society, that needs technical support may partner with an outside entity such as a health IT vendor to qualify as a QCDR. While entities, such as QCDRs, Health IT vendors, and qualified registries, can collaborate with external organizations, those entities could only do so to meet requirements to be a QCDR. We did not explicitly create a policy for entities to collaborate to meet the requirements to be a qualified registry.

(B) Proposal To Extend to Qualified Registries

We believe we should extend the previously finalized policy to apply to entities that wish to collaborate to become a qualified registry as well because extending this policy to qualified registries would also help smaller specialty societies that may not have the resources on their own to become a qualified registry. This will allow those societies to be able to partner with other entities to meet the definition of a qualified registry. Therefore, in the CY 2022 PFS proposed rule, we proposed to revise and redesignate existing paragraph (b)(2)(ii) to new paragraph (b)(3)(ii) to state, if the entity seeking to qualify as a QCDR or qualified registry uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period. For example, an entity, such as a specialty society, that needs technical support may partner with an outside entity such as a health IT vendor to qualify as a qualified registry. We solicited comments on this proposal.

We did not receive public comments on this proposal, and therefore, we are finalizing it as proposed.

(iii) Data Validation Audit and Targeted Audit Requirements

(A) Information Required at the Time of Self-Nomination

In the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367; 81 FR 77383 through 77384) we discussed our expectation for QCDRs and qualified registries to conduct validation on the data they intend to submit for the MIPS performance period. We also discussed that the full self-nomination process would require the following: A submission of basic information, a description of the process the QCDR and qualified registry will use for completion of a targeted audit of a subset of data prior to submission, the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period. Additionally, in the Quality Payment Program provisions in the CY 2021 PFS final rule (85 FR 84930 through 84937; 85 FR 84944 through 84947) at existing § 414.1400(b)(2)(iv) and (v), and (c)(2)(iii) and (iv), we finalized the data validation audit requirements as condition for approval. While we did finalize the requirements for the data validation audits as condition for approval, we did not codify the requirements for QCDR and qualified registries to submit data validation plan during self-nomination along with the results of the executed data validation plan by May 31 of the year following the performance period.

In order to provide clarification and to better align with the previously finalized policy (81 FR 77366 through 77367; 81 FR 77383 through 77384), we proposed to codify the following revisions. As stated in previous polices (81 FR 77366 through 77367;81 FR 77383 through 77384), QCDRs and qualified registries are required to submit the results of their data validation plan to CMS by May 31 of the year following the performance period. Therefore, we proposed to codify at § 414.1400(b)(3)(v)(G)(*1*) to state that QCDRs and qualified registries must conduct validation on the data they intend to submit for the applicable MIPS performance period, and provide the results of the executed data validation plan by May 31st of the year following the performance period.

Furthermore, QCDRs and qualified registries are required to submit their data validation plan explaining their process of data validation submission annually during self-nomination, and it must be approved by CMS for before use. To provide further clarity and to better align with the existing policy (81 FR 77366 through 77367; 81 FR 77383 through 77384), we also proposed to codify a new requirement at § 414.1400(b)(3)(iv) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the agency.

As discussed above we proposed to codify at § 414.1400(b)(3)(iv) to provide further clarity to better align with previous policies. Therefore, we proposed to reorganize at § 414.1400(b)(2)(iv) though (viii) to better align with the above changes. We proposed with the following revisions:

- We proposed to revise and redesignate existing paragraph (b)(2)(iv) to paragraph (b)(3)(v) to state, that beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct annual data validation audits in accordance with this paragraph (b)(3)(v).
- We proposed to revise and redesignate existing paragraph (b)(2)(iv)(A) to paragraph (b)(3)(vi)(A) to state that, if a data validation audit under paragraph (b)(3)(v) identifies one or more deficiency or data error, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.
- We proposed to revise and redesignate existing paragraph (b)(2)(v) to paragraph (b)(3)(vi) to state that beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with this paragraph (b)(3)(vi).
- We proposed to revise and redesignate paragraph (b)(2)(vi) to paragraph (b)(3)(vii), to state for the CY 2023 performance period/2025 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for any of the CY 2017 through 2021 performance periods/2019 through 2023 MIPS payment years must submit a participation plan for CMS' approval. This participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.
- We proposed to revise and redesignate existing paragraph (b)(2)(vii) to paragraph (b)(4)(viii) to state that beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval.

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the ''overly burdensome'' nature and significant cost of the CMS data validation audit requirements for third party intermediaries. One commenter expressed concerns with the randomized auditing resulting in an unintended consequence of increasing burden on small and mid-sized group practices because of the low number of participants reporting via the qualified registry as individuals. One commenter stated that the audit requirements are duplicative, unnecessary, and do not enhance data quality and validity because QCDRs already have rigorous internal data and quality standards. A few commenters stated that clinicians and registries were impacted by the COVID–19 pandemic, specifically that dozens of audits were conducted and QCDRs and qualified registries have encountered practices struggling to collect and report data while a majority of their time and effort has been spent on responding to the COVID–19 pandemic.

Response: While we understand that data validation requires a level of effort, time, and cost by the QCDRs and qualified registries, we disagree that this causes undue burden. While we acknowledge and appreciate the efforts and participation of all group practices of varying sizes including small and mid-sized groups, we believe it is important to hold all practices to the same standards for data validation audits to ensure that all data submitted is true, accurate, and complete. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367; 81 FR 77383 through 77384), we expect that QCDRs and qualified registries would conduct validation on the data they intend on submitting for the MIPS performance period and provide the results of the data validation to CMS in the form of a data validation execution report by May 31st of the year following the performance period. As noted in the CY 2017 PFS final rule (81 FR 77366 through 77367), we believe it is necessary to establish a requirement that QCDRs conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. We also believe it is important for QCDRs to validate the data that they intend to submit to us for purposes of the MIPS program to ensure that the data submitted is true, accurate, and complete (85 FR 84936). We disagree that audit requirements are duplicative, unnecessary, and do not enhance data quality and validity because QCDRs already have rigorous internal data and quality standards. While we appreciate that many QCDRs already have rigorous internal data and quality standards, we are not asking QCDRs to duplicate work. If QCDRs have their own auditing requirements, they can use the same auditing process or combine the efforts to reduce duplication as long as they meet the data validation requirements specified by the regulation at a minimum (81 FR 77366 through 77367; 81 FR 77383 through 77384). For example, if a QCDR already audits 10 percent of their data prior to submission for all performance categories, this would meet the 3 percent portion of the data validation requirement. Additionally, despite our requirements to have validation audits, each year there are still some QCDRs that submit inaccurate data. As payment adjustments increase, this could adversely affect a practice with respect to their payment because these payment calculations were based on inaccurate data submitted to CMS.

Furthermore, while we do acknowledge that the impact of the PHE for COVID–19 may have affected some providers and registries ability to conduct audits due to practices struggling to collect and report data due to majority of their time and effort being spent on responding to the COVID–19 pandemic, as stated above, we believe it is important to enforce the requirements for data validation audits to ensure all data submitted is true, accurate, and complete. We will continue to assess the implications of the PHE for COVID–19 and will consider whether to make any policy changes in future rulemaking.

Comment: One commenter expressed that NCQA data validation alleviates the burden on health plans having to perform their own audit of data received from an HIE and on providers from having to respond to data requests from health plans. This commenter suggested that CMS leverage NCQA processes for data validation.

Response: We thank the commenter for their suggestion. We may consider it for future rulemaking.

After consideration of public comments, we are finalizing these policies as proposed.

(4) New Requirements Specific to QCDRs

(a) Background

We refer readers to § 414.1400(b), the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (84937 through 84944) for where we previously finalized standards and criteria for QCDRs, specifically QCDR measure requirements. In this section, we proposed to update policies related to QCDR measure rejections.

(b) QCDR Measures

(i) QCDR Measure Rejections

(A) New QCDR Measure Rejection Criteria

We refer readers to the Quality Payment Program provisions in the CY 2020 PFS final rule (84 FR 63070 through 63073) at § 414.1400(b)(3)(vii) where we have previously adopted QCDR measure rejection criteria. In the CY 2022 PFS proposed rule, we proposed to add two new criteria: (1) QCDR does not have permission to use a QCDR measure; and (2) QCDR not approved or not in good standing. These are discussed in more detail below in this section.

(aa) QCDR Does Not Have Permission To Use a QCDR Measure

In the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), we discussed that beginning with the 2018 performance period and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. We noted that the QCDR measure owner (QCDR vendor) would still own and maintain the QCDR measure, but would allow other QCDRs to utilize their measure with proper notification. We intended for this policy to help reduce the number of QCDR measures that are similar in concept or clinical topic, or duplicative of other QCDR measures that are being approved. Additionally, in the Quality Payment Program provisions in the CY 2020 PFS final rule (84 FR 63070 through 63073) at § 414.1400(b)(3)(vii), we finalized the QCDR measure rejection criteria considerations. We noted that these considerations would help to ensure that QCDR measures are meaningful and measurable. Although we finalized the QCDR measure rejection criteria, we did not codify that QCDRs may seek permission from another QCDR to use an existing measure that is owned by another QCDR. In order to provide further clarity to the existing policies (82 FR 53813 through 53814; 84 FR

63070 through 63073), we proposed to codify a new requirement and add a rejection criterion at § 414.1400(b)(4)(iv)(M) to state, a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. We solicited comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to add the rejection criterion that ''A QCDR does not have permission to use QCDR measure owned by another QCDR for the applicable performance period'' because CMS currently allows QCDRs to seek permission from another QCDR to report on an existing measure that is owned by the other QCDR, and because if a QCDR would like to use an existing QCDR measure that is owned by another QCDR, it must obtain permission from the QCDR measure owner that it can use the measure for the performance period and include proof of such permission in its self-nomination application.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing this policy as proposed.

(bb) QCDR Not Approved or Not in Good Standing

Additionally, if a QCDR measure owner is not approved or is not in good standing, any QCDR measures associated with that QCDR would also not be approved. We believe it is important to have an approved QCDR measure owner for all approved QCDR measures. This would ensure that there is active involvement by the QCDR measure owner so that any potential measure issues can be mitigated during the specified MIPS performance period. For example, any mid-year guideline changes or measure questions would need to be immediately clarified to avoid negative impacts to clinicians such as the inability to construct a benchmark due to an error in the measure specifications. Therefore, we proposed to codify another rejection criterion at § 414.1400(b)(4)(iv)(N) to state that, if a QCDR measure owner is not approved during a given self-nomination period, any associated QCDR measures with that QCDR would also not be approved. We solicited comments on this proposal.

We have received inquiries from stakeholders on what can be done in circumstances when an active QCDR wishes to use an inactive QCDR's measure. We are interested in feedback from stakeholders on what should be done in such circumstances. For example, what should happen if ''QCDR A'' is using ''QCDR B's'' measures in a given performance period and ''QCDR B'' is terminated mid performance period? Alternatively, what if ''QCDR A'' is using a measure from ''QCDR B'' and ''QCDR B'' decides not to self-nominate for the subsequent performance period? While ''QCDR A'' could partner with ''QCDR B'' as described at § 414.1400(b)(3)(ii), are there other policy options we should consider to minimize impact to the MIPS eligible clinician who has selected the QCDR measure for reporting?

We solicited comments on the above circumstances. The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with the proposal to add a rejection criterion requiring permission to use an inactive QCDR's measures. One commenter stated that there is no evidence that inactive QCDRs are withholding access to these measures. The commenter noted the ability of QCDRs to license measures allows QCDRs to ensure the appropriate use of their measures and incentivizes organizations to invest in developing new and improved measures. The commenter suggested that CMS should continue its policy that allows active or inactive QCDR measure owners to choose to license their measures only to QCDRs that have the experience and expertise to properly implement a measure in a particular specialty. Therefore, there is no reason to change CMS' current policy under which an active QCDR that wishes to use an inactive QCDR's measure can approach the inactive QCDR and the two QCDRs can negotiate an agreement regarding the transfer of ownership if the active QCDR has the appropriate experience and expertise in QCDR measure development. In the event that such agreement cannot be reached between the two parties, the inactive QCDR can decline to license rights to the QCDR measure. One commenter suggested that CMS require that either there be an agreement between the two QCDRs to transfer ownership of the measure or that the initial QCDR should maintain their measures and license it to other QCDRs.

Response: We thank the commenters for their comments and suggestions. We clarify that if a QCDR measure owner is not approved or is not in good standing, any QCDR measures owned or maintained with that QCDR would also not be approved. We disagree that the proposal to add a rejection criterion requiring permission to use an inactive QCDR's measures is not supported by evidence that inactive QCDRs are withholding access to these measures. We note that there have been instances where active QCDRs have inquired about using QCDR measures of inactive QCDR measure stewards. We also disagree that this policy is not needed. We believe it is imperative that all QCDR measures in the MIPS program have an active QCDR measure steward to provide ongoing maintenance and updates to QCDR measures. For example, recently, a QCDR who shares their measures with several other QCDRs discovered multiples discrepancies, including risk adjustment calculation issues. If they had not been an active QCDR and performing quality assurance on these QCDR measures, this issue would likely not have been discovered and resolved.

We do agree that the ability of QCDRs to license measures allows QCDRs to ensure the appropriate use of their measures and incentivizes organizations to invest in developing new and improved measures. We also agree that active or inactive QCDR measure owners may choose to license their measures only to QCDRs that have the experience and expertise to properly implement a measure in a particular specialty. Furthermore, this process is consistent with what CMS requires for all other measures available for all clinicians to report in the MIPS program (the non-QCDR measures). That is, every measure in the program needs an active measure steward that agrees to support and maintain the measure. A non-active QCDR cannot be compelled to meet this requirement.

In this context, we interpret the commenter's reference to a ''policy under which an active QCDR that wishes to use an inactive QCDR's measure can approach the inactive QCDR and the two QCDRs can negotiate an agreement regarding the transfer of ownership'', to apply to our statements regarding QCDR licensing as discussed in the CY 2018 PFS final rule (82 FR 53813). There we noted that, beginning with the 2018 performance period and for future program years, a QCDR vendor may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. While we thank the commenter for the suggestion to require the transfer of ownership of a measure from an inactive QCDR to an active QCDR or that the inactive QCDR should maintain the measure and license it to active QCDRs, we note that such approaches are beyond the scope of our regulations, which in this case is limited to approval and disapproval criteria for QCDRs and

QCDR measures. We are considering building out additional policies to ensure that all QCDR measures that are used/owned are properly maintained throughout the performance period.

After consideration of public comments, we are finalizing this policy as proposed.

(5) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548), CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), and the CY 2021 PFS final rule (85 FR 84930 through 84937) for previously finalized policies for remedial action and termination of third party intermediaries.

In the Quality Payment Program provisions in the CY 2019 PFS final rule (83 FR 59908 through 59910), we discussed that the threshold for ''inaccurate, unusable or otherwise compromised'' may be met if the submitted data includes TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more 3 percent of the total number of MIPS eligible clinicians or groups for which data was submitted by the third party intermediary. We proposed to update the existing language at § 414.1400(f)(3)(ii) to broadly explain that it is up CMS' discretion on whether third party intermediaries' inaccuracies may lead to possible remedial action or termination. As discussed earlier, we proposed consolidating and redesignating the existing language at § 414.1400(f) as paragraph (e) and § 414.1400(g) as paragraph (f) to provide clarity and alignment with the aforementioned proposals to consolidate the duplicative criteria of QCDRs and qualified registries. Therefore, we proposed to revise and redesignate existing language at § 414.1400(f)(3)(ii) to paragraph (e)(3) to state, contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

We did not receive public comments on this policy, and therefore, we are finalizing it as proposed.

i. Public Reporting on the Compare Tools Hosted by the U.S. Department of Health & Human Services (HHS)

In the CY 2022 PFS proposed rule, we proposed to amend § 414.1395(c) to add a 1-year delay of publicly reporting new improvement activities and Promoting Interoperability measures and attestations reported via MVP. We also proposed a one-time, 1-year delay to subgroup-level public reporting, such that subgroup-level public reporting will begin with CY 2024 performance information available in 2025, and each year thereafter, on the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as ''compare tool'' throughout this final rule, available at *https://www.medicare.gov/care-compare/* and *data.medicare.gov,* as technically feasible. We proposed to add facility affiliations, beyond the hospital affiliations currently displayed on individual profile pages. Additional facility affiliations would include: Inpatient rehabilitation facilities (IRFs); long-term care hospitals (LTCHs); skilled nursing facilities (SNFs); inpatient psychiatric facilities (IPFs); home health agencies (HHAs); hospices; and dialysis facilities. Finally, we solicited comments on publicly reporting utilization data on clinician and group profile pages (86 FR 39466 through 39469).

For previous discussions on public reporting, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2021 PFS final rule (85 FR 84947 through 85 FR 84948) and the Care Compare: Doctors and Clinicians Initiative Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Compare-DAC.*

(1) MVP and Subgroup Public Reporting

The introduction of MVPs and subgroup reporting provides for new types of performance information that are available for public reporting, provided they meet the established public reporting standards at § 414.1395(b). In consideration of our MVP and subgroup performance information public reporting proposals, we wish to remind readers that all submitted MIPS performance information is available for public reporting (81 FR 77395 through 77397). Additionally, we previously finalized at § 414.1395(c) that, for each program year, CMS does not publicly report any first-year measures for the first 2 years, meaning any measure in its first 2 years of use in the quality and cost performance categories. We also note that MIPS performance category and composite final scores for MIPS eligible clinicians participating in MVPs will continue to be publicly reported as required under section 1848(q)(A)(i)(I) of the Act and finalized at § 414.1395(a)(1)(i).

We believe delaying public reporting of certain MVP and subgroup performance information provides a catalyst to encourage clinician participation in MVPs and subgroups while they familiarize themselves with these options. For this reason, we proposed, for individuals, groups, and subgroups reporting via MVP, to add a 1-year delay for publicly reporting new improvement activities and Promoting Interoperability measures and attestations, as technically feasible. This means that new improvement activities and Promoting Interoperability measures and attestations would be available for public reporting at their inception in traditional MIPS, but we would delay public reporting of new improvement activities and Promoting Interoperability measures and attestations by 1 year after inception for those reporting via MVP. We note that improvement activities and Promoting Interoperability measures and attestations that have already been in MIPS for more than 1 year and become newly available as part of an MVP would be available for public reporting in the first year the MVP is in the program. That is, non-first year improvement activities and Promoting Interoperability measures and attestations that are newly part of an MVP would be available for public reporting in the first year the MVP is in the program (86 FR 39466 through 39467). Table 74 further clarifies when this 1-year delay would apply.

TABLE 74: MVP vs Traditional MIPS: Performance Information Delay Amount

New Improvement Activities and Promoting Interoperability measures and attestations	Delay Amount
Reported via traditional MIPS	No delay; CMS publicly reports new improvement activities and Promoting Interoperability measures and attestations at their inception.
Reported via MVP	CMS does not publicly report the new improvement activities and Promoting Interoperability measures and attestations for the first year.

We recognized that under this proposal, we would be further delaying the release of performance information for improvement activities and Promoting Interoperability measures and attestations reported via MVP. Because of this, as a potential incentive, we also considered whether to delay public reporting of quality and cost measure information reported via MVP by 1 additional year, for a total of 3 years. We solicited comments on our proposal to delay public reporting of new improvement activities and Promoting Interoperability measures and attestations reported via MVP by 1 year, as well as any feedback on alternate approaches we should consider spurring clinicians to report performance data on MVPs while making performance data available for patients on the compare tool. We proposed to amend this MVP public reporting policy at § 414.1395(c)(2) to state CMS does not publicly report any MVP data on new improvement activities or Promoting Interoperability measure, objective, or activity included in an MVP for the first year in which it is included in the MVP. We also proposed to amend § 414.1395(c)(1) to state that CMS does not publicly report any data on new quality or cost measure for the first 2 years in which it is in the program, after which CMS evaluates the measure to determine whether it is suitable for public reporting under § 414.1395(b). Currently, § 414.1395(c) refers to these quality and cost measures as ''first year measures''. We proposed to change ''first year measures'' to ''new measures'' (86 FR 39467).

The introduction of MVPs and subgroup reporting in MIPS provides for new types of performance information that are available for public reporting, provided they meet the public reporting standards. Currently, we display information on profile pages at the individual clinician and group level, since this is the level of information we provide for and at which patients and caregivers search for on the compare tool. To ensure that patients and caregivers have access to subgroup performance information, we proposed creating a separate workflow from the established ones for individuals and groups, since we only display information at the level at which it was publicly reported (86 FR 39467). That is, we only publicly report individual-level performance information on individual clinician profile pages and group-level performance information on group profile pages. We do not publicly report group-level performance information on individual profile pages or individual-level information on group profile pages, as doing so would not be truly representative of either the group's or individual's own performance, and we do not want to mislead website users. Instead, we would link from the individual or group profile page to the corresponding subgroup performance information. That is, we proposed to create a subgroup public reporting workflow, in which we would indicate with plain language on an individual profile page that the clinician reports performance information as part of a subgroup or on a group profile page that the group has subgroups for purposes of performance information and then link to that subgroup's performance information. Future user testing would determine how to best display and put in plain language subgroup performance information. Subgroup performance information will also be available on *http://data.medicare.gov/*.

Subgroups represent a new type of reporting for MIPS, that is available for clinicians reporting on MVPs or via the APP. For this reason, we also proposed to delay all subgroup-level public reporting for 1 year, including measures, activities and attestations across the quality, cost, improvement activities, and Promoting Interoperability performance categories in order to encourage clinician participation in subgroups without the risk of displaying subgroup performance information as clinicians familiarize themselves with the option of subgroup reporting. This would only be a one-time delay in public reporting of subgroup-level information. That is, we would not publicly report any CY 2023 subgroup-level measure, attestation, or activity performance information; this information would be available for public reporting beginning with CY 2024 performance period/2026 MIPS payment year. We would publicly report CY 2024 performance period/2026 MIPS payment year subgroup information and for each performance period thereafter if the information meets our established public reporting standards. Since we are moving toward more granular level performance information, we believe delaying subgroup public reporting by 1 year provides an incentive for subgroup participation and experience. As an alternative, we also considered a 1-year public reporting delay of performance information for all new subgroups each performance year, as technically feasible. For example, subgroups that begin in CY 2023 are not eligible for public reporting until CY 2024, subgroups that begin in CY 2024 are not eligible for public reporting until CY 2025, and so on for each subsequent year. Another alternative we considered was to publicly report all subgroup performance information without delay and provide new subgroups the opportunity to opt-out, during the preview period, of having their performance information publicly reported for their first year. Some subgroups may want to have their performance information publicly reported and having an overall 1-year delay may be a disincentive to subgroup participation. We solicited comments on these considerations. We noted that MIPS performance category and composite final scores for MIPS eligible clinicians participating in MVPs will continue to be publicly reported for those participating in subgroups, as required under section 1848(q)(A)(i)(I) of the Act and finalized at § 414.1395(a)(1)(i), and will not be delayed by 1 year for public reporting.

We also solicited comments on additional factors that we should consider as we look to expand the availability of MVP and subgroup data on the compare tools. For example,

should there be a certain threshold of MVPs available, or clinicians participating in MVPs prior to public reporting? For public reporting of subgroups, are there factors we should consider to make this information usable to the patient but reflective of the subgroups characteristics and composition? Should we test an indicator of MVP participation for compare tool profile pages to see if this is useful information for patients making healthcare decisions? We solicited comments on this proposal and additional ways public reporting may encourage MVP participation.

The following is a summary of the comments we received and our responses.

Comments: Several commenters supported the proposal to delay, by 1 year, the public reporting of new improvement activities and Promoting Interoperability measures attestations reported through MVPs. One commenter requested clarification as to why new Promoting Interoperability measures and attestations would be delayed only for MVP participants. While some commenters supported the delay, they recommended extending the delay beyond 1 year. Two commenters stated a concern that delaying public reporting for MVPs and not traditional MIPS may be confusing for patients. One of the commenters recommended adding a note to profile pages explaining why there may not be performance information. The same commenter also recommended that instead of delaying public reporting for MVPs, CMS should allow MVP participants to opt-out of public reporting for their first year. Another commenter recommended beginning public reporting MVP performance information only once MVP reporting becomes mandatory.

Response: We agree with most commenters that a 1-year delay of new improvement activities and Promoting Interoperability measures and attestations is an appropriate way to incentivize participation in MVPs. We also want to clarify that we proposed this 1-year delay as an incentive because new quality and cost measures already have a delay in public reporting for the first 2 years of use for clinicians in traditional MIPS. This delay is for new improvement activities and Promoting Interoperability measures, objectives, and activities in all MVPs whether they are new or existing MVPs. We appreciate the recommendations to extend the delay beyond 1 year, to allow MVP participants to opt-out of public reporting in their first year, and to only publicly report performance information reported via MVPs once MVP reporting becomes mandatory. We do believe that a 1-year delay is enough time to allow clinicians to familiarize themselves with MVPs as we do not want to further delay valid performance information that consumers can use to make informed healthcare decisions. It is for this same reason that we do not want to have MVP participants opt-out of public reporting or to delay public reporting of performance information reported via MVPs until MVP reporting becomes mandatory. We also want to clarify that performance information available via MVPs is the same as the performance information available in traditional MIPS and that we are required to publicly report performance information submitted by MIPS eligible clinicians. We do not believe that a delay for MVP participants and not traditional MIPS will be confusing to website users. Under traditional MIPS, we delay public reporting of new quality and cost measures by 2 years, and this has not caused any confusion to date. We also clarify that improvement activities and Promoting Interoperability measures and attestations that are already in traditional MIPS will be available for public reporting without any 1-year delay.

After consideration of public comments, we are finalizing this policy as proposed.

Comment: Several commenters supported the one time, 1-year delay of subgroup public reporting, such that subgroup public reporting will begin with the availability of CY 2024 performance period/2026 MIPS payment year performance information. One commenter recommended extending the delay to 3 years.

Response: We agree that a one-time 1-year delay is enough time for participants to familiarize themselves with this subgroup-level reporting. We also clarify that CY 2023 performance period/2025 MIPS payment year subgroup-level measure, attestation, or activity performance information across all MIPS performance categories would not be available for public reporting. We would begin publicly reporting subgroup-level performance information with CY 2024 performance period/2026 MIPS payment year, which would be available for public reporting in CY 2025. After consideration of the public comments, we are finalizing this policy as proposed.

After consideration of all of the public comments received on MVP and subgroup public reporting, we are finalizing all policies in this section as proposed. We did not receive any public comments on the proposal to create a separate subgroup workflow, and therefore, are finalizing it as proposed.

(2) Publicly Reporting APM Performance Pathway Information

In the CY 2021 Quality Payment Program final rule, we finalized to establish an APM performance pathway (APP) beginning in the 2021 MIPS performance year. This is an optional MIPS reporting and scoring pathway for MIPS eligible clinicians who participate in MIPS APMs. We also note that since APP participants are MIPS eligible clinicians, their MIPS performance category and composite final scores will be publicly reported as required under section 1848(q)(A)(i)(I) of the Act and finalized at § 414.1395(a)(1)(i).

In the CY 2017 Quality Payment Program final rule, we finalized, as technically feasible, to use ACO profile pages as a guide to publicly reporting more APM data (81 FR 77398). Currently, groups who participate in an ACO have an indicator showing their participation, as well as a link to the ACO profile page with available performance information. User testing has shown that website users find the ACO information meaningful and displayed in a user-friendly way. For this reason, we plan to continue this approach for APM performance information, including that which comes in via the APP, as technically feasible. We also solicited comments on alternative ways to publicly report performance information reporting via APPs and additional considerations to publicly reporting this information (86 FR 39467).

We did not receive public comments on alternative ways to publicly report performance information reported via APPs or any additional considerations to publicly reporting this information.

(3) Facility Affiliations

Compare tool profile pages for clinicians currently provide demographic information, including names, addresses, phone numbers, medical specialties, APM affiliations, Medicare assignment status, board certifications, education and residency, gender, and group and hospital affiliations. User testing consistently shows that Medicare patients and caregivers find value in these types of information. For hospital affiliations, website users have consistently noted the importance of understanding up front the relationships clinicians may have with facilities where they perform services when searching for a clinician. Specifically, patients and caregivers have noted during user testing that hospital affiliation is important to them,

since they may be looking for a clinician to perform a procedure at a hospital or want to know the hospitals a clinician could potentially admit them if needed. Linking from the clinician profile page to their affiliated hospital page has provided a seamless experience for patients and caregivers, as they do not need to separately search for clinicians and hospitals; rather, they can navigate to a hospital profile page directly from the clinician's profile page.

With these user testing findings in mind, and because the Compare Tools include information on a number of other types of facilities beyond hospitals, we believe it would benefit patients and caregivers to also be able to navigate from clinician profile pages to profile pages for other types of facilities such as: IRFs; LTCHs; SNFs; IPFs; HHAs; hospices; and dialysis facilities (86 FR 39468).

Expanding the types of clinician-facility affiliations, beyond hospital affiliation, publicly reported would allow us to provide additional information about clinicians with or without any hospital affiliation but who are affiliated with other types of facilities. User testing with patients and caregivers has shown that facility affiliations not only for hospitals but also for IRFs, LTCHs, SNFs, IPFs, HHAs, hospices, and dialysis facilities would be helpful to their healthcare decision-making. Specifically, we proposed adding affiliations to clinician profile pages for each of the following types of facilities, pending the results of user testing, as applicable and technically feasible: IRFs; LTCHs; SNFs; IPFs; HHAs; hospices; and dialysis facilities. User testing will determine how to best display these affiliations on compare tool clinician profile pages. To determine clinician affiliations to these facilities, we would use claims data the same way we do to display the hospital affiliations currently available on clinician profile pages (77 FR 69165). We build the clinician-hospital affiliations based on observing a clinician practicing at a given hospital caring for at least three different Medicare patients on three different dates of service in the preceding 6 months, as documented in Medicare claims. We would use similar criteria for determining additional facility affiliations. Clinicians can email the Quality Payment Program Service Center at *http://www.QPP@cms.hhs.gov* if they believe their facility affiliations are displayed incorrectly. We solicited comments on the proposal to add affiliations to clinician profile pages for each of the following types of facilities and link to the specific facility's page on the compare tool: IRFs; LTCHs; SNFs; IPFs; HHAs; hospices; and dialysis facilities. Further, we also solicited comment on whether there should be a limit on the number of procedures done or conditions treated at a given facility to determine clinician-facility affiliations.

The following is a summary of the comments we received and our responses.

Comments: Several commenters supported adding facility affiliations beyond hospital affiliations to clinician profile pages on the compare tools. Specifically, these commenters supported the addition of affiliations for all facilities proposed, including IRFs, LTCHs, SNFs, IPFs, HHAs, hospices, and dialysis facilities. One commenter also recommended including clinicians' role as SNF medical directors on their profile pages. A few commenters noted concern, with two of these commenters opposing the proposal, related to the threshold for determining facility affiliations and how CMS would handle a clinician with multiple affiliations. These commenters believed that the three different Medicare patients on three different dates of service in the preceding 6 months threshold may be too low for determining facility affiliations. One of the commenters recommended CMS conduct user testing to determine how consumers react when a clinician is affiliated with multiple facilities or with a facility that has poor quality ratings. Another commenter requested clarification on how we plan to obtain and verify facility affiliation and noted concern about location and specialty accuracy.

Response: We agree with commenters that adding affiliations to facilities beyond hospitals, on clinician profile pages, will aid patients in making healthcare decisions. We currently do not have a mechanism or source of data for verifying medical director or other healthcare administrative roles in SNFs or other types of care settings. Rather, if the clinician has filed a claim, it is because that clinician is actively treating patients and furnishing healthcare services, even if they also have an administrative role. We would not have information to report for a medical director or other healthcare administrator unless they have filed a claim. We understand the commenters concern and will explore alternative data sources that are found to be reliable. Regarding the concern about a clinician having multiple affiliations, we have user tested clinician profile pages that display multiple facility affiliations and have found that if a clinician has multiple affiliations, beneficiaries and their caregivers consider it important for them to know when making healthcare decisions. We also want to note that the threshold for determining facility affiliations has been reliable for determining the hospital affiliations that are currently on clinician profile pages, which is why we proposed using this threshold for the additional facility affiliations. We will continue to monitor this process as we expand using our currently methodology to affiliate other settings of care to clinicians. In response to questions regarding how we plan to obtain and verify facility affiliation, we plan to determine additional facility affiliations by using claims data in the same way we determine the hospital affiliations currently on clinician profile pages. This analysis includes reviewing claims for clinicians practicing at a given facility caring for at least three different Medicare patients on three different dates of service in the preceding 6 months, as documented in Medicare claims. Clinicians can email the Quality Payment Program Service Center at *http://www.QPP@cms.hhs.gov* with the correct information if they believe their facility affiliations are displayed incorrectly, as they do today for hospital affiliation. We would then manually edit the affiliation on the website. This manual edit would remain in effect for 6 months only. To ensure a more permanent change, clinicians must update their information in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). For more information, clinicians can visit the Care Compare: Doctors and Clinicians Initiative Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Compare-DAC.* Regarding the accuracy of clinician specialty and location, we note that this information is obtained from the PECOS. We rely on clinicians to ensure that their information in PECOS is up to date to ensure the most accurate information is publicly reported.

After consideration of public comments, we are finalizing this policy as proposed.

(4) Utilization Data Request for Information

Under section 104(e) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), beginning with 2016, the Secretary is required to integrate utilization data information on

Physician Compare.[260] To satisfy section 104(e) of the MACRA, we previously implemented a policy to begin to include utilization data in a downloadable format in late 2017 using the most currently available data, and previously finalized that the specific codes to be included will be determined via data analysis and reported at the eligible clinician level (80 FR 71130). We finalized to continue to include utilization data in the downloadable database (81 FR 77398). This information continues to be available today on *www.data.cms.gov/provider-data.*

To date, we have gathered utilization data for procedures from physician/supplier Medicare Part B non-institutional claims on certain services and procedures and published it in the public use file (PUF) file entitled ''Physician and Other Supplier Data.'' These data are useful to the healthcare industry, healthcare researchers, and other stakeholders who can accurately interpret these data and use them in meaningful analyses. However, this information is presented in a technical way that is not easily accessible or usable by patients, who do not frequently visit *data.cms.gov* or understand medical procedure coding. This information also does not provide detail on the specific conditions clinicians treat, though in select cases it may be inferred by the clinicians and researchers reviewing this information.

Section 10331(b)(3) of the Affordable Care Act requires that for public reporting, to the extent practicable, to include processes to assure that the data made available provides a robust and accurate portrayal of a clinician's performance. In our efforts to continue to provide patients and caregivers with meaningful information to make informed healthcare decisions, we believe utilization data may also have a place on clinician and group profile pages, if presented in a consumer-friendly way. We envision utilization data on patient-facing profile pages providing two main areas of benefit. The first is allowing for more granular clinician searches, so that patients not only find specific types of clinicians but also those clinicians experienced in performing specific types of procedures and/or treating specific conditions. The second is providing categories of utilization data in a more plain language display that is usable to patients and their caregivers. In summary, utilization data could provide information to Medicare patients and their caregivers on the specific diagnoses clinicians treat and the frequency with which certain services or procedures are performed by a clinician or group and/or which types of clinicians do not provide certain services.

For example, someone with severe arthritis of the knee may want to search for an orthopedic surgeon who specifically does knee replacements. The way the clinician search works currently would only show results for ''orthopedic surgeons'' generally. That is, the patient would not see which of these clinicians specialize in this procedure, and likely would need to spend time calling clinicians to ascertain more detail. This could similarly be the case for finding a clinician who focuses on treatment of a certain condition. We believe indicating which clinicians focus on certain procedures or conditions would relieve some of this patient burden, as it would yield more specific search results. There are a number of factors that could influence how procedure- and condition-specific information is determined, which is why we solicited comments on this topic in several areas.

For display purposes, we may wish to apply a minimum experience level, such as the number of times a clinician performed a procedure or treated a condition, before a clinician profile is annotated to indicate experience with the condition or procedure. Regarding the methods in which we would identify clinician volume of procedures conducted or treat specific conditions, we would need to set a threshold for making these assertions. We have considered several options. The threshold could be based on the number of times a clinician has performed a procedure or treated a condition within a certain time-period, or the proportion of the clinician's practice that is represented by the procedure or condition. Alternatively, thresholds may be devised based on ranking clinicians compared to their peers (specialty and geography may be considered when defining peers) in volume of procedures performed or frequency with which they treat each condition.

We note also that these approaches utilize Medicare claims data only. That is, these data would not include procedures performed or conditions treated for patients who have other types of insurance, since this information is not available. We also acknowledge that this utilization data only represents the care provided to Medicare beneficiaries and clinicians offer care to those with other forms of insurance. This disclaimer could be added to any data that may be publicly reported. We solicited comments on these approaches and whether there are any additional ones we should consider.

Additionally, because the Compare Tools utilize a location-based search, national or local thresholds may be appropriate. For example, clinicians in urban centers may specialize in a small number of procedures that they perform on a weekly basis, while a clinician in a rural area might be the most experienced at a given procedure, but not have comparable volume to the urban clinician who practices a very narrow scope. We solicited comments on these considerations, as well as if there are others.

We also solicited comments on the potential types of utilization data that, if publicly reported, could help Medicare patients and their caregivers make informed healthcare decisions, as well as on technical considerations for presenting a specific affiliation between clinicians and diagnoses and/or procedures. Specifically, we solicited comments on:

- The types of conditions and procedures that would most benefit patients' clinician searches;
- Important features and considerations for clinician searches by conditions or procedures;
- The lookback period for Medicare claims in order to identify a clinician's volume of procedures balancing frequency with recent experience (for example, 6 months, 1 year, 2 years);
- Clinician specialties or conditions with special considerations (for example, non-patient facing clinicians);
- The maximum number of conditions treated or procedures performed to display on a given clinicians profile page; and
- Methods to set a threshold of treatment volume to display that a clinician commonly performs a procedure or treats a condition. For example, the threshold could be: (1) The number of times a clinician treated a condition or performed a procedure; (2) the total scope that a condition or treatment represents in a clinician's practice; or (3) the clinician's rank—either overall among all clinicians or among a subset of clinicians—in the number of times that clinician treated a condition or performed a procedure.
- Any other factors or considerations not listed above.

We received public comments on considerations for publicly reporting utilization data. We thank the commenters' feedback and will take these comments into consideration in future years.

[260] Physician Compare is defined at § 414.1305 as Physician Compare internet website of CMS (or a successor website).

4. Overview of the APM Incentive

(a) Overview

Under the Quality Payment Program, eligible clinicians who are Qualifying APM Participants (QPs) for a year are eligible to receive an APM Incentive Payment in the corresponding payment year for payment years 2019 through 2024. In the CY 2017 Quality Payment Program final rule (81 FR 77480 through 77489), we finalized at § 414.1450(d) that this payment is made based on the clinician's QP status in the QP Performance Period that is 2 years prior (for example, the 2021 payment will correspond to the 2019 performance year), and at § 414.1450(b)(1) that the payment is equal to 5 percent of the estimated aggregate payments for covered professional services in the base period (the year between the QP performance and payment years).

We also finalized at § 414.1450(c)(1) (82 FR 31729) that the APM Incentive Payment will go to the TIN associated with the Advanced APM Entity through which an eligible clinician becomes a QP during the QP Performance Period. In 2019, our first year of making APM Incentive Payments, we learned that the amount of time between the QP Performance Period (during which QP status is attained) and the QP payment year (during which APM Incentive Payments are issued) creates challenges to disbursing the payment for some QPs in a routine and efficient manner, for example for QPs who may have changed practices in the interim. Consistent with section 1833(z) of the Act, QP status is determined for, and connected to, an eligible clinician (identified by their NPI) for the QP payment year based on their Advanced APM participation during the QP Performance Period. In the proposed rule, we stated that we do not believe that changes in a QP's practice or TIN in the interim year between the QP determination and the QP payment year should affect a QP's ability to receive the APM Incentive Payment. To address some of the unanticipated challenges we encountered in disbursing the APM Incentive Payments, in the CY 2021 PFS final rule, we finalized a hierarchy, codified at § 414.1450, that, based on our experience and lessons learned in making payments in 2019, provides more ways to identify an appropriate TIN to which we can make the APM Incentive Payment when a QP has experienced changes in their practice or TIN since the performance year in which they attained QP status.

(c) APM Incentive Payment Recipient

In the 2021 PFS final rule (85 FR 84472), we revised our approach to identifying the TIN or TINs to which we make the APM Incentive Payment and established a process that enables QPs to provide CMS with updated enrollment information that could be used to complete the payment in the event our approach does not yield an appropriate TIN or TINs to which to send their APM Incentive Payments. The process for those QPs to update their information, as well as a preliminary list of NPIs to whom it may be applicable, is included in a public notice published annually in the **Federal Register**. We explained in the CY 2021 PFS final rule that the revised approach would involve looking at a QP's relationship with TINs at different, specified periods in time, as well as considering the relationships such TINs have with certain APM Entities and Advanced APMs. We stated that we believe this revised approach enables us to more appropriately identify TINs with which QPs currently have relationships to receive other Medicare payments, and through which the QPs likely would anticipate receiving their APM Incentive Payments. We noted that, when the QP is no longer affiliated with the TIN through which they achieved QP status, this approach will prioritize identifying an alternate TIN with which the QP is affiliated at the time the APM Incentive Payment is made, and to which it is appropriate to make the payment. The approach we adopted also serves to reduce uncertainty for QPs as they anticipate the APM Incentive Payments, as well as potential delays in our ability to make their payments.

To improve and expand the ways we identify the TIN(s) to which we make the APM Incentive Payment for a QP in a timely and efficient manner, we finalized a policy to sequentially apply a decision hierarchy and codified the hierarchy in § 414.1450(c). We apply the hierarchy by beginning at the first step, and if we are unable to identify one or more TINs with which the QP has a current affiliation at this step, we move to the next and successive steps of the hierarchy until we do identify one or more TINs with which the QP is affiliated.

As discussed in the CY 2021 PFS final rule, if we identify more than one TIN at the applicable step in the hierarchy, we divide the APM Incentive Payment proportionally between the QP's TINs based on the relative paid amount for Part B covered professional services that are billed through each of the TINs. We proposed to clarify that, when we divide the APM Incentive Payment between two or more TINs, we apportion the APM Incentive Payment among TINs based on the share of total payments for covered professional services made to each TIN in the same base year that we use to calculate the APM Incentive Payment for the year. To calculate the APM Incentive Payment, we sum the total estimated aggregate payments for covered professional services for a QP for the base year, which is based on claims submitted for covered professional services, as codified at § 414.1450(b)(1) through (3). We proposed to codify this policy at § 414.1450(c).

In the course of making APM Incentive Payments during CY 2020 PFS final rule, we explored the possibility of expanding our search at each step of the hierarchy at § 414.450(c) to identify potential payee TINs that are associated with the QP during the QP payment year. Based on our findings, we stated we believe expanding our search in this way would enable us to make payments earlier in the calendar year and reduce the number of QP NPIs for whom we cannot identify a payee TIN using our hierarchy, and thus, rely on our public notice to request additional information. Therefore, we proposed to revise the hierarchy at § 414.1450(c) so that, using the criterion described in each step of our current regulation, we would first seek to identify a TIN associated with the QP during the base year, and if no such TIN is identified in the base year, we would then seek to identify a TIN associated with the QP during the payment year. We have found in many instances that there are changes in enrollment information in PECOS for a QP over the span of 2 years between the QP performance period and payment year. By using enrollment information for the QP during the payment year, we are more likely to identify an appropriate TIN to which to make the APM Incentive Payment hierarchy. Under the proposal, applying the steps in the APM Incentive Payment hierarchy, we would make the APM Incentive Payment to one or more solvent TINs associated with the QP, identified by paid Medicare Part B claims for covered professional services and associated PECOS enrollment information during the base period; and if no such TIN is identified, we will make the payment to such TINs associated with the QP during the payment year. We proposed to codify this policy in the regulation at § 414.1450(c).

If no such TIN or TINs can be identified at a particular step, we will

move to the next and successive steps listed in § 414.1450(c)(1) through (8) until we identify one or more solvent TINs with which the QP is associated, and then would make the APM Incentive Payment to any such TIN(s). If more than one TIN is identified at a step based on paid claims during the applicable year either the base year or payment year, as we explain earlier and proposed to codify in the regulation under § 414.1450(c), would divide the APM Incentive Payment proportionately among such TINs according to the relative total paid amounts for Part B covered professional services to each TIN in same the base year we use to calculate the APM Incentive Payment.

We proposed, for each step in the APM Incentive Payment decision hierarchy, we would first search for a payment TIN or TINs associated with the QP during the base period. If no such TIN is found during the base year, we would search for any TIN or TINs that are similarly situated with respect to the criterion at that step in the hierarchy and associated with the QP during the payment year. If such a TIN or TINs are found, we would make the APM Incentive Payment to such TIN or TINs. We will continue at each step in the hierarchy to first attempt to identify the relevant base year TIN or TINs associated with the QP because, as noted in the proposed rule, we believe such TINs are more likely to be associated with the APM Entity through which the QP attained their QP status during the QP performance period. However, if no such TIN is found in the base year, we would proceed at that step to search for a TIN or TINs with which the QP is associated in the payment year.

We explained that we believe this approach creates the greatest opportunity to identify and pay an appropriate TIN as efficiently and early as possible during the payment year. The proposed change would maintain the current hierarchy while adding a sub-step at each level in which we would conduct our search based on more current enrollment information. The proposed change would allow for the identification of an appropriate TIN or TINs at each step by first checking the base year, and then checking the payment year before moving on to the next step in the process. We stated we believe that by maintaining the current hierarchy we would continue to incent Advanced APM participation by prioritizing making payments to TINs affiliated with Advanced APMs, even if they are not in the same Advanced APM Entity through which QP status originally was achieved. For example, we stated that we anticipate that many eligible clinicians who earned QP status in 2020 through a practice participating in the CPC+ model will join the new Primary Care First (PCF) model in 2022.

In the event the eligible clinician's CPC+ participant TIN is no longer active, our proposed modification to the hierarchy would enable us to pay the APM Incentive Payment to a TIN participating in the PCF model in 2022. We stated that we continue to believe it would be appropriate to first identify the relevant base year TIN or TINs at each step in of the hierarchy because we believe those TINs are more likely to be associated with the APM Entity through which the QP attained their QP status during the QPs performance period. However, if no TIN is found in the base year, we would proceed to identify any TINs associated with the QP in the payment year, and then use the same process for the subsequent steps in the hierarchy until we identify one or more TINs associated with the QP at a particular step for a particular year (base year or payment year). We explained that we believe this approach will be a more efficient and expeditious way to identify a TIN or TINs to which to make the APM Incentive Payment for QPs.

We solicited comments on this proposal to amend our APM Incentive Payment decision hierarchy to include an additional attempt to identify and pay, at each step, one or more solvent TINs associated with the QP during the payment year when no such TIN is identified for the QP in the base year.

We received several comments on this proposal.

Comment: We received many public comments in support of this approach to identifying payee TINs during the payment year.

Response: We thank commenters for their support of this policy.

Comment: We received two public comments advocating that the APM Incentive Payment should be paid directly to the ACO or APM Entity.

Response: We disagree with this comment for several reasons. First, the APM Incentive Payment is not earned by the APM Entity in the way a shared savings payment may be earned by the ACO under the Shared Savings Program. Although QP determinations are in some cases are made at the APM Entity group level, QP status is conferred on an individual eligible clinician. As a result, the individual QP is excluded from the MIPS reporting and payment adjustment requirements, and it is the QP who earns the APM incentive payment. Therefore, the payment is disbursed for the eligible clinician who is a QP to a TIN that is affiliated with the QP, even in instances where the QP is no longer affiliated with the APM Entity. The payment is designed as an incentive in lieu of the pursuance of a MIPS payment adjustment. CMS makes the APM Incentive Payment to one or more TINs to which the QP has reassigned their billing rights. Thus, the QP and TIN may resolve between themselves the handling of the APM Incentive Payment. Some APM Entities are the same as the Medicare enrolled TIN to which QPs have reassigned their Medicare payment rights, and to which we would make the APM Incentive Payment. Other APM Entities, such as ACOs, are not. For these reasons, we do not make the APM Incentive Payment directly to an ACO, and we do not believe it would be appropriate to do so.

Comment: One commenter suggested that we should allow QPs to individually identify their preferred payee TIN to receive the APM Incentive Payment.

Response: It would not be practically feasible for every QP to individually identify a recipient TIN for the QP incentive payment. Our experience working with PECOS and other voluntary systems, including our annual public notice, indicate that requiring individual eligible clinicians to elect a recipient TIN for the incentive payment could cause significant delays in completing the payments. These delays would be of such duration that CMS would likely miss the statutory deadline of December 31 of the payment year in which we are required to have completed these payments. Further, some QPs might never complete the prerequisite step, which would make it difficult if not impossible to disburse APM Incentive Payments for them. Moreover, eligible clinicians are not without an opportunity to indicate to CMS the TINs with which they have current billing arrangements. In fact, all Medicare enrolled eligible clinicians are required to update their billing information, including reassignments within the PECOS system within a specified timeframe. By ensuring PECOS is updated at all times, eligible clinicians have an opportunity to ensure that if they become QPs for a year, the APM Incentive Payment will be received by a TIN to which they have reassigned their billing rights. We believe it is both appropriate and efficient for clinicians to use the longstanding and required processes that are in place to update their billing information, which enables us to identify one or more appropriate TINs to which to make the APM Incentive Payment. Finally, we have established in regulations a payment decision

hierarchy that specifies how we will identify the TIN or TINs to which we will distribute the APM Incentive Payment. One of the main purposes for establishing this hierarchy and for updating it this year is to provide predictability for eligible clinicians regarding the APM Incentive Payment disbursements.

After consideration of the public comments, we are finalizing our proposed update to the APM Incentive Payment decision hierarchy, and amending our regulation at § 415.1415(c), as proposed.

c. Advanced APMs

1. Qualifying APM Participant Determination

a. General Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy at § 414.1425(b) for Qualifying APM Participant (QP) determinations. For the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any one of such dates is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for the eligible clinicians in an APM entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations at the APM Entity group level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List in more than one APM Entity, but do not to achieve QP status based on any APM Entity level determinations, we make QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM we make QP determinations at the individual level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

b. QP Thresholds and Partial QP Thresholds

Section 1833(z)(2)(B) of the Act describes the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019. The All-Payer Combination Option, which uses the Medicare Option, as well as an eligible clinician's participation in Other Payer Advanced APMs, is applicable beginning in the payment year 2021. In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439) we finalized our policy for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Option at § 414.1430(b).

Section 114 of Division CC of the CCA amended section 1833(z)(2)(B) of the Act with regard to payment years 2023 and 2024 (which correspond respectively to performance years 2021 and 2022), by freezing for such years the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, the CAA amended section 1833(z)(2)(B) of the Act to continue the QP payment amount thresholds that apply in payment years 2021 and 2022 to payment years 2023 and 2024. Additionally, the CAA amended section 1833(z)(2)(D) of the Act to require that, for payment years 2023 and 2024, the Secretary use the same percentage criteria for the QP patient count threshold that are applied in payment year 2022. As such, the Medicare Option QP thresholds for payment years 2023 and 2024 (performance years 2021 and 2022) will remain at 50 percent for the payment amount method and 35 percent for the patient count method. The CAA also amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2024 the Partial QP thresholds that are established for payment years 2021 and 2022. Therefore, the Partial QP thresholds for payment years 2023 and 2024 (performance years 2021 and 2022) will remain at 40 percent for the payment amount method and 25 percent for the patient count method. For performance years beginning with 2023 (corresponding to payment years beginning with 2025) the statute prescribes the QP thresholds for the payment amount method, and the QP thresholds we established for the patient count method at § 414.1430 will take effect. Specifically, for performance years beginning with 2023, the Medicare Option QP thresholds will be 75 percent for the payment amount method and 50 percent for the patient count method. The Partial QP thresholds under the Medicare Option will be 50 percent for the payment amount method and 35 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for performance years 2021 and 2022 (corresponding to payment years 2023 and 2024) will be 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for performance years 2021 and 2022 will be 40 percent for the payment amount method and 25 percent for the patient count method. In order to become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain threshold percentages under the Medicare Option. For performance years 2021 and later (corresponding to payment year 2023 and later), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 25 percent for the payment amount method or 20 percent under the patient count method.

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TABLE 75: QP Threshold Score Updates

Medicare Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Payment Amount Threshold	50		50		75	
Partial QP Payment Amount Threshold	40		40		50	
Medicare Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35		35		50	
Partial QP Patient Count Threshold	25		25		35	
All-Payer Combination Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

Although we included proposed amendments to our regulation at § 414.1430(a)(1) and (2) in the CY 2022 PFS proposed rule to reflect the changes made by the CAA to the QP and Partial QP Thresholds under the Medicare Option payment amount method, we inadvertently neglected to discuss those proposed amendments in the preamble. Additionally, we inadvertenly did not include proposed regulation text at § 414.1430(a)(3) or (4) to reflect the amendments made by the CAA to the QP and Partial QP thresholds under the Medicare Option patient count method; or to the regulation text at § 414.1430(b) to reflect amendments to the All Payer Option payment amount and patient count QP and Partial QP thresholds. However, we believe it is preferable to revise the regulation text to consistently and accurately reflect the statutory threshold percentages for each year in accordance with the CAA amendments for both the Medicare Option and All Payer Option and for both the payment amount and patient count methods for each of the options. Therefore, we are finalizing the proposed amendments to § 414.1430(a)(1) and (2) and making amendments to § 414.1430(a)(3) and (4); and § 414.1430(b)(1) through (4) to reflect the applicable statutory threshold percentages as amended by the CAA.

We received four public comments, all in support of the statutory changes to the QP and Partial QP threshold levels. We thank the commenters for their input and will implement the amendments made by the CAA as discussed and revise the regulation at § 414.1430 as proposed.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of OMB's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 76 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 76: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Administrative Support Worker	43-9000	18.41	18.41	36.82
Anesthesiologists	29-1211	130.50	130.50	261.00
Billing and Posting Clerks	43-3021	20.01	20.01	40.02
Bookkeeping, Accounting, and Auditing Clerks	43-3031	21.20	21.20	42.40
Computer System Analysts	15-1211	47.61	47.61	95.22
Family Medicine Physicians	29-1215	103.06	103.06	206.12
General Internal Medicine Physicians	29-1216	101.42	101.42	202.84
Licensed Practical and Licensed Vocational Nurses	29-2061	24.08	24.08	48.16
Medical and Health Services Managers	11-9111	57.12	57.12	114.24
Obstetricians and Gynecologists	29-1218	114.96	114.96	229.92
Office and Administrative Support Workers, All Other	43-9199	18.91	18.91	37.82
Pediatricians, General	29-1221	88.74	88.74	177.48
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1228	105.22	105.22	210.44
Psychiatrists	29-1223	104.38	104.38	208.76
Secretaries and Administrative Assistants	43-6014	19.43	19.43	38.86
Surgeons, Except Ophthalmologists	29-1248	120.99	120.99	241.98

For the CY 2019 and CY 2020 PFS final rules, we used the BLS wage for ''Physicians and Surgeons'' (occupation code 29–1060) to estimate the cost for Physicians. In BLS' most recent set of occupational wage rates (dated May 2020) they have discontinued this occupation in their wage data. As a result, in order to estimate the burden for Physicians, similar to the estimates in the CY 2021 PFS final rule (85 FR 84958), we are using a rate of $217.32/hr which is the average of the following BLS occupations and adjusted wage estimates.

TABLE 77: Physician Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	130.50	130.50	261.00
Family Medicine Physicians	29-1215	103.06	103.06	206.12
General Internal Medicine Physicians	29-1216	101.42	101.42	202.84
Obstetricians and Gynecologists	29-1218	114.96	114.96	229.92
Pediatricians, General	29-1221	88.74	88.74	177.48
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1228	105.22	105.22	210.44
Psychiatrists	29-1223	104.38	104.38	208.76
Surgeons, Except Ophthalmologists	29-1248	120.99	120.99	241.98
Total				1,738.54
Average Wage (1,738.54/8)				217.32

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As indicated, we adjusted BLS' hourly wage estimates by a factor of 100 percent to obtain the adjusted hourly wage estimate. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of

estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802 and 414.806)

The following provisions will be subject to the standard PRA process under OMB control number 0938–0921 (CMS–10110). The standard PRA process includes the publication of 60- and 30-day **Federal Register** notices that will provide the public with opportunities for public review and comment. We expect to publish the 60-day notice shortly after the publication of this final rule.

The new provisions at §§ 414.802 and 414.806 will implement new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section of this final rule, hereinafter is referred to as ''section 401''), which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Specifically, to implement the new reporting requirements for manufacturers without Medicaid drug rebate agreements, we proposed to modify: (1) The definition of drug at § 414.802; and (2) the regulations describing civil money penalties at § 414.806. The new requirements will improve the accuracy of reported payment limits and limit the use of WAC-based pricing.

For the purposes of section 401's new reporting requirements, for manufacturers without Medicaid drug rebate agreements, confidentiality requirements appear in section 1847A(f)(2)(D) of the Act which states that the ASP data are confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs or biologicals by such manufacturer or wholesaler, except—as the Secretary determines to be necessary to carry out section 1847A of the Act (including the determination and implementation of the payment amount), or to carry out section 1847B of the Act; to permit the Comptroller General of the United States to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; to permit the MedPAC to review the information provided; and to permit the Medicaid and CHIP Payment and Access Commission to review the information provided.

For manufacturers with Medicaid drug rebate agreements, confidentiality requirements appear in section 1927(b)(3)(D) of the Act which states that the ASP data are confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—in relevant part, as the Secretary determines to be necessary to carry out section 1847A of the Act (including the determination of the payment amount), or to carry our section 1847B of the Act, to permit the Comptroller General to review the information provided, to permit the Director of the Congressional Budget Office to review the information provided, and to permit the Executive Director of the Medicare Payment Advisory Commission (MedPAC) and the Executive Director of the Medicaid and CHIP Payment and Access Commission to review the information provided.

The burden associated with these requirements is the time and effort required by manufacturers of drugs and biologicals payable under Medicare Part B to prepare and submit the required ASP data to CMS. We have previously estimated the burden associated with ASP reporting requirements for manufacturers with Medicaid drug rebate agreements. Because section 401 extends the ASP reporting requirements to manufacturers without Medicaid drug rebate agreements, we are updating our burden estimates to account for the additional manufacturers who will now be required to report ASP data to us.

As described in section III.D.1. of this final rule, in considering whether to exclude repackagers from the reporting requirements at section 1847A(f)(2) of the Act, we conducted analyses to estimate: (1) The proportion of repackaged products in our existing ASP data; (2) the number of new ASP submissions we can expect as a result of the new reporting requirements under section 401; and (3) the proportion of those (new) submissions that involve repackaged products.

Based on our existing ASP data, 547 manufacturers (respondents) report ASP data to us. Of these, 331 respondents have products for which they are required to submit ASP data, and 216 respondents have products for which they currently submit ASP data voluntarily, but will now be required to do so under section 1847A(f)(2) of the Act. (331 + 216 = 547)

We also estimate that under the new reporting requirements of section 401, a total of 568 respondents have products for which they will now be required to report ASP data to us. The 568 includes the 216 respondents (above) and 361 respondents who have products (identified by us) for which they will now be required to submit ASP data under section 1847A(f)(2) of the Act and did not previously voluntarily submit these data to us. There were 9 respondents who voluntarily submitted ASP data for some, but not all, of their products identified in our analysis. (216 + 361 − 9 overlap = 568)

We estimate a total of 740 respondents will report ASP data to us. This includes the 547 respondents who currently submit ASP data to us (voluntarily, or as currently required), and the 361 respondents who have products (identified by us) for which they will now be required to submit ASP data under section 1847A(f)(2) of the Act and did not previously voluntarily submit these data to us. However, there were 168 respondents who currently are required to submit ASP data to us, or who voluntarily submit ASP data to us, for whom we identified additional products that they did not previously submit ASP data, and will now be required to submit ASP data for these additional products under the new reporting requirements of section 401. (547 + 361 − 168 overlap = 740)

These respondents submit ASP data four times per year for a total of 2,960 submissions (740 respondents × 4 submissions/year).

Based on our experience with ASP data reporting, we continue to estimate that the time associated with reporting, record keeping, and third-party disclosure for ASP data reporting is 13 hours: 10 hours to review instructions and search existing data resources and 3 hours to gather the data, compile the data, submit via electronic media and upload to the automated system. This estimate includes labor costs for respondents to extract data from their information systems and to compile and submit the ASP data, including signature, to CMS via the internet-based automated system and electronic media. This estimate also includes the cost of the compact disc (CD) and overnight mail service used to report the data,

time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

Based on these analyses and assumptions, we estimate an annual burden of 38,480 hours (2,960 submissions/yr × 13 hours per response) at a cost of $1,495,332.80 (38,480 hr × $38.86/hr), rounding to $1,495,333.

TABLE 78: Annual Requirements and Burden for Requiring Certain Manufacturers to Report Drug Pricing Information for Part B

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802, 414.806 (Requiring Certain Manufacturers to Report Drug Pricing Information for Part B)	0938-0921	740	2,960	13	38,480	38.86	1,495,333

We solicited comment on the likely costs or savings manufacturers from this provision.

We did not receive public comments on the analyses or the estimates. We are finalizing the definition of the term ''drug'' at § 414.802 as proposed.

2. ICRs Regarding the Medicare Shared Savings Program (Sections VI.F.8.a. and b.)

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to sections VI.F.8.a. and b. of this final rule for a discussion of the impacts associated with this rule's changes to the Shared Savings Program's quality reporting requirements, quality performance standard, beneficiary assignment methodology, repayment mechanism requirements, requirements for disclosure of prior participation in the Shared Savings Program by the ACO, ACO participants, and ACO providers/suppliers, requirements for ACOs to submit sample ACO participant agreements and executed ACO participant agreements to CMS, and beneficiary notification requirements.

3. ICRs Regarding the Medicare Ground Ambulance Data Collection System (§ 414.626)

Section 1834(l)(17) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, this collection of information section does not set out any burden for the proposed provisions that we are finalizing in this final rule. Please see section VI. of this final rule for a discussion of the estimated impacts.

We received no public comments on the collection of information requirements for the Medicare Ground Ambulance Data Collection System. We are finalizing as proposed.

4. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model (§§ 410.79, 414.84, 424.205, and 424.502)

In section III.L. of this final rule, we finalize policies necessary to shorten the Medicare Diabetes Prevention Program (MDPP) services period to one (1) year on a prospective basis, amend and update the amount of the performance payments for the Core Sessions and Core Maintenance Sessions, and make changes to eliminate the ongoing maintenance phase for MDPP beneficiaries who start MDPP set of services on or after January 1, 2022. In addition, we are finalizing a provision to waive the provider enrollment Medicare application fee for all organizations enrolling in Medicare as MDPP suppliers during the MDPP expanded model on or after January 1, 2022. We expect the finalized policies will increase the number of eligible organizations willing to enroll as MDPP suppliers. We also anticipate that the shortened service period will make MDPP more marketable to beneficiaries in that their time commitment is reduced and less intimidating with a 12-month vs. 24-month service period. We anticipate the shortened MDPP services period will reduce the recordkeeping burden for suppliers. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the provisions. Please see section VI. of this final rule for a discussion of the estimated impacts.

5. ICRs for Prepayment and Post-Payment Definitions, Documentation Request Timeframes, and Payment Denials for Noncompliance With Documentation Requests (§§ 405.902, 405.903, 405.929, and 405.930)

In section III.N.2. of this final rule, we proposed to: (1) Define key terms including ''additional documentation,'' ''additional documentation request,'' ''post-payment medical review,'' and ''prepayment medical review;'' (2) codify contractors' authority to request additional documentation for prepayment and post-payment review within established timeframes; (3) codify timeframes for response to requests for documentation; (4) codify result of a failure to comply with prepayment or post-payment documentation request(s) by a provider or supplier, specifically denial of payment.

The codification of contractor authority to request additional documentation for post-payment reviews, associated timeframes, and resulting denials for failure to comply with these requests is not subject to the PRA per 5 CFR 1320.3(h)(9). The request for additional documentation will be on a case-by-case basis using non-standardized follow-up questions.

With regard to the (1) definitions for ''additional documentation'' and ''additional documentation request,'' ''post-payment medical review,'' and ''prepayment medical review;'' (2) the codification of contractor authority to

request additional documentation for pre-payment reviews; (3) the associated provider and supplier timeframes for providing additional documentation from the pre-payment reviews; and (4) possible denials for failure to comply with these requests, we do not expect that these proposals will affect our information collection burden estimates because these policies do not require providers or suppliers to submit any more documentation to CMS than what is already approved by OMB under control number 0938–0969 (CMS–10417). The regulations simply codify certain requirements by clarifying definitions, timeframes, and results for noncompliance.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

6. ICRs Regarding the Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (§ 423.160(a))

Pending our finalization of the following provisions, the changes will be subject to the standard PRA process under OMB control number 0938–1396 (CMS–10755) to give stakeholders optimal opportunity to comment on our burden for this provision, given how dynamic the burden for EPCS is. The standard PRA process includes the publication of 60- and 30-day **Federal Register** notices that will provide the public with opportunities for public review and comment. We expect to publish the 60-day notice shortly after the publication of the final rule.

The purpose of this provision is to continue to implement section 2003 of the SUPPORT for Patients and Communities Act, which requires that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. We refer readers to the CY 2021 PFS final rule (85 FR 84472) for our previously finalized requirements and burden for the first phase of implementing this statutory mandate, which required prescribers to use the NCPDP SCRIPT 2017071 standard for Electronic Prescription for Controlled Substances (EPCS) prescription transmissions. The purpose of this final rule is to delay the date for CMS to begin taking compliance actions, implement certain exceptions to the mandate, and implement a compliance threshold.

In the CY 2021 PFS final rule, we estimated that the one-time burden to implement this provision would be 828,750 hours (165,750 prescribers * 6 hr) at a cost of $36,418,590 (994,500 hr * $36.62/hr). We arrived at the estimate of 165,750 prescribers having to implement EPCS based on taking the 425,000 Part D prescriber practices, and decreasing that amount by 60 percent to account for the 60 percent of prescriber practices that likely already had EPCS in place by January 1, 2021. Based on our current PDE data, we estimate that 70 percent of Part D prescribers already conduct EPCS,[261] which would leave 30 percent of Part D prescribers that would have to implement EPCS, if we did not propose any exceptions to this mandate. We also proposed that prescribers writing prescriptions for beneficiaries in long term care facilities will have an extension for those prescriptions until January 1, 2025 along with the following exceptions to the EPCS mandate: (1) For prescriptions issued when the prescriber and dispensing pharmacy are the same entity; (2) cases where prescribers issue only a small number of Part D; (3) cases where a prescriber's NCPDP database address is in a geographic service area of an emergency or disaster declared by a Federal, State or local government entity; and (4) cases where a prescriber has received a CMS-approved waiver. These exceptions will result in fewer prescribers being required to conduct EPCS.

Based on our PDE data, we believe that these exceptions will substantially decrease the number of prescribers having to implement EPCS as a result of this regulation. We have listed the exceptions and the estimated number of prescribers falling under each exception in Table 79.[262] We do not anticipate that our proposal to include a compliance threshold of 70 percent will have any material effect on the impact of this provision. The reason for this is that based on our PDE data and conversations with prescribers, we believe that the 30 percent or less of the time that prescribers are not e-prescribing is because they are unable to e-prescribe, so they would have applied for a waiver. Although there are sometimes scenarios where beneficiaries may request that their prescriptions not be transmitted electronically, it appears as though those circumstances are not enough to make a material impact, since beneficiaries often change their views when they are given countervailing reasons that the prescriptions should be transmitted via EPCS.

[261] This information is based on PDE data pulled on April 6, 2021.

[262] This information is based on PDE data pulled on April 6, 2021.

TABLE 79: Number of Affected Prescribers by Exception Type

Exception	Estimated Number of Impacted Prescribers*
Cases where the Practitioner and Dispensing Pharmacy Are the Same Entity	75,927
Prescribers who Prescribe fewer than 100 Part D controlled substance prescriptions per year	470,000
Cases where Prescriber is in a Disaster or Emergency Area	30,964
Cases where Prescriber Applies for a Waiver	100
Individuals in Long Term Care Facilities	5,773
Total Number of Impacted Prescribers	582,764

* This information is based on PDE data pulled on April 6, 2021.

Table 79 gives our estimate of the number of prescribers affected by our exceptions broken down by the type of exception. As shown in Table 79, we estimate that our exceptions will exempt approximately 582,664 prescribers from the EPCS requirement, which consistutes approximately 38 percent of prescribers, since there are an estimated 1,548,221 Part D prescribers [263] (582,664/1,548,221). Since the number of exempted prescribers from this mandate far exceeds the number of prescribers who currently do not e-prescribe controlled substances in Part D, we do not expect that the total number of Part D prescribers who electronically prescribe controlled substances will increase following our implementation of this mandate. As a result, we do not believe there will be a measurable impact to the prescriber community as a whole, once this provision is finalized.

However, for individual prescribers who have to implement this mandate, we expect that the implementation costs will be the same amounts that we finalized in the CY 2021 PFS final rule. Based on the modeling that we have seen, we have found that EHR companies provide the initial set-up of e-prescribing software free of charge, provided the prescribers pay the per transaction cost of $1.88 mentioned in the CY 2021 PFS final rule. Based on the comments received on our CY 2021 PFS proposed rule, we understand that implementing EPCS can lead to technological glitches, and then fixing those issues. We understand that the EHR companies remedy the issues free of charge. However, we also understand that such fixes take time away from the medical office staff. We estimate that such fixes would take the staff approximately 1 extra hour from the estimate given in our CY 2020 PFS proposed rule, when averaged across all prescribers. As a result, we have changed our one-time burden estimate of e-prescribing set-up from 5 hours to 6 hours per provider, which means a total of 994,500 hours (165,750 prescribers * 6 hr) at a cost of $36,617,490 (994,500 hr * $36.82/hr), since we anticipate that this work will be completed by an Administrative Support Worker. In this regard, the impact of this rule is plus 1 hour per response, plus 165,750 hours (165,750 prescribers × 1 hr/response), and $6,102,915 (165,750 hr × $36.82/hr).

We proposed that prescribers have the ability to apply for a waiver from the EPCS requirement, should they be facing circumstances beyond their control that prevent them from e-prescribing, and these circumstances are not the result of a natural disaster or emergency. Due to the high prevalence of EPCS, the miniscule compliance actions that we proposed for non-compliance, and the number of prescribers that we expect to exempt from the mandate, we only expect to receive about 100 attestations per year. Although we proposed certain fields be in this attestation, these were minimal, and there was no accompanying documentation required. (Note, as outlined in section II.Q. of this final rule, to meet the standard for a waiver, prescribers must provide documentation showing the existence of a circumstance beyond their control and that such a circumstance prevents them from conducting EPCS.) We expect that each attestation will take 10 minutes (0.1667 hr) for a prescriber at $217.32/hr to complete. In aggregate, CMS estimates an annual burden for filling out attestations of 16.67 hours (100 attestations × 0.1667 hr) at a cost of $3,622.72 (16.67 hr × $217.32/hr). In addition, we solicit comment on any other potential information collection implications.

We received no comments on our proposed burden estimates and assumptions, and have finalized our provision as proposed. As a result, we are finalizing our burden estimates and assumptions as proposed.

[263] This information is based on PDE data pulled on April 6, 2021.

TABLE 80: Burden for Electronic Prescribing of Controlled Substances Requirement

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan)	0938-1396	100	100	0.1667	16.67 hours	217.324	3,622.72

7. ICRs Regarding Open Payments Provisions Included in the CY 2022 PFS (42 CFR Part 403)

The following requirement and burden changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). The following estimates burden changes to the Open Payments final rule at §§ 403.900 through 403.914 in this final rule.

a. Payment Context Field for Teaching Hospitals

The mandatory context field is a new requirement for reporting entities submitting and attesting to records that are attributed to teaching hospitals only. The field will be freeform text entry. We estimate that for each applicable manufacturer and applicable group purchasing organization (GPO), the inclusion of this field for collection and reporting activities will average an additional 6 total hours. The applicable instrument for these activities in the current PRA package is the ''General-Research-Ownership Submission Data Elements''. At the support staff cost per FTE of $42.40/hr, this will increase costs by $254.40 (6 hr × $42.40/hr) per applicable manufacturer or applicable GPO submitting teaching hospital records. However, because we anticipate fewer disputes due to this field, we believe it will decrease dispute resolution by 2 total hours for support staff at $42.40/hr respectively, reducing costs by $84.80 (2 hr × $42.40/hr) per applicable manufacturer and applicable GPO. This results in a net increase in burden for each applicable manufacturer and applicable GPO submitting teaching hospital records of $169.60 ($254.40 − $84.80). In Program Year (PY) 2019, 794 applicable manufacturers and applicable GPOs submitted at least one teaching hospital record, meaning the increase in burden will be a total of 3,176 hours (4 hours × 794 reporting entities) at a cost of $42./40/hr or a total of $134,662.40 (3,176 × $42.40).

In addition, we estimate this will reduce teaching hospital dispute resolution estimates by 2 hours per support staff FTE at $37.82/hr or $75.64 (2 hr × $37.82/hr) per teaching hospital with records attributed to them. In PY 2019, 1,202 hospitals had record attributed to them, so for teaching hospitals we estimate a total burden reduction of 2,404 hours at a cost of $90,919.28 (2,404 × $75.64).

In aggregate, we estimate an annual burden of 772 hours (3,176 − 2,404) at a cost of $43,743.12 ($134,662.40 − $90,919.28).

b. Optional Annual Recertification

The annual recertification is voluntary for applicable manufacturers or applicable group purchasing organizations. We approximate that 15 percent of applicable manufacturers and group purchasing organizations, or 240 reporting entities (0.15 [1,595 applicable manufacturers and applicable GPOs]) will complete and submit the proposed optional annual recertification. We anticipate that it will be a simple check box form to be included in the AM (Attestation) and GPO (Attestation) Annual IC Requirement and the ''Attestation and Assumptions Screen Shots'' Instrument in the existing PRA package. We estimate that it will take 0.5 hours at $42.40/hr for support staff to complete and submit the recertification. In aggregate, we estimate an added annual burden of 120 hours (240 entities × 0.5 hr/response) at a cost of $5,088 (120 hr × $42.40/hr).

c. Defining a Physician-Owned Distributorship (42 CFR 403.902)

The new definition is not subject to the PRA since it will not revise, add, or remove any collection of information requirements or burden.

d. Disallowing Record Deletion Without Reason (§ 403.904(a)(3))

This provision clarifies that entities are not permitted to delete records without reason once their timeliness, completeness, and accuracy has been attested to. In order to ensure compliance with this requirement, a freeform text dialogue box will be added to the system when records are deleted that asks the applicable manufacturer or GPO to input a reason for the deletion. This will be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the ''Open Payments User Guide'' Instrument in the existing PRA package. We anticipate that this will take an average of 2 hours at $42.40/hr to input a reason for the deletion. In aggregate, we estimate an added annual burden of 80 hours (40 applicable manufacturers or GPOs deleting records annually × 2 hr/response) at a cost of $3,392 (80 hr × $42.40/hr).

e. Disallow Publication Delays of General Payments

A very small number of general payments are delayed from publication by reporting entities every year, and these records will simply either be reported as research records instead, or not delayed at all. Therefore, we anticipate a negligible burden for this provision.

f. Short Term Loans (§ 403.902)

This provision is merely a clarification of an existing requirement in regulation text. The purpose of this language is to clarify that the exemption for short-term loans from reporting requirements only applies for loans of less than 91 cumulative days per calendar year. In other words, multiple short-term loans in a calendar year will still meet reporting requirements if they add up to 91 days or greater. We do not believe this provision will change reporting behavior, and therefore do not anticipate an increase in burden.

g. Remove General Ownership Records

Currently the Open Payments system allows for a reporting entity to submit either a general record with a nature of payment category of ownership, or an ownership and investment interest record. For Program Years 2015–2019, approximately 92 applicable

manufacturers and GPOs reported records with the nature of payment category of ownership. Since reporting these general records as ownership records will require the addition of two additional pieces of information, we anticipate that it will take these 92 entities an additional 3 hours at $42.40/hr to report the two extra fields. In aggregate, we estimate an added annual burden of 276 hours (92 entities × 3 hr/response) at a cost of $11,702 (276 hr × $42.40/hr). This will be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the ''Open Payments User Guide'' Instrument in the existing PRA package.

h. Updated Contact Information (§ 403.908(c)(3))

This provision creates a requirement for reporting entities to keep their contact information up to date with CMS. The ability to communicate with a reporting entity is important because CMS may need to contact the entity in the case of perceived issues with the records. Applicable manufacturers and applicable GPOs will only be required to update their contact information if the two contacts provided become obsolete due to a change in the organization. This will also only apply to entities that do not have records to report for 2 years after a program year in which they reported. Therefore, we anticipate that it will only affect approximately 30 applicable manufacturers and applicable group purchasing organizations. We estimate that it will take 0.5 hours at $42.40/hr to update the contact information. In aggregate, we estimate an added annual burden of 15 hours (30 entities × 0.5 hr/response) at a cost of $636 (15 hr × $42.40/hr). This will be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the ''Open Payments User Guide'' Instrument in the existing PRA package.

i. Summary

TABLE 81: Open Payments Burden Changes

	Total Increase in Burden	Total Decrease in Burden	Total
Teaching Hospital Contact Field	$201,993.60	$158,250.48	$43,743.12
Optional Annual Recertification	$5,088.00	$0.00	$5,088.00
Defining a Physician Owned Distributorship	$0.00	$0.00	$0.00
Disallowing Record Deletion Without Reason	$3,392.00	$0.00	$3,392.00
Disallow Publication Delays of General Payments	$0.00	$0.00	$0.00
Short Term Loans	$0.00	$0.00	$0.00
Remove General Ownership Records	$11,702.00	$0.00	$11,702.00
Updated Contact Information	$636.00	$0.00	$636.00
			$64,561.12

8. The Quality Payment Program (QPP) (42 CFR Part 414 and Section IV. of This Final Rule)

The following QPP-specific ICRs reflect this final rule's policy changes as well as adjustments to the policies that have been finalized in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), the CY 2019, CY 2020, and CY 2021 PFS final rules (83 FR 59452, 84 FR 62568 and 85 FR 84472, respectively).

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

There is a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The MIPS ICRs consist of: Registration for virtual groups (see section V.B.8.b of this final rule); QCDR self-nomination applications and other requirements (see section V.B.8.c.(2) of this final rule); qualified registry self-nomination applications and other requirements (see section V.B.8.c.(3) of this final rule); CAHPS survey vendor applications (see section V.B.8.c.(4) of this final rule); Health IT vendors (see section V.B.8.c.(5) of this final rule); Open Authorization credentialing and token request process (see section V.B.8.d of this final rule); Quality Payment Program Identity Management Application Process (see section V.B.8.e.(3) of this final rule); quality performance category data submission by Medicare Part B claims collection type (see section V.B.8.e.(4) of this final rule), QCDR and MIPS CQM collection type (see section V.B.8.e.(5) of this final rule), eCQM collection type (see section V.B.8.e.(6) of this final rule), MVP Quality submission (see section V.B.8.e.(7)(a)(iii) of this final rule), and CMS Web Interface collection type (see section V.B.8.e.(8) of this final rule); CAHPS for MIPS survey beneficiary participation (see section V.B.8.e.(9) of this final rule); group registration for CMS Web Interface (see section V.B.8.e.(10) of this final rule); group registration for CAHPS for MIPS survey (see section V.B.8.e.(11) of this final rule); MVP registration (see section V.B.8.e.(7)(a)(i) of this final rule); subgroups registration (see section V.B.8.e.(7)(a)(ii) of this final rule); all for quality measures (see section V.B.8.f of this final rule); reweighting applications for Promoting Interoperability and other performance categories (see section V.B.8.g.(2) of this final rule); Promoting Interoperability performance category data submission (see section V.B.8.g.(3) of this final rule); call for Promoting Interoperability measures (see section V.B.8.h of this final rule); improvement activities performance category data submission (see section V.B.8.i of this final rule); nomination of improvement activities (see section V.B.8.j of this final rule); nomination of MVPs (see section

V.B.8.k of this final rule); and opt-out of Physician Compare for voluntary participants (see section V.B.8.o of this final rule).

The ICRs for Advanced APMs consist of: Partial Qualifying APM Participant (QP) election (section V.B.8.m of this final rule); Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes (sections V.B.8.n.(1) and V.B.8.n.(2) of this final rule); and submission of data for QP determinations under the All-Payer Combination Option (section V.B.8.n.(3) of this final rule).

(2) Summary of Quality Payment Program Changes: MIPS

We have included the change in estimated burden for the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years due to the finalized policies and information collections in this final rule. The finalized policies in this rule impact the burden estimates for the CY 2022 and CY 2023 MIPS performance periods/ 2024 and 2025 MIPS payment years. However, our currently approved burden estimates for the CY 2021 performance period (85 FR 84958 through 84998) approved by OMB on May 28, 2021, included estimated burden due to finalized policies and assumptions for the CY 2021 and CY 2022 performance periods/2023 and 2024 MIPS payment years. The currently approved estimated burden for the package does not include the CY 2023 performance period/2025 MIPS payment year. To understand the burden implications of the policies finalized in this final rule relative to the current package that was approved by OMB on May 28, 2021:

- We have subtracted the burden for the policies and information collections set forth for the CY 2021 performance period/2023 MIPS payment year in the CY 2021 PFS final rule (see Table 128).
- We have revised our burden estimates for the CY 2022 performance period/2024 MIPS payment year due to the finalized policies in this rule and changes for continuing the policies and information collections set forth in the CY 2021 PFS final rule into the CY 2022 performance period/2024 MIPS payment year (see Table 129).
- We are setting forth new burden for the CY 2023 performance period/2025 MIPS payment year (see Table 130), meaning that there will be no currently approved figures for these estimates.

In the CY 2022 PFS proposed rule (86 FR 39479 through 39528), we compared our proposed burden estimates for the CY 2022 and 2023 performance periods/ 2024 and 2025 MIPS payment years to the CY 2022 performance period/2024 MIPS payment year in the CY 2021 PFS final rule (85 FR 84994). We believe that using the approach described above for the final rule will help readers easily understand and follow the changes in the estimated burden due to the policies and assumptions in the CY 2022 PFS final rule relative to the currently approved burden.

The following nine MIPS ICRs show changes in burden due to the finalized policies in this rule: (1) QCDR self-nomination applications; (2) Qualified Registry self-nomination applications; (3) Quality performance category data submission by QCDR and MIPS CQM collection type; (4) Quality performance category data submission by eCQM collection type; (5) Group registration for CMS Web Interface; (6) CMS Web Interface submission burden; (7) Reweighting applications for Promoting Interoperability and other performance categories; (8) Promoting Interoperability performance category data submission; and (9) Nomination of improvement activities. In aggregate, we estimate the finalized policies will result in a net increase in burden of 3,805 hours and $358,305 for the CY 2022 performance period/2024 MIPS payment year. The remaining changes to our currently approved burden estimates are adjustments due to the revised burden assumptions based on the updated data available at the time of publication of this final rule.

We have also added 3 new ICRs (MVP Registration, MVP Quality Submissions, and Subgroups Registration) for the associated burden related to the policies for implementation of MVPs and subgroups beginning with the CY 2023 performance period/2025 MIPS payment year. The MVP and subgroup registration ICRs reflect the burden associated with the MVP and subgroup registration requirements described in section IV.A.3.b(4)(f) of this rule. The MVP quality submission ICR reflects the change in burden associated with the requirements for the quality performance category of MVPs described in section IV.A.3.b(4)(d)(ii) of this rule.

With these new ICRs and the other policy changes discussed for the CY 2022 performance period/2024 MIPS payment year, we estimate the finalized policies will result in a net increase in burden of 1,383,049 hours and $139,501,770 for the CY 2023 performance period/2025 MIPS payment year. As discussed above, we are setting forth our estimates for the CY 2023 performance period/2025 MIPS payment year as new burden with no currently approved estimates for comparison.

We are not making any changes or adjustments to the following ICRs: Registration for virtual groups; CAHPS survey vendor applications; Quality Payment Program Identity Management Application Process; group registration for CAHPS for MIPS survey; CAHPS for MIPS survey beneficiary participation; Open Authorization (OAuth) Credentialing and Token Request Process; nomination of MVPs and call for Promoting Interoperability measures. See section V.B.8. of this final rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted by two primary factors. First, we are unable to predict with absolute certainty who will be a QP for the CY 2022 performance period/2024 MIPS payment year. New eligible clinician participants in Advanced APMs who become QPs will be excluded from MIPS reporting requirements and payment adjustments, and as such, are unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians may not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict what Partial QPs, who can elect whether to report to MIPS, will do in the CY 2022 performance period/2024 MIPS payment year compared to the CY 2019 performance period/2021 MIPS payment year, and therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data. Additionally, we will continue to update our estimates annually as data becomes available.

In the 2022 PFS proposed rule (86 FR 39480), we discussed a recent JAMA article (Khullar, et al., 2021) [264] which included new data on the burden involved in submitting data for the Quality Payment Program. We have chosen not to include this data in our estimates because of the small sample size included (30 TINs, half of which are APM participants, which we do not include in our estimates). In addition, the article did not indicate the time

[264] JAMA Health Forum. 2021;2(5):e210527. doi:10.10001/jamahealthforum.2021.527.

spent per activity involved in submissions for MIPS, so we are unable to determine if the totals in the article represent only the activities relevant for regulatory burden or separate the totals for the individual ICRs. We solicited comment on our assumptions for estimating the burden for clinicians submitting data for the Quality Payment Program.

We did not receive public comments regarding our burden estimates for clinicians submitting data in the Quality Payment Program. We are finalizing to not include the data from the above referenced article in our assumptions.

We made updates to our figures to correct a few technical errors that we observed in the CY 2022 PFS proposed rule.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), the changes to currently approved burden estimates are adjustments based on updated projections for the CY 2022 performance period/2024 MIPS payment year. We did not implement any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process and submission of Data for QP determinations under the All-Payer Combination Option ICRs.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 82 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 82, MIPS eligible clinicians and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. We want to note that we have included subgroups to Table 82 due to the introduction of subgroups for clinicians choosing to report MVPs or the APP in the CY 2023 performance period/2025 MIPS payment year described in section IV.A.3.b.(2)(d)(ii) of this final rule. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 82.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. As discussed in section IV.A.3.c. of this final rule, for clinicians in APM Entities, the APM Performance Pathway is available for both ACO and non-ACOs to submit quality data. Due to data limitations and our inability to determine who will use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2022 performance period/ 2024 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. We also want to note that as finalized in section IV.A.3.d.(1)(d) of this final rule, we are finalizing to extend the CMS Web Interface as a collection type beyond the CY 2022 performance period/2024 MIPS payment year for clinicians participating in the Shared Savings Program. Per section 1899 of the Act (42 U.S.C. 1395jjj), submissions received from eligible clinicians in ACOs are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 PFS final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the improvement activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 PFS final rule (82 FR 53841 through 53844).

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TABLE 82: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures (CMS Web Interface will be available to only clinicians in ACOs after the CY 2022 performance period/2024 MIPS payment year.)	As virtual group, group, subgroup, individual clinicians, or APM Entity.[a]	As virtual group, group, subgroup, individual clinicians, or APM Entity. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting].[b]	As virtual group, group, subgroup, or individual clinicians. MIPS APMs do not submit information. CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. MVP participants electing to submit data for the measures and activities in an MVP must register. MIPS APMs electing the APM Performance Pathway. **(CMS Web Interface will be available to only clinicians in ACOs after the CY 2022 performance period/2024 MIPS payment year.)** APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email.[d]

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Submissions by the ACO are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. Section 1899 of the Act (42 U.S.C. 1395jjj) states that the Shared Savings Program is not subject to the PRA.

[b] Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[c] The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

[d] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019, CY 2020, and CY 2021 PFS final rules, and continued in this final rule create some additional data collection requirements not listed in Table 82. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs Related to MIPS Third-Party Intermediaries (See Section V.B.8.c)

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and

83 FR 59998 through 60000) (OMB 0938–1314).

- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (New) (OMB 0938–1314) (see section V.B.8.d).

Additional ICRs Related to the Data Submission and the Quality Performance Category (See Section V.B.8.e)

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs Related to the Promoting Interoperability Performance Category (See Section V.B.8.g)

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs Related to Call for New MIPS Measures and Activities (See Sections V.B.8.f, V.B.8.h, V.B.8.j. and V.B.8.k)

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (OMB 0938–1314).

Additional ICRs Related to MIPS (See Section V.B.8.o)

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs Related to APMs (See Sections V.B.8.m and V.B.8.n)

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule is not implementing any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any changes to the virtual group election process under that control number.

c. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

The finalized requirements and burden associated with this rule's data submission changes related to qualified registries and QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section IV.A.3.h. of this rule, we are finalizing policies related to the third-party intermediary regulations at § 414.1400. Specifically, we are finalizing: (1) Requirement for third-party intermediaries to submit MIPS data for APM Entities; (2) requirement for QCDRs and qualified registries to support MVPs, QCDRs and qualified registries may also support the APP; (3) requirement for all QCDRs and qualified registries to support subgroup reporting; (4) requirements for approved QCDRs and qualified registries that have not submitted performance data; and (5) new QCDR measure rejection criteria. The burden associated with each of these topics is discussed separately below for qualified registries, QCDRs, and survey vendors.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nomination process annually.[265] The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

As described below, in this rule we are adjusting the number of self-nomination applications based on current data (from 82 to 84), change the number of QCDR measures submitted for consideration by each QCDR at the time of self-nomination (from 2 to 12), and adjust the average time required to submit information for each QCDR measure (from 2.5 hours to 0.75 hours).

(a) Self-Nomination Process and Other Requirements

In section IV.A.3.h.(1) of this rule, we are reorganizing and consolidating § 414.1400 generally. We assume that this provision does not change the existing requirements for third-party intermediaries during the self-nomination process. Therefore, we are not revising our burden estimates related to these provisions. We refer readers to § 414.1400 which states that QCDRs interested in submitting MIPS data to us on behalf of a MIPS eligible clinician, group, or virtual group will need to complete a self-nomination process to be considered for approval to do so. We also refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59998 through 60000), the CY 2020 PFS final rule (84 FR 63116 through 63121) and the CY 2021 PFS final rule (85 FR 84964 through 84969) for our previously finalized requirements and burden for self-nomination of QCDRs and nomination of QCDR measures.

In section IV.A.3.h.(2)(a) of this rule, we are finalizing to add APM Entities to § 414.1400(a)(1), and expand the general participation requirements of third-party intermediaries, to third-party intermediaries reporting to MIPS on behalf of APM Entities reporting to MIPS in order to align reporting requirements for all participants in

[265] As stated in the CY 2019 PFS final rule (83 FR 59998), health IT vendors are not included in the burden estimates for MIPS.

MIPS. We are also finalizing that beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support the APP, and MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. As finalized in the CY 2017 PFS final rule, third-party intermediaries currently support MIPS data submission on behalf of eligible clinicians (81 FR 77016). APM Entities have historically used third party intermediaries for submitting their quality measures to their APMs. Additionally, QCDRs, qualified registries and health IT vendors are required under existing § 414.1400(a)(1) to submit data for the quality, improvement activities, and Promoting Interoperability performance categories in MIPS. Therefore, we anticipate no additional steps being added to the self-nomination process as a result of this provision for third-party intermediaries to submit MIPS data on behalf of APM Entities, and to support measures and activities in MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. For this final rule, we assume that there will be no impact on the time required for QCDRs to complete either the simplified or full self-nomination process because of the above provisions. Additionally, we are finalizing to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 performance period/2025 MIPS payment year. We anticipate that at the time of self-nomination, QCDRs would be using a checkbox to indicate their compliance for the requirement to support data submission for subgroups beginning with the CY 2023 performance period/2025 MIPS payment year. We assume that this will not impact the overall time estimated for QCDRs to submit their information at the time of self-nomination. Therefore, as discussed in the CY 2022 PFS proposed rule (86 FR 84965) we did not make any adjustments in the time required for QCDRs during the simplified or full self-nomination process because of this provision. However, we anticipate that third-party intermediaries will need to make administrative changes to their existing workflows for submission of MVPs and APP data for clinicians participating as subgroups beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to section VI.F.18.g(2)(f) of this final rule where we discuss our impact analysis.

In section IV.A.3.h.(3)(a)(iii) of this rule, to provide further clarity and to better align with the existing policy (81 FR 77366 through 77367; 81 FR 77383 through 77384), we are finalizing to codify that QCDRs, and qualified registries must conduct validation on the data they intend to submit for the applicable MIPS performance period and provide the results of the executed data validation plan by May 31st of the year following the performance period. Additionally, we are finalizing to codify a new requirement at § 414.1400(b)(3)(iv) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the agency. We anticipate that this provision does not make any changes to the existing data validation requirements for QCDRs and qualified registries. Through this provision, we are codifying the finalized policies related to data validation for QCDRs and qualified registries in previous rules. In the CY 2022 PFS proposed rule (86 FR 39483), we did not revise our burden estimates as a result of the above provision because the associated burden was captured in the CY 2017 PFS final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section IV.A.3.h(3)(a)(i) of this final rule, we are finalizing new requirements for approved QCDRs and qualified registries that have not submitted performance data. First, we are finalizing to create a new requirement at § 414.1400(b)(3)(vii) to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 performance period/2019 MIPS payment year) through the CY 2020 performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023. If the QCDRs and qualified registries did not submit data, their participation plan must be submitted as part of self-nomination for the 2023 self-nomination period and must be accepted by CMS to continue to be an approved QCDR or qualified registry. We are also finalizing to codify a new requirement at paragraph § 414.1400(b)(3)(viii) to state that, beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. Under this provision, the participation plan must explain the QCDR and/or qualified registry's detailed plans about how the vendor intends to encourage clinicians to submit MIPS data to CMS through the third-party intermediary on behalf of clinicians or groups. The vendor must also explain why they should still be allowed to participate as a qualified vendor.

Based on our review of the existing list of approved QCDRs that did not submit performance data since the inception of MIPS (CY 2017 performance period/2019 MIPS payment year), we estimate that approximately 10 QCDRs will submit participation plans for the CY 2022 and the CY 2023 self-nomination periods. Similar to our assumptions for submission of a Corrective Action Plan (CAP) in the CY 2021 PFS final rule (85 FR 84968), we anticipate that the effort involved in developing a participation plan including the policies specified in this rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $95.22/hr. For the CY 2022 performance period/2024 MIPS payment year, we estimate an annual burden of 30 hours (3 hr × 10 participation plans) at a cost of $2,857 (30 hr × $95.22/hr) for QCDRs that will need to develop and submit a participation plan.

In section IV.A.3.h.(4) of this rule, we are finalizing to codify new requirements that if a QCDR measure owner is not an approved active QCDR for a given self-nomination period, that QCDR measure will not be available for use. Additionally, we are finalizing to codify a new requirement in section IV.A.3.h.(4)(a)(i)(A) of this rule and add a rejection criterion at § 414.1400(b)(4)(iv)(M) to state, a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. It was finalized in the CY 2018 PFS final rule (82 FR 53813) that beginning with the CY 2018 performance period/2020 MIPS payment year, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. Additionally, in the CY 2020 PFS final rule (84 FR 63070 through 63073), we finalized the QCDR measure rejection criteria considerations. Specifically, we stated that all previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review

process that occurs after the self-nomination period closes on September 1st) to determine whether they are appropriate for the program. In the CY 2020 PFS final rule, we indicated to stakeholders that as information becomes available in future years, we will revisit our assumptions to better reflect the impact of these requirements on QCDRs and the quantity of measures annually (84 FR 63118 through 63119). As discussed in the CY 2019 PFS final rule (83 FR 60000) and CY 2020 PFS final rule (84 FR 63118), we are not accounting for QCDR measure licensing costs as part of our burden estimate.

Based on the number of QCDR measures submitted at the time of self-nomination for the CY 2021 performance period/2023 MIPS payment year, we assume that 82 QCDRs will submit 984 measures for consideration in the CY 2022 performance period/2024 MIPS payment year, approximately 12 measures per QCDR, on average. We anticipate that out of the 984 measures, 820 measures will be existing or borrowed measures, approximately 10 measures submitted per QCDR self-nomination application. The remaining 104 measures will be new measures, approximately 2 measures on average per QCDR.

Using the above assumption that each QCDR submitting measures for approval during the self-nomination process will submit approximately 12 measures (10 existing or borrowed measures + 2 new measures), we estimate an increase of 10 measures from the currently approved estimate of 2 measures per QCDR. The estimated increase in the total number of measures submitted by a QCDR at the time of self-nomination is due to the inclusion of the existing or borrowed QCDR measures in our assumptions. Additionally, we anticipate that less information is needed for a QCDR to submit an existing or borrowed measure for approval, therefore, we estimate that the time needed for a QCDR to submit an existing or borrowed measure is 0.5 hours, independent of the selection of the simplified or full self-nomination process. Consistent with our assumption in the CY 2020 PFS final rule (84 FR 63119), we continue to estimate that each QCDR will require 2 hours to submit a new QCDR measures for approval, independent of the selection of the simplified or full self-nomination process. To account for the difference in the time for submission of new vs existing QCDR measures for approval, we are using the weighted average to estimate the time required for QCDR measure submission at the time of self-nomination. Therefore, we assume that the weighted average of the time required for each QCDR to submit a new or existing or borrowed measure for approval during the self-nomination process is 0.75 hours [((2 new measures × 2 hours) + (10 existing or borrowed measures × 0.5 hours))/total # of measures (12)]. Based on the above assumptions, we are finalizing to revise our estimates in the amount of time required for a QCDR to submit measures during the self-nomination process from a total of 2 hours to approximately 0.75 hours, a decrease of 1.75 hours from the currently approved estimated burden per QCDR measure submission.

In the CY 2019 PFS final rule, we estimated that it would take 0.5 hours and 3 hours for a QCDR to submit all the required information during the simplified and full self-nomination process, respectively (83 FR 59999). Based on our experience with the amount of time needed for QCDRs during the 2020 self-nomination period, we assume that the estimated time of 3 hours per QCDR for a full self-nomination process is an overestimate and therefore, are adjusting our estimated time required for the QCDR full-self-nomination process to 2.5 hours, a decrease of 0.5 hours. We are not making any adjustments in the amount of time needed for simplified self-nomination process.

For this final rule, we are adjusting the number of QCDRs that submitted applications for self-nomination from 90 to 84 based on the actual number of applications received during the CY 2021 self-nomination period for the CY 2022 performance period/2024 MIPS payment year, an increase of two applications from the currently approved estimate of 82. This is a decrease of 6 from the estimate of 90 provided in the CY 2022 PFS proposed rule (86 FR 39484). For QCDRs that submit measures as part of their self-nomination process, while simultaneously accounting for the estimated increase in the number of existing or borrowed QCDR measures submitted with the self-nomination application and the decrease in the estimated time for the QCDR full-nomination process, we are finalizing to revise our estimated time for the QCDR self-nomination process to a minimum of 9.5 hours [0.5 hours for the simplified self-nomination process + (12 measures × 0.75 hr/measure for QCDR measure submission)] and a maximum of 11.5 hours [2.5 hours for the full self-nomination process + (12 measures × 0.75 hr/measure for QCDR measure submission)], an increase of 4 hours at a cost of $ 380.88 (4 hr × $95.22/hr) and 3.5 hours at a cost of $333.27 (3.5 hr × $95.22/hr) from the currently approved burden per respondent estimate in the CY 2021 PFS final rule (85 FR 84965).

Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84967), based on updated data for the number of QCDR applications submitted during the CY 2020 self-nomination period, we are adjusting our estimate that 18 QCDRs will submit targeted audits for the CY 2022 performance period/2024 MIPS payment year, an increase of 1 from the currently approved estimate of 17 targeted audits in the CY 2021 PFS final rule (85 FR 84965). This is a decrease of 2 compared to our estimate of 20 targeted audits in the CY 2022 PFS proposed rule (86 FR 39484). Using the currently approved unchanged burden per respondent estimate, the estimated burden associated with QCDRs completing targeted audits will range from 90 hours (18 audits × 5 hr/audit) at a cost of $8,570 (18 audits × $476.10/audit) for the simplified self-nomination process to 180 hours (18 audits × 10 hr/audit) at a cost of $17,140 (18 audits × $952.20/audit) for the full self-nomination process (see Table 68 for the cost per audit). We assume that this would adjust our burden estimates for targeted audits by +5 hours (+1 respondents × 5 hr/audit) at a cost of $476 (5 hrs × $95.22/hr) and +10 hours (+1 respondents × 10 hr/audit) at a cost of $952 (10 hrs × $95.22/hr) for the simplified and full self-nomination process, respectively. Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on behalf of MIPS eligible clinicians.

As shown in Table 83, we assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $95.22/hr. Using the change in the number of respondents and the estimated time per respondent for QCDRs that submit measures for approval during the self-nomination process, the annual burden for the simplified and full-self nomination process will range from 798 hours (84 QCDRs × 9.5 hr) to 966 hours (84 QCDRs × 11.5 hr) at a cost ranging from $75,986 (798 hr × $95.22/hr) and $91,983 (966 hr × $95.22/hr), respectively.

As shown in Table 83, combined with our adjusted estimate of annual burden for targeted audits and the burden for submission of participation plans, we are finalizing to revise our estimated

burden for the QCDR self-nomination process, ranging from 918 hours [798 hr (84 QCDRs × 9.5 hr) + 90 hr (18 audits × 5 hr) + 30 hr (10 participation plans × 3 hr)] at a cost of $87,413 [$75,986 (798 hr × $95.22/hr) + $8,570 (18 audits × $476.10/audit) + $2,857 (30 hr × $95.22/hr)] for a simplified self-nomination process to 1,176 hours [966 hr (84 QCDRs × 11.5 hr) + 180 hr (18 audits × 10 hr) + 30 hr (10 participation plans × 3 hr)] at a cost of $111,980 [$91,983 (966 hr × $95.22/hr) + $17,140 (18 audits × $952.20/audit) + $2,857 (30 hr × $95.22/hr)] for the full self-nomination process.

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TABLE 83: Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	84	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	84
Total Applications (c)	**84**	**84**
Annual Hours Per QCDR for Simplified Process (d)	9.5	0
Annual Hours Per QCDR for Full Process (e)	0	11.5
Total Annual Hours for Self-nomination (f) = (a) * (d) and (b) * (e)	**798**	**966**
# of Hours per Completion of Targeted Audit (g)	5	10
Total Annual Hours for Completion of 18 Targeted Audits (h)	**90**	**180**
# of Hours per Submission of Participation Plan (i)	3	3
Total Annual Hours for Submission of 10 Participation Plans (j)	**30**	**30**
Total Annual Time (Hours) (k) = (f) + (h) + (j)	**918**	**1,176**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $95.22/hr) (l) = (d) * $95.22/hr	$904.60	$904.60
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $95.22/hr) (m) = (e) * $95.22/hr	$1,095.03	$1,095.03
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $95.22/hr) (n) = (h) * $95.22/hr	$476.10	$952.20
Cost Per Participation Plan (@ computer systems analyst's labor rate of $95.22/hr) (o) = (j) * $95.22/hr	$285.70	$285.70
Total Annual Cost (l) = (a) * (l) + (h) * 18 + (0) * 10 (min) and (b) * (l) + (h) * 18 + (0) * 10 (max)	**$87,413**	**$111,980**

As shown in Table 84, for the CY 2022 performance period/2024 MIPS payment year, independent of the change to our per response time estimate, the estimated increase in 2 respondents from the currently approved 82 respondents to 84 results in an increase of between +19 hours (+2 respondents × 9.5 hrs/respondent for the simplified self-nomination process) and +23 hours (+ 2 respondents × 11.5 hrs/respondent for the full self-nomination process) at a cost of between +$1,809 (+2 respondents × $904.60/respondent for the simplified self-nomination process) and +$2,190 (+2 respondents × $1,095.03/respondent for the full self-nomination process) (see Table 83 for the cost per QCDR).

Accounting for the change in time required for the QCDR self-nomination process results in an adjustment of between +328 hours (82 respondents × +4 hr for the simplified self-nomination process or also referred to as minimum burden) at a cost + $31,232 [82 respondents × $380.88 (+4 hr × $95.22/hr)/respondent) and +287 hours (82 respondents × 3.5 hr for the full self-nomination process or also referred to as maximum burden) at a cost of and +$27,328 (82 respondents × $333.27 (+3.5 hr × $95.22/hr)/respondent). The reason for the increase in minimum burden compared to the maximum burden is due to an increase in the change in the number of hours required for the simplified self-nomination process compared to the increase in the number of hours for the full self-nomination process.

In aggregate, when these impacts are combined with the estimate for targeted audits and participation plans discussed above, the net impact ranges between + 382 hours [19 hr (+2 respondents × 9.5 hrs/respondent) + 5 hr (+1 targeted audit × 5 hrs/audit) + 30 hr (10 participation plans × 3 hr/plan) + 328 hr (82 respondents × 4 hr)] at a cost of $36,374 ($1,809 + $476 + $2,857 + $31,232) for the simplified self-nomination process (also referred to as minimum burden) and +350 hours [23 hr (+2 respondents × 11.5 hrs/respondent) + 10 hr (+1 targeted audits × 10 hrs/audit) + 30 hr (10 participation plans × 3 hr/plan) + 287 hr (+82 respondents × 3.5 hr)] at a cost of $33,328 [$2,190 (+2 respondents × $1,095.03/respondent + $952 (10 hr × $95.22/hr) + $2,857 (30 hr × $95.22/hr) + $27,328 (82 respondents × $333.27/respondent)] for the full self-nomination process (also referred to as maximum burden) for the CY 2022 performance period/2024 MIPS payment year.

As discussed above in this section of the rule, we are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year. Therefore, we estimate the total change in burden for the QCDR self-nomination process would be 918 hours at a cost of $87,413 for the simplified self-nomination process (also referred to as minimum burden) and 1,176 hours at a cost of $111,980 for the full self-nomination process (also referred to as maximum burden). For the purposes of calculating estimated change in burden in Tables 128, 129, and 130 of this final rule, we use only the maximum burden estimate.

TABLE 84: Change in Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

Burden and Respondent Descriptions	Minimum Burden	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	536	826	826	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 83, row (c))	918	0	1,176	1,176
Difference (c) = (b) - (a)	**+382**	**-826**	**+350**	**+1,176**
Total Currently Approved Annual Cost (d)	$51,038	$78,652	$78,652	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 83, row (e))	$87,413	0	$111,980	$111,980
Difference (f) = (c) - (d)	**+36,375**	**-$78,652**	**+33,328**	**+$111,980**

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(b) QCDR Measure Requirements

In the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), we discussed that beginning with the CY 2018 performance period/2020 MIPS payment year and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. Additionally, in the CY 2020 Quality Payment Program rule (84 FR 63070 through 63073) we finalized the QCDR measure rejection criteria considerations.

In section IV.A.3.h.(4)(a)(i)(A)(aa) of this rule, we are finalizing to codify a new requirement and add a rejection criterion that a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. Additionally, we are finalizing to codify new requirements that if a QCDR measure owner is not an approved active QCDR for a given self-nomination period, that QCDR measure will not be available for use. The inactive QCDR measure owner has the option to transfer ownership of the QCDR measure to an active QCDR or agree upon terms set forth with the active QCDR allowing co-ownership of the QCDR measure. We refer readers to section IV.A.3.h.(4)(a)(i)(A) of this rule for additional details on the finalized policies for transfer of ownership of QCDR measures. This provision is to codify the existing requirements for the QCDR self-nomination process. We are not adjusting our burden estimates as result of this provision because we assume that this does not change the requirements, or the time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

Additionally, we are finalizing to codify another rejection criterion at § 414.1400(b)(4)(iv)(N) to state that, if a QCDR measure owner is not approved during a given self-nomination period, any associated QCDR measures with that QCDR will also not be approved. We are not revising our burden estimates as a result of the above provision because we assume that there will not be additional requirements for QCDRs to submit at the time of self-nomination. This is part of the measure specification requirements for QCDRs which submit measures for approval during the self-nomination process.

(3) Qualified Registry Self-Nomination Process and Other Requirements

The requirements and burden associated with this rule's data submission changes related to qualified registries will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to § 414.1400 which states that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so. We also refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59997 through 59998), CY 2020 PFS final rule (84 FR 63114 through 63116) and the CY 2021 PFS final rule (85 FR 84967 through 85 FR 84969) for our previously finalized requirements and burden for self-nomination of qualified registries.

In section IV.A.3.h.(1) of this rule, we are finalizing reorganization and consolidation of § 414.1400 generally. We assume that this provision does not change the existing requirements for third-party intermediaries during the self-nomination process. Therefore, we did not revise our burden estimates related to these provisions.

In section IV.A.3.h.(2)(a) of this rule, we are finalizing to add APM Entities to § 414.1400(a)(1), expanding the general participation requirements of third-party intermediaries, to third party intermediaries reporting to MIPS on behalf of APM Entities reporting to MIPS to align reporting requirements for all participants in MIPS. We are also finalizing that beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support APP, and MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. As finalized in the CY 2017 PFS final rule, third-party intermediaries currently support MIPS data submission on behalf of eligible clinicians (81 FR 77016). APM Entities have historically used third party intermediaries for submitting their quality measures to their APMs. Additionally, QCDRs, qualified registries and health IT vendors are required under existing § 414.1400(a)(1) to submit data for the quality, improvement activities, and promoting interoperability performance categories in MIPS. Similar to our discussion for QCDRs above, we anticipate no additional steps being added to the qualified registry self-nomination process as a result of this provision for third-party intermediaries to submit MIPS data on behalf of APM Entities, and to support measures and activities in MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. For this final rule, we assume that there will be no impact on the time required for qualified registries to complete either the simplified or full

self-nomination process because of the above provisions. Additionally, we are finalizing to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 performance period/2025 MIPS payment year. We anticipate that at the time of self-nomination, qualified registries would be using a checkbox to indicate their compliance for the requirement to support data submission for subgroups beginning with the CY 2023 performance period/2025 MIPS payment year. We assume that this would not impact the overall time estimated for qualified registries to submit their information at the time of self-nomination. Therefore, we are not making any adjustments in the time required for qualified registries during the simplified or full self-nomination process because of this provision. However, we anticipate that third-party intermediaries would need to make administrative changes to their existing workflows for submission of MVPs and APP data for clinicians participating as subgroups beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to section VI.F.18.g.(2)(f) of this rule where we discuss our impact analysis.

For this final rule, we are adjusting the number of qualified registries that submitted applications for self-nomination from 210 to 147 based on the number of applications received during the CY 2021 self-nomination period for the CY 2022 performance period/2024 MIPS payment year, a decrease of 36 applications from the currently approved estimate of 183. This is also a decrease of 63 from the estimate of 210 provided in the CY 2022 PFS proposed rule (86 FR 39487). Therefore, we are revising our estimates for this information collection related to the qualified registry self-nomination process. We are not making any new adjustments to the estimated burden per respondent as a result of this updated data.

Based on our estimates in the CY 2021 PFS final rule (85 FR 84967) and the updated data received for the number of qualified registries that submitted self-nomination applications, we are adjusting the estimated number of qualified registries that will submit targeted audits for the CY 2022 performance period/2024 MIPS payment year. Similar to our assumptions in the CY 2021 PFS final rule (85 FR 84967) and based on the updated data received from the CY 2021 self-nomination period, we are adjusting our estimate that 46 qualified registries will be required to conduct targeted audits, a decrease of 10 from the currently approved estimate of 56 in the CY 2021 PFS final rule (85 FR 84965). Therefore, we estimate the total impact associated with qualified registries completing targeted audits will range from 230 hours (46 registries × 5 hours/audit) at a cost of $21,901 (46 registries × $476.10/audit) to 460 hours (46 registries × 10 hours/audit) at a cost of $43,801 (46 registries × $952.20/audit) for the simplified and full self-nomination process, respectively (see Table 83 for the cost per audit). We assume that this would adjust our burden estimates for targeted audits by −50 hours (−10 respondents × 5 hr/audit) at a cost of −$4,761 (−50 hrs × $95.22/hr) and + −100 hours (−10 respondents × 10 hr/audit) at a cost of −$9,522 (−100 hrs × $95.22/hr) for the simplified and full self-nomination process, respectively.

Using our currently approved time per response estimate of 3 hours, the resulting adjustment in burden for QCDRs and qualified registries to submit CAPs is 30 hours (10 respondents × 3 hrs/respondent) at a cost of $2,857 (30 hours × $95.22/hr).

In section IV.A.3.h.(3)(a)(i) of this final rule, we are finalizing new requirements for approved QCDRs and qualified registries that have not submitted performance data. First, we are finalizing to create a new requirement at paragraph at § 414.1400(b)(3)(vii) to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 performance period/2019 MIPS payment year) through the CY 2020 performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023. Exceptions to this requirement may occur if data is received for the CY 2021 performance period/2023 MIPS payment year. Under this scenario, QCDRs and qualified registries will not need to submit a participation plan for the CY 2023 self-nomination process. If the QCDRs and qualified registries did not submit data, their participation plan must be submitted as part of self-nomination for the CY 2023 MIPS self-nomination period and must be accepted by CMS to continue to be an approved QCDR or qualified registry. We are also finalizing to codify a new requirement that, beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. Under this provision, the participation plan must explain the QCDR and/or qualified registry's detailed plans about how the vendor intends to encourage clinicians to submit MIPS data to CMS through the third-party intermediary on behalf of clinicians or groups. The vendor must also explain why they should still be allowed to participate as a qualified vendor.

Based on our review of the existing list of approved qualified registries that did not submit performance data since the inception of MIPS (CY 2017 performance period/2019 MIPS payment year), we estimate that 19 qualified registries would submit participation plans for the CY 2023 self-nomination period. Similar to our assumptions used for submission of a CAP in the CY 2021 PFS final rule (85 FR 84968), we anticipate that the effort involved in developing a participation plan including the policies specified in this rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $95.22/hr. For the CY 2023 performance period/2025 MIPS payment year, we estimate an annual burden of 57 hours (3 hr × 19 participation plans) at a cost of $5,428 (57 hr × $95.22/hr) for qualified registries to develop and submit a participation plan.

As stated above, based on the number of self-nominations received for the CY 2022 performance period/2024 MIPS payment year, we are finalizing to adjust the estimated number of qualified registries that will self-nominate for the CY 2022 self-nomination period to 147, a decrease of 36 from the currently approved estimate of 183 in the CY 2021 PFS final rule (85 FR 84969). In the CY 2019 PFS final rule, we estimated that it would take 3 hours for a qualified registry to submit all the required information during the full self-nomination process (83 FR 59998). Based on our experience with the self-nomination process, we believe that the number of fields needed to be submitted for a qualified registry are fewer than those needed for a QCDR. We assume that our previous assumption of 3 hours is an overestimate. Therefore, we are adjusting the estimated time required for a qualified registry submitting a full-self-nomination process to 2 hours, a decrease of 1 hour.

We assume that the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $95.22/hr. Using the change in estimated burden per respondent time, associated with the self-nomination process range from a minimum of 0.5 hours to a maximum of 2 hours, we

estimate that the annual burden would range from 74 hours (147 qualified registries × 0.5 hr) to 294 hours (147 qualified registries × 2 hr) at a cost ranging from $7,046 (74 hr × $95.22/hr) and $27,995 (294 hr × $95.22/hr), respectively (see Table 85).

Both the minimum and maximum burden shown in Table 85 reflect the adjustments to the number of respondents due to availability of more recent data. Combined with our estimates of burden associated with completing targeted audits and developing and submitting participation plans and corrective action plans, our total burden estimate ranges from 391 hours [74 hr (147 qualified registries × 0.5 hr) + 57 hr (+19 participation plans × 3 hr/plan) + 230 hr (46 targeted audits × 5 hours/audit) + 30 hr (10 CAPs × 3 hr) at a cost of $37,232 [$7,046 (74 hr × $95.22/hr) + $5,428 (57 hr × $95.22/hr) + $21,901 (46 registries × $476.10/audit) + $2,857 (30 hours × $95.22/hr)] to 841 hours [294 hr (147 qualified registries × 2 hr) + 57 hr (+19 participation plans × 3 hr/plan) + 460 hr (46 targeted audits × 10 hours/audit) + 30 hr (10 CAPs × 3 hr)] at a cost of $80,081 [$27,995 (294 hr × $95.22/hr) + $5,428 (57 hr × $95.22/hr) + $43,801 (46 registries × $952.20/audit) + $2,857 (30 hours × $95.22/hr) for the simple self-nomination process (see minimum burden in Table 85) and full self-nomination process (see maximum burden in Table 85) respectively.

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

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TABLE 85: Estimated Burden for Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Minimum	Maximum
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	147	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	0	147
Total Applications (c)	**147**	**147**
Total Annual Hours Per Qualified Registry for Simplified Process (d)	0.5	0
Total Annual Hours Per Qualified Registry for Full Process (e)	0	2
Total Annual Hours for Self-Nomination for min. (f) = (a) * (d) and max. (b) * (e)	**74**	**294**
Total Annual Hours for Completion of 46 Targeted Audits (g)	**230**	**460**
Total Annual Hours for development and submittal of 19 Participation Plans (h)	**57**	**57**
Total Annual Hours for Submittal of 10 CAPs (i)	**30**	**30**
Total Annual Time (Hours) (j) = (e) + (f) + (g) + (h)	**391**	**841**
Cost Per Simplified Process Per Qualified Registry (@ computer systems analyst's labor rate of $95.22/hr) (k)	$47.61	$47.61
Cost Per Full Process Per Qualified Registry (@ computer systems analyst's labor rate of $95.22/hr) (l)	$190.44	$190.44
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $95.22/hr) (m)	$476.10	$952.20
Cost Per Participation Plan (@ computer systems analyst's labor rate of $95.22/hr) (n)	$285.66	$285.66
Cost per CAP (@ computer systems analyst's labor rate of $95.22/hr) (o)	$285.66	$285.66
Total Annual Cost for min. (p) = (a) * (k) + (m) *46 + (n) * 19 + (o) * 10 and max. (b) * (l) + (m) * 46 + (n) * 19 + (o) * 10	**$37,232**	**$80,081**

As shown in Table 86, for the CY 2022 performance period/2024 MIPS payment year, independent of the change to our per response time estimate, the estimated decrease in 36 respondents from the currently approved 183 respondents to 147 results in a change of −18 hours (−36 respondents × 0.5 hrs/respondent) at a cost of −$1,714 (−18 hours × $95.22/hr) for the simplified self-nomination process and a change of −72 hours (−36 respondents × 2 hrs/respondent) at a cost of −$6,856 (−72 hours × $95.22/hr). Accounting for the change in time required for the qualified registry self-nomination process results in an adjustment of 0 hours for the simplified self-nomination process and −183 hours (183 respondents × −1 hours) at a cost of −$17,425 (−183 hours × $95.22/hr) for the full self-nomination process.

When the above impacts are combined with the estimates for targeted audits, participation plans and corrective action plans discussed above, the net impact ranges between −11 hours [−18 hr (−36 respondents × 0.5 hrs/respondent) + 0 hr + −50 hr (−10 audits × 5 hr/audit) + 57 hr (+19 participation plans × 3 hr/plan) + 0 hr)] at a cost of −$1,046 [(−$1,713 (−18 hours × $95.22/hr) + $0 + −$4,761 (−50 hrs × $95.22/hr) + $5,428 (+57 hr × $95.22/hr) + $0)] for the simplified self-nomination process and −298 hours [(−72 hr (−36 respondents × 2 hrs/respondent) + −183 hr (183 respondents × −1 hours) + −100 hr (−10 audits × 10 hr/audit) + 57 hr (+19 participation plans × 3 hr) + 0 hr)] at a cost of −$28,375 [(−$6,856 (−72 hours × $95.22/hr) − $17,425 (−183 hours × $95.22/hr) − $9,522 (−100 hrs × $95.22/hr) + $5,428 (+57 hr × $95.22/hr) + $0)] for the full self-nomination process for the CY 2022 performance period/2024 MIPS payment year.

As discussed above in this section of the rule, we are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year. Therefore, we estimate the total change in burden for the qualified registry self-nomination process would be 391 hours at a cost of $37,232 for the simplified self-nomination process and 841 hours at a cost of $80,081 for the full self-nomination process. For the purposes of calculating estimated change in burden in Tables 128, 129, and 130 of this final

rule, we use only the maximum burden estimate.

TABLE 86: Change in Estimated Burden for Qualified Registry Self Nomination

Burden and Respondent Descriptions	Minimum Burden	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	401.5	1,139	1,139	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 85, row (c))	391	0	841	841
Difference (c) = (b) - (a)	**-11**	**-1,139**	**-298**	**+841**
Total Currently Approved Annual Cost (d)	$38,278	$108,456	$108,456	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 85, row (e))	$37,232	0	$80,081	$80,081
Difference (f) = (e) - (d)	**-1,046**	**-$108,456**	**-28,375**	**+$80,081**

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We received public comments for our burden estimates related to QCDRs and qualified registries. The following is a summary of the public comments received for the Quality Payment Program ICRs regarding the burden estimates for QCDR and qualified registries.

Comment: One commenter did not agree with CMS burden estimates for audits conducted by QCDRs and qualified registries and shared their belief that the time required for a QCDR was two to three-fold more than CMS estimates. The commenter shared their concern that our estimate does not accurately represent the total amount of time it takes for a QCDR or qualified registry to conduct data audits.

Response: We would like to clarify that our burden estimates provided for the QCDR and qualified registry self-nomination process are not intended to capture the holistic total annual time for a QCDR or a qualified registry to participate in MIPS. Our burden estimate of 9.5 hours to 11.5 hours for the QCDR and 0.5 hours to 2 hours for the qualified registry self-nomination process specifically includes the estimated time it takes for a QCDR or qualified registry to populate and submit a self-nomination form and QCDR measures, if applicable. These burden estimates do not include any time needed to comply with third-party intermediary requirements outside of the self-nomination process. We believe our burden estimate is a reasonable average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to self-nominate as a QCDR or registry.

After consideration of public comments, we are not making any changes to our estimates of the time required for the QCDR and qualified registry self-nomination process.

(4) Survey Vendor Requirements

In section IV.A.3.h(2)(b)(ii) of this rule, we are finalizing to require CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 performance period/2025 MIPS payment year. Because of this provision, we anticipate no additional steps being added to the requirements for CAHPS for MIPS survey vendors to submit a participation form and assume there would be no impact on the time required for the survey vendors. Therefore, we are not making any adjustments in the time required for CAHPS survey vendors to submit their information because of this provision. The requirements and burden for CAHPS survey vendors to submit data for eligible clinicians are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any changes to the CAHPS for MIPS Survey vendor information collection request under that control number.

(5) Health IT Vendors

In section IV.A.3.h.(2)(b) of this rule, we are finalizing to create a new requirement at paragraph § 414.1400(c)(1)(iii) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. Health IT vendors may also support the APP. Additionally, we are finalizing to require health IT vendors to support subgroup reporting beginning with the CY 2023 performance period/2025 MIPS payment year. We do not anticipate any requirement or burden changes as it relates to the support of reporting data. As stated in the CY 2019 PFS final rule (83 FR 59998), health IT vendors are not included in the burden estimates for MIPS.

d. ICR Regarding Open Authorization (OAuth) Credentialing and Token Request Process

This rule is not implementing new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the identity management application process under that control number.

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77502 through 77503), CY 2018 Quality Payment Program final rule (82 FR 53908 through 53912), CY 2019 PFS final rule (83 FR 60000 through 60003), CY 2020 PFS final rule (84 FR 63121 through 63124), and the CY 2021 PFS final rule (85 FR 84970 through 84974) for our previously finalized requirements for data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: Those who submit as MIPS eligible clinicians and those who submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly

enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2019 QP performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2022 performance period/2024 MIPS payment year. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future CY 2022 performance period/2024 MIPS payment year (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the CY 2019 performance period/2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). As in the CY 2021 PFS final rule, we continue to use CY 2019 performance period/2021 MIPS payment year data to estimate the number of respondents in the CY 2022 PFS final rule.

There may be an undercount in submissions due to the PHE for COVID–19, because of the automatic extreme and uncontrollable circumstances policy, and application-based policy that allowed clinicians to elect not to submit during the submission period for the CY 2019 performance period/2021 MIPS payment year that we are using to inform our burden estimates. Despite this limitation, we believe the data from the CY 2019 performance period/2021 MIPS payment year is still the best data source available as it most accurately reflects the impacts of policies finalized in previous rules and trends toward increased group reporting.

In section IV.A.3.d.(1)(d) of this rule, we are finalizing to continue the CMS Web Interface measures as a collection type for the CY 2022 performance period/2024 MIPS payment year. Additionally, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the CY 2023 performance period/2025 MIPS payment year. In the CY 2021 PFS final rule (85 FR 84981), we finalized the sunset of CMS Web Interface as a collection type for the CY 2022 performance period/2024 MIPS payment year. We refer readers to the CY 2021 PFS final rule for discussion on our assumptions for the CY 2022 performance period/2024 MIPS payment year, where we estimated a burden of zero due to our assumption that all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types. Based on the number of groups that submitted quality performance data via the CMS Web Interface in the CY 2019 performance period/2021 MIPS payment year, we are not able to ascertain what alternative collection type(s) the groups would elect. In order to estimate the number of groups that will select each of these collection types, we first clustered the number of groups which submitted data via the CMS Web Interface collection type during the CY 2019 performance period/2021 MIPS payment year by practice size (between 25 and 49 clinicians, between 50 and 99 clinicians, etc.). Then, for each cluster, we allocated these groups to each of the MIPS CQM and QCDR and eCQM collection types based on the percent of TINs that submitted MIPS data via these two collection types. For example, of the 1,629 TINs with a practice size of 25 to 49 clinicians which submitted data for the CY 2019 performance period/2021 MIPS payment year, 1,066 (65 percent) submitted data via the MIPS CQM and QCDR collection type and 563 (35 percent) submitted data via the eCQM collection type. We applied these percentages to the 7 TINs with a practice size of 25 to 49 clinicians which submitted data via the CMS Web Interface collection type for the CY 2019 performance period/2021 MIPS payment year to estimate that 4 (7 TINs $\times$ 0.56) would elect to submit data via the MIPS CQM and QCDR collection type and the remaining 3 (7 TINs $\times$ 0.44) would elect to submit data via the eCQM collection type. In total, beginning with the CY 2023 performance period/2025 MIPS payment year, we estimate that 64 of the 114 groups that submitted data via the CMS Web Interface collection type for the CY 2019 performance period/2021 MIPS payment year will submit quality data via the MIPS CQM and QCDR collection type and 50 groups will now submit quality data via the eCQM collection type. We note that 114 groups are an increase of 114 from our currently approved estimate of 0 groups in the CY 2022 performance period/2024 MIPS payment year. We also performed this analysis to determine the number of clinicians that will be affected and will need to submit quality data via an alternate collection type beginning with the CY 2023 performance period/2025 MIPS payment year. In total, of the estimated 45,599 individual clinicians affected by this provision, we estimate that 11,432 will submit quality data as part of a group via the MIPS CQM and QCDR collection type and 34,167 will submit quality data as part of a group via the eCQM collection type. These estimates are reflected in Tables 90 and 92 and the associated changes in burden are reflected in Tables 91 and 93. In aggregate, as discussed in section V.B.8.p. of this final rule, we estimate the provision to sunset the CMS Web Interface measures as a collection type/submission type will result in a net decrease in quality performance data reporting burden while acknowledging the additional financial impacts on clinicians as discussed in section VI.F.18.g.(2)(a) of the Regulatory Impact Analysis. We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2020 and CY 2021 PFS final rules (84 FR 63122 and 85 FR 84972), we include all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section V.B.8.e.(2) of this final rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the CY 2022 performance period/2024 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2019 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2019 performance period/2021 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their reporting as a group or individual

for the CY 2019 performance period/2021 MIPS payment year.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this final rule because sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[266] Tables 84, 85, and 86 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 87 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years based on data from the CY 2019 performance period/2021 MIPS payment year.

For the CY 2022 performance period/2024 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and Web Interface. For the CY 2023 performance period/2025 MIPS payment year, respondents will no longer have the option to submit quality performance category data via the Web Interface. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintaining consistency with previous rulemaking.

For the CY 2023 performance period/2025 MIPS payment year, we are finalizing in section IV.A.3.b.(2)(c) of this rule that clinicians in MIPS will have the option to submit measures and activities in MVPs. We refer readers to section IV.A.3.b.(4)(d) of this rule for additional details on the reporting requirements for MVPs. For the quality performance category of MVPs, we assume that MVP Participants will choose to report via the Medicare Part B claims, QCDR, MIPS CQMs, and eCQMs collection type. Table 99 of this rule includes the estimated burden for collecting data for the quality performance category of MVPs.

As shown in Table 87, using participation data from the CY 2019 performance period/2021 MIPS payment year, combined with the estimate of QPs for the CY 2022 performance period/2024 MIPS payment year, we estimate a total of 625,703 clinicians will submit quality data as individuals or groups in each of the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years, a decrease of 25,811 clinicians when compared to our estimate of 651,514 clinicians in the CY 2021 PFS final rule (85 FR 84972). For the CY 2022 performance period/2024 payment year, we estimate 28,252 clinicians will submit data as individuals for the Medicare Part B claims collection type; 279,247 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 273,819 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 44,385 clinicians will submit as part of groups via the CMS Web Interface. Compared to the CY 2022 performance period/2024 MIPS payment year burden estimated in the CY 2021 PFS final rule (85 FR 84972), these are decreases from the estimates of 29,273, 295,941, and 326,300 for Medicare Part B claims, MIPS CQM and QCDR, eCQM, and an increase of 44,385 for the CMS Web Interface collection types, respectively. These adjustments are due to the availability of updated data from the CY 2019 performance period/2021 MIPS payment year and the delay in sunsetting the CMS Web Interface from the CY 2022 performance period/2024 MIPS payment year to the CY 2023 performance period/2025 MIPS payment year. For the CY 2023 performance period/2025 MIPS payment year, we estimate 25,427 clinicians will submit data as individuals for the Medicare Part B claims collection type; 288,637 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 311,326 clinicians will submit data as individuals or as part of groups via the eCQM collection type.

Table 87 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

[266] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

TABLE 87: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type (as Individual Clinicians or as Part of Groups)

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2022 MIPS performance period (excludes QPs) (a)	28,252	279,247	273,819	44,385	625,703
* Currently approved 2022 MIPS performance period (excludes QPs) (b)	29,273	295,941	326,300	0	651,514
Difference (c) = (a) - (b)	-1,021	-16,694	-52,481	44,385	-25,811
2023 MIPS performance period prior to MVP and Web Interface adjustments (excludes QPs) (d)	28,252	295,941	326,300	0	650,493
Adjustment for Web Interface Sunset (e)	0	24,767	19,618	0	44,385
Adjustment for Shift to MVP (10% reduction) (f) = ((d) + (e)) * -.1	-2,825	-32,071	-34,592	0	-69,488
2023 after adjustments (g) = (d) + (e) + (f)	25,427	288,637	311,326	0	625,390
* Currently approved 2022 MIPS performance period (excludes QPs) (h)	N/A	N/A	N/A	0	N/A
Difference (i) = (g) - (h)	+25,427	+288,637	+311,326	-0	+625,390

*Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the CY 2019 performance period/2021 MIPS payment year. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 88 uses methods similar to those described to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years. For the CY 2022 performance period/2024 MIPS payment year, we estimate that approximately 28,252 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 40,507 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 40,446 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2019 performance period/2021 MIPS payment year, these are decreases of −1,021, −833, and −1,809 respondents from the currently approved estimates of 29,273, 41,340, and 42,255 for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, respectively.

As shown in Table 88, for the CY 2023 performance period/2025 MIPS payment year, we estimate that approximately 25,427 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 36,456 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 36,401 clinicians will submit data as individuals using eCQMs collection type. As stated above, we are setting forth our estimates for the CY 2023 performance period/2025 MIPS payment year as new burden with no currently approved estimate.

TABLE 88: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2022 MIPS Performance Period (excludes QPs) (a)	28,252	40,507	40,446	0	109,205
*Currently approved 2022 MIPS performance period (excludes QPs) (b)	29,273	41,340	42,255	0	112,868
Difference (c) = (a) - (b)	-1,021	-833	-1,809	0	-3,663
2023 MIPS Performance Period (excludes QPs) prior to MVP adjustment (d)	28,252	40,507	40,446	0	109,205
MVP adjustment (10% reduction) (e) = (d)*- 0.1	-2,825	4,051	-4,044	0	-10,920
2023 MIPS Performance Period (excludes QPs) (f) = (d) + (e)	25,427	36,456	36,401	0	98,285
*Currently approved 2022 MIPS performance period (excludes QPs) (g)	N/A	N/A	N/A	0	N/A
Difference (h) = (f) - (g)	+25,427	+36,456	+36,401	0	+98,285

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 88 are not mutually exclusive.

Table 89 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years. We assume that clinicians that submitted quality data as groups in the CY 2019 performance period/2021 MIPS payment year will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the CY 2022 and 2023 performance periods/2024 and 2025 MIPS payment years. Specifically, for the CY 2022 performance period/2024 MIPS payment year we estimate that 11,529 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 243,169 clinicians; 8,127 groups and virtual groups will submit for eCQM collection types on behalf of 249,878 eligible clinicians; and 114 groups will submit data via the CMS Web Interface on behalf of 44,385 clinicians. These are decreases of −75 and −93 respondents from the currently approved estimates of 11,604, and 8,220 groups and virtual groups for the MIPS CQM and QCDR and eCQM collection types, and an increase of +114 groups from the currently approved estimates of 0 groups for the CMS Web Interface collection types, respectively.

As shown in Table 89, for the CY 2023 performance period/2025 MIPS payment year we estimate that 10,434 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 313,038 clinicians and 7,359 groups and virtual groups will submit for eCQM collection types on behalf of 339,109 eligible clinicians. As stated above, we are setting forth our estimates for the CY 2023 performance period/2025 MIPS payment year as new burden with no currently approved estimate. The reason for the difference in estimated number of respondents from the estimates for the CY 2022 performance period/2024 MIPS payment year described above, is due to the sunset of the CMS Web Interface as a collection type and the implementation of MVPs beginning with the CY 2023 performance period/ 2025 MIPS payment year. As the data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM entities, we assume non-ACO APM Entities will participate through traditional MIPS and base our estimates on submissions received in the CY 2019 performance period/2021 MIPS payment year.

TABLE 89: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type on Behalf of Clinicians

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2022 MIPS performance period (excludes QPs) (a)	0	11,529	8,127	114	19,770
*Currently approved 2022 MIPS performance period (excludes QPs) (b)	0	11,604	8,220	0	19,824
Difference (c) = (a) - (b)	0	-75	-93	+114	-54
2023 MIPS performance period (excludes QPs) (d) prior to adjustments	0	11,529	8,127	114	19,770
Adjustment for Web Interface (e)	0	64	50	-114	0
Adjustment for MVPs (10%) (g) = ((d) + (e)) * 0.1	0	-1,159	-817.7	0	-1,977
2023 MIPS performance period (excludes QPs) – Adjusted. (h) = (d) + (e) + (f) + (g)	0	10,434	7,359	0	17,793
*Currently approved 2022 MIPS performance period (excludes QPs) (i)	N/A	N/A	N/A	N/A	N/A
Difference (j) = (h) - (i)	0	+10,434	+7,359	0	+17,793

*Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

The burden associated with the submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. For the CY 2023 performance period/2025 MIPS payment year we refer readers to section IV.A.3.b.(4)(d) of the rule for the changes related to MVP and subgroup reporting requirements. In terms of the quality measures available for clinicians and groups to report for the CY 2022 performance period/2024 MIPS payment year, we are finalizing that the total number of quality measures will be 200. The new MIPS quality measures finalized for inclusion in MIPS for the CY 2022 performance period/2024 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures finalized for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 90, as well as counts of new, removed, and substantively changed measures.

TABLE 90: Summary of Quality Measures Finalized for the CY 2022 Performance Period/2024 MIPS Payment Year

Collection Type	# Measures Finalized as New	# Measures Finalized for Removal*	# Measures Finalized with a Substantive Change*	# Measures Finalized for CY 2022*
Medicare Part B Claims Specifications	0	-13	16	34
MIPS CQMs Specifications	+2	-13	70	174
eCQM Specifications	+1	0	41	48
Survey – CSV	0	0	0	1
CMS Web Interface Measure Specifications	0	0	10	10
Administrative Claims	+1	0	0	3
Total	+4	-13*	+87*	200*

*A measure may be specified under multiple collection types but will only be counted once in the total.

For the CY 2022 performance period/2024 MIPS payment year, we are finalizing a net reduction of 9 quality measures across all collection types compared to the 209 measures finalized for the CY 2021 performance period/2023 MIPS payment year (85 FR 84974). Specifically, as discussed in section IV.A.3.d.(1)(e) of this rule, we are finalizing to add 1 new administrative claims outcome measure, remove 13 quality measures, and make substantive updates to 87 quality measures. We do not anticipate that our provision to remove these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures. For the change in associated burden related to the provisions introducing MVP and subgroup reporting beginning in the CY 2023 performance period/2025 MIPS payment year, we refer readers to Table 99 of this section.

(3) Quality Payment Program Identity Management Application Process

This rule is not implementing any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the identity management application process under that control number.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule is not implementing any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are adjusting our currently approved burden estimates based on more recent data. For the change in associated burden related to the provisions introducing MVP and subgroup reporting beginning in the CY 2023 performance period/2025 MIPS payment year, we refer readers to Table 99 of this section.

The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77501 through 77504), CY 2018 Quality Payment Program final rule (82 FR 53912), CY 2019 PFS final rule (83 FR 60004 through 60005), CY 2020 PFS final rule (84 FR 63124 through 63126) and the CY 2021 PFS final rule (85 FR 84975 through 84976) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 88, based on data from the CY 2019 performance period/2021 MIPS payment year, we assume that 28,252 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. In this rule, we are finalizing to adjust the number of Medicare Part B claims respondents from the currently approved estimate of 29,273 to 28,252 (a decrease of 1,021) based on more recent data and our methodology of accounting only for clinicians in small practices who submitted such claims data in the CY 2019 performance period/2021 MIPS payment year rather than all clinicians who submitted quality data codes to us for the Medicare Part B claims collection type.

As shown in Table 91, consistent with our currently approved per response time figures, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) for a computer systems analyst at a cost of $14.28 (0.15 hr × $95.22/hr) to 7.2 hours for a computer systems analyst at a cost of $685.58 (7.2 hr × $95.22/hr). The burden will involve becoming familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time figures, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $114.24/hr for a medical and health services manager, 1 hour at $217.32/hr for a physician, 1 hour at $48.16/hr for an LPN, 1 hour at $95.22/hr for a computer systems analyst, and 1 hour at $40.02/hr for a billing and posting clerk. We are not revising our currently approved per response time estimates.

As shown in Table 91, considering both data submission and start-up requirements for our adjusted number of clinicians, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual time for the CY 2022 performance period/2024 MIPS payment year ranges from 202,002 hours (7.15 hr × 28,252 clinicians) to 401,178 hours (14.2 hr × 28,252 clinicians). The estimated annual cost (per clinician) ranges from $758 [(0.15 hr × $95.22/hr) + (3 hr × $114.24/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr) + (1 hr × $217.32/hr)] to a maximum of $1,429.02 [(7.2 hr × $95.22/hr) + (3 hr × $114.24/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr) + (1 hr × $217.32/hr)]. The total annual cost for the CY 2022 performance period/2024 MIPS payment year ranges from a minimum of $21,407,105 (28,252 clinicians × $758)

to a maximum of $40,372,673 (28,252 clinicians × $1,429.02).

As shown in Table 91, for purposes of calculating total burden associated with the Claims collection type for the CY 2023 performance period/2025 MIPS payment year only the maximum burden is used. The decrease in the number of annual respondents results in an estimated total annual time of 361,063 hours (14.2 hr × 25,427 clinicians) for the CY 2023 performance period/2025 MIPS payment year. Using the currently approved unchanged estimate for cost per respondent, the total annual cost for the CY 2023 performance period/2025 MIPS payment year is $36,335,692 (25,427 clinicians × $1,429.02 per respondent).

Table 91 summarizes our estimated range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims for both the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years.

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TABLE 91: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden (CY 2022)	Maximum Burden (CY 2023)
# of Clinicians (a)	28,252	28,252	28,252	25,427
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2	14.2
Total Annual Hours (i) = (a) * (h)	**202,002**	**227,429**	**401,178**	**361,063**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr @ varying times) (j)	$14.28	$99.98	$685.58	$685.58
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr @ 3 hr) (k)	$342.72	$342.72	$342.72	$342.72
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr @ 1 hr) (l)	$95.22	$95.22	$95.22	$95.22
Cost to Review Measure Specifications (@ LPN's labor rate of $48.16/hr @1 hr) (m)	$48.16	$48.16	$48.16	$48.16
Cost to Review Measure Specifications (@ billing clerk's labor rate of $40.02/hr @ 1 hr) (n)	$40.02	$40.02	$40.02	$40.02
Cost to Review Measure Specifications (@ physician's labor rate of $217.32/hr @ 1 hr) (o)	$217.32	$217.32	$217.32	$217.32
*Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$758	$843	$1,429.02	$1,429.02
***Total Annual Cost (q) = (a) * (p)**	**$21,407,105**	**$23,828,302**	**$40,372,673**	**$36,335,692**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 91, using the unchanged currently approved hours per respondent, we estimate that the burden per respondent for quality data submission using the Medicare Part B Claims collection type will range from $758 to $1,429.02. The decrease in number of respondents from 29,273 to 28,252 results in a total adjustment of between −7,300 hours (−1,021 respondents × 7.15 hr/respondent) at a cost of −$773,918 (−1,021 respondents × $758/respondent) and −14,498 hours (−1,021 respondents × 14.2 hr/respondent) at a cost of −$1,459,029 (−1,021 respondents × $1,429.02/respondent). For purposes of calculating total burden associated with this final rule as shown in Tables 125, 126, 127, and 128, only the maximum burden is used.

As shown in Table 92, for purposes of calculating total burden associated the CY 2023 performance period/2025 MIPS payment year only the maximum burden is used. We are setting forth our CY 2023 performance period/2025 MIPS payment year estimate as new burden, which results in an increase of 361,063 hours (25,427 respondents × 14.2 hr/respondent) at a cost of $36,355,692 (25,427 respondents × $1,429/respondent).

TABLE 92: Adjusted Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden (CY 2021)	Maximum Burden (CY 2022)	Maximum Burden (CY 2023)
Total Currently Approved Annual Hours (a)	209,302	235,648	415,677	415,677	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (see Table 91, row (i))	202,002	227,429	0	401,178	361,063
Difference (c) = (b) - (a)	**-7,300**	**-8,219**	**-415,677**	**-14,499**	**361,063**
Total Currently Approved Annual Cost (d)	$21,575,050	$24,010,973	$41,630,421	$ 41,831,702	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (see Table 91, row (q)	$21,407,105	$23,828,302	0	$40,372,673	$36,335,692
Difference (f) = (e) - (d)	**-$167,945**	**-$182,671**	**-$41,630,421**	**-$1,459,029**	**$36,335,692**

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(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77504 through 77505), CY 2018 Quality Payment Program final rule (82 FR 53912 through 53914), CY 2019 PFS final rule (83 FR 60005 through 60006), CY 2020 PFS final rule (84 FR 63127 through 63128), CY 2021 PFS final rule (85 FR 84977 through 84979) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2023 performance period/2025 MIPS payment year, we refer readers to Table 99.

As noted in Tables 84, 85, and 86, and based on data from the CY 2019 performance period/2021 MIPS payment year, for the CY 2022 performance period/2024 MIPS payment year, we assume that 279,247 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 52,036 clinicians will submit as individuals and the remaining 279,223 clinicians will submit as members of 11,527 groups and virtual groups. This is an increase of 10,696 individuals and a decrease of 32 groups from the estimates of 41,340 individuals and the 11,559 groups provided in the CY 2021 PFS final rule (85 FR 84977). Given that the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf. We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data is total of 9 hours at a cost of $922.76 per response. This consists of 3 hours at $95.22/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $114.24/hr for a medical and health services manager, 1 hour at $95.22/hr for a computer systems analyst, 1 hour at $48.16/hr for an LPN, 1 hour at $40.02/hr for a billing clerk, and 1 hour at $217.32/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) at $95.22/hr for a computer systems analyst at a cost of $7.90 (0.083 hr × $95.22/hr). Overall, we estimate 9.083 hr/response (3 hr + 2 hr + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hr) at a cost of $922.76/response [(3 hr × $95.22/hr) + (2 hr × $114.24/hr) + (1 hr × $217.32/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr) + (0.083 hr × $95.22/hr)].

For the CY 2022 performance period/2024 MIPS payment year, in aggregate, we estimate a burden of 472,643 hours [9.083 hr/response × (40,507 clinicians submitting as individuals + 11,527 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 52,036 responses)] at a cost of $ $48,016,739 (52,036 responses × $922.76/response).

For the CY 2023 performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 425,902 hours [9.083 hr/response × (36,456 clinicians submitting as individuals + 10,434 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 46,890 responses)] at a cost of $43,268,216 (46,890 responses × $922.76/response). Based on these assumptions, we have estimated in

Table 93 the burden for these submissions.

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TABLE 93: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	2022 Performance Period	2023 Performance Period
# of clinicians submitting as individuals (a)	40,507	36,456
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	11,529	10,434
# of Respondents (groups plus clinicians submitting as individuals) (c)=(a)+(b)	**52,036**	**46,890**
Hours Per Respondent to Report Quality Data (d)	3	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physician Review Measure Specifications (i)	1	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083	9.083
Total Annual Hours (l) = (c)*(k)	**472,643**	**425,902**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr) (m)	$285.66	$285.66
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr) (n)	$228.48	$228.48
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr) (o)	$95.22	$95.22
Cost LPN Review Measure Specifications (@ LPN's labor rate of $48.16/hr) (p)	$48.16	$48.16
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $40.02/hr) (q)	$40.02	$40.02
Cost Physician Review Measure Specifications (@ physician's labor rate of $217.32/hr) (r)	$217.32	$217.32
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $95.22/hr) (s)	$7.90	$7.90
*Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$922.76	$922.76
***Total Annual Cost (u) = (c) * (t)**	**$48,016,739***	**$43,268,216***

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 94, using the unchanged currently approved hours per respondent burden estimate, the decrease of 913 respondents from 52,944 to 52,036 for the CY 2022 performance period/2024 MIPS payment year results in a decrease of −8,247 hours (−908 respondents × 9.083 hr/respondent) and −$837,866 (908 respondents × $922.76/respondent).

We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 425,902 hours (46,890 respondents × 9.083 hr/respondent) and $43,268,216 (46,890 respondents × $922.76/respondents).

TABLE 94: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	480,482	480,890	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (see Table 93, row (l))	0	472,643	425,902
Difference (c) = (b) - (a)	**-480,482**	**-8,247**	**+425,902**
Total Currently Approved Annual Cost (d)	$48,813,081	$48,854,605	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (see Table 93, row (u))	0	$48,016,739	$43,268,216
Difference (f) = (e) - (d)	**-$48,813,081**	**-$837,696**	**+$43,268,216**

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(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77505 through 77506), CY 2018 Quality Payment Program final rule (82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), CY 2020 PFS final rule (84 FR 63128 through 63130) and the CY 2021 PFS final rule (85 FR 84979 through 84980) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the provisions introducing MVP and subgroup reporting beginning in the CY 2023 performance period/2025 MIPS payment year, we refer readers to Table 99 of this section.

Based on CY 2019 performance period/2021 MIPS payment year data, for the CY 2022 performance period/2024 MIPS payment year, we assume that 322,392 clinicians will elect to use the eCQM collection type; 40,446 clinicians are expected to submit eCQMs as individuals; and 8,127 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 273,819 clinicians. This is a decrease of 2,109 individuals and 27 groups from the estimates of 42,555 individuals and 8,154 groups provided in the CY 2021 PFS final rule (85 FR 84979). We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $95.22/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $114.24/hr for a medical and health services manager, 1 hour at $217.32/hr for a physician, 1 hour at $95.22/hr for a computer systems analyst, 1 hour at $48.16/hr for an LPN, and 1 hour at $40.02/hr for a billing clerk. Overall, we estimate a cost of $812.76/response [(2 hr × $95.22/hr) + (2 hr × $114.24/hr) + (1 hr × $217.32/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr)].

For the CY 2022 performance period/2024 MIPS payment year, in aggregate, we estimate a burden of 388,584 hours [8 hr × 48.573 (40,446 clinicians + 8,127 groups and virtual groups)] at a cost of $39,812,374 (48,573 responses × $819.64/response). For the CY 2023 performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 350,186 hours [8 hr × 43,773 (36,401 clinicians + 7,372 groups and virtual groups)] at a cost of $35,878,102 (43,773 responses × $819.64/response). Based on these assumptions, we have estimated in Table 95 the burden for these submissions.

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TABLE 95: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	CY 2022 Performance Period	CY 2023 Performance Period
# of clinicians submitting as individuals (a)	40,446	36,401
# of Groups submitting via EHR on behalf of individual clinicians (b)	8,127	7,372
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	48,573	43,773
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physicians Review Measure Specifications (i)	1	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8	8
Total Annual Hours (k) = (c) * (j)	**388,584**	**350,186**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr) (l)	$190.44	$190.44
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr) (m)	$228.48	$228.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr) (n)	$95.22	$95.22
Cost to Review Measure Specifications (@ LPN's labor rate of $48.16/hr) (o)	$48.16	$48.16
Cost to Review Measure Specifications (@ clerk's labor rate of $40.02/hr) (p)	$40.02	$40.02
Cost to Review Measure Specifications (@ physician's labor rate of $217.32/hr) (q)	$217.32	$217.32
*Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$819.64	$819.64
***Total Annual Cost (s) = (c) * (r)**	**$39,812,374**	**$35,878,102**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 96, using the unchanged currently approved hours per respondent burden estimate, the decrease of 1,902 respondents from 50,475 to 48,573 for the CY 2022 performance period/2024 MIPS payment year results in a total difference of ×15,216 hours at a cost of ×$1,558,955. For CY 2023 performance period/2025 MIPS payment year, we are setting forth our estimate as new burden, which represents an increase of 350,184 hours (43,773 respondents × 8 hr/respondent) and $35,878,102 (43,773 respondents × $819.64/respondent).

TABLE 96: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	403,272	403,800	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (see Table 95, row (k))	0	388,584	350,186
Difference (c) = (b) - (a)	**-403,272**	**-15,216**	**+350,186**
Total Currently Approved Annual Cost (d)	$40,317,233	$41,371,239	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (see Table 95, row (s))	0	$39,812,374	$35,878,348
Difference (f) = (e) - (d)	**-40,193,112**	**-$1,558,955**	**+35,878,348**

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(7) ICRs Regarding Burden for MVP Reporting

Section IV.A.3.b.(2)(d) of this rule describes provisions related to implementing MVPs beginning with the CY 2023 performance period/2025 MIPS payment year. The MVPs will include the Promoting Interoperability performance category as a foundational element and incorporate population health claims-based measures, as feasible, along with the relevant measures and activities in the quality, cost, and improvement activities performance categories. For the CY 2023 performance period/2025 MIPS payment year, we are finalizing an inventory of seven MVPs included in Appendix 3: MVP Inventory of this rule to assess performance across MVPs for the quality, cost, improvement activities, and Promoting Interoperability performance categories. Additionally, in section IV.A.3.b.(2)(b)(i) of this rule, we are finalizing to use the term ''MVP Participant'' to refer to clinicians who will choose to participate in MIPS for reporting MVPs.

The following new ICRs reflect the burden associated with the first year of data collection related to the implementation of MVPs and subgroup reporting in the CY 2023 performance period/2025 MIPS payment year as described in section IV.A.3.b.(2)(c) of this rule. The requirements and burden associated with the implementation of MVPs and subgroups will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

While MVP respondents report on all performance categories, we believe that for purposes of data submission, the burden for clinicians submitting information for the Promoting Interoperability and improvement activities performance categories of MVPs will be consistent with the currently approved estimated burden per respondent for clinicians submitting data for these performance categories in traditional MIPS. We acknowledge that clinicians participating through MVPs will have fewer requirements to meet for the improvement activity performance category as discussed in section IV.A.3.b.(4)(d)(iv) of this final rule. We assume that these requirement changes will not significantly lower the burden for clinicians reporting MVPs. Therefore, we will not add additional ICRs to capture the burden for the Promoting Interoperability and Improvement Activity performance categories. For this rule, we are finalizing to create a separate ICR for estimating the burden associated with data submission for the Quality performance category of MVPs. We considered whether we should have a separate ICR to estimate burden for submission of measures and activities in the Promoting Interoperability performance category of MVPs. Based on our assumption above that the burden for clinicians submitting information for these performance categories of MVPs will be consistent with the currently approved estimated burden per respondent for clinicians submitting data in traditional MIPS, we anticipate that the separate ICRs will not be of value to clinicians.

We solicited comment on our proposal to distinctly estimate burden only for data submission in the Quality performance category of MVPs and whether we should revise the MVP submission ICR to include all the four MIPS performance categories and whether our assumptions on Promoting Interoperability and Improvement Activities should be modified for MVPs.

We did not receive public comments on this provision. We are finalizing as proposed.

(a) Burden for MVP Quality Submission

In section IV.A.3.b.(4)(d)(ii) of this rule, we are finalizing to implement voluntary MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. Therefore, clinicians participating in MIPS will have the option to voluntarily submit data using MVPs starting with the CY 2023 performance period/2025 MIPS payment year. While we recognize the implementation of MVPs in MIPS will result in a burden for registration, we also assume that MVP reporting will result in a decline in burden for MVP participants due to the finalized changes in the MVP reporting requirements described in section IV.A.3.b.(4)(d) of this rule. We anticipate that the clinicians choosing to participate in MIPS for reporting MVPs will need to select from a reduced inventory of measures and activities for the quality and improvement activities performance categories. This reduction in burden is described in the quality, improvement activities and Promoting Interoperability performance categories sections below.

For the ICRs related to MVP participants, we used the MIPS submission data from the CY 2019 performance period/2021 MIPS payment year. Based on our review of the inventory of 7 MVPs in Appendix 3: MVP Inventory of this rule and the existing submission trends in MIPS for the measures and activities included in these MVPs, we anticipate that 10 percent of the clinicians who participate in traditional MIPS in the CY 2022 performance period/2024 MIPS payment year will report MVPs in the CY 2023 performance period/2025 MIPS payment year. Given that MVPs are new, voluntary, and represent a

reduction in burden per response, we believe that we should be conservative in estimating the number of clinicians submitting through MVPs during the initial year. Given that MVPs are a new mechanism available for clinicians, we believe that initial participation numbers will be relatively low. In an effort to be conservative in our estimate of burden reduction due to MVP reporting and reflect the anticipate low uptake by clinicians in the first year of MVP availability, we assume that a total of 10 percent of MIPS submitters will become MVP participants in the CY 2023 performance period/2025 MIPS payment year.

As described in section IV.A.3.b.(2)(c)(ii) of this rule, beginning with the CY 2023 performance period/2025 MIPS payment year, we are finalizing voluntary subgroup reporting within MIPS limited to clinicians reporting the MVP or the APP. We recognize the implementation of subgroups for clinicians to participate in MVP and APP reporting in MIPS will result in additional burden. However, we believe that subgroup participation option will allow clinicians in certain specialties and subspecialties to report on measures and activities meaningful to the scope of care provided. We anticipate that public reporting of subgroup performance information will allow patients to identify clinicians in multispecialty groups that are representative of the care specific to their clinical condition. Clinician participation in subgroups is new to MIPS and we do not have any historical participation data to estimate the submission burden for clinicians who will choose to participate as subgroups for reporting the MVP or the APP. We refer readers to section IV.A.3.b.(3) of this final rule for details on the provisions related to subgroup composition.

We anticipate that the subgroup reporting option will increase reporting and allow clinicians in specialties to report on measures and activities meaningful to their practice. Due to the delay in implementation of subgroup reporting in the CY 2023 performance period/2025 MIPS payment year, we anticipate that there is an adequate amount of time for clinicians that historically participate in MIPS to determine if they will be able to participate as subgroups for reporting on the measures and activities in an MVP. However, due to the limited number of MVPs available for clinicians to choose, the additional burden involved in reporting, and also given the voluntary option to participate as subgroups for reporting the MVPs or the APP, we anticipate that a relatively small number of clinicians will choose to participate as subgroups in the CY 2023 performance period/2025 MIPS payment year. Therefore, we assume there will be 20 subgroups reporters in the CY 2023 performance period/2025 MIPS payment year. We assume that more clinicians will choose to participate as subgroups in future years. We solicited comment on our MVP and subgroup reporting assumptions for the CY 2023 performance period/2025 MIPS payment year.

We received public comments on our MVP and subgroup reporting assumptions for the CY 2023 MIPS performance period/2025 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that our estimate that 10 percent of eligible clinicians would report as MVP participants in the first year of implementation is low. The commenter shared their belief that the number of MVP participants would be higher because of the reduced reporting burden associated with MVP reporting.

Response: We thank the commenter for their feedback. We acknowledge the commenter's concern that our assumptions for MVP reporting are low. We agree with the commenter that MVP reporting is associated with a reduction in reporting burden. However, we believe that our estimates are appropriate because there would be a limited number of MVPs available for all clinicians during the CY 2023 performance period/2025 MIPS payment year. We expect that there would be increased participation in MVP reporting as more MVPs become available for clinicians in future years. We plan to revise our estimates for future years as more data becomes available.

After consideration of public comments, we are finalizing our proposed estimate for the number of MIPS eligible clinicians that would participate in MVP reporting during the CY 2023 performance period/2025 MIPS payment year.

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

Beginning with the CY 2023 performance period/2025 MIPS payment year, we are finalizing that clinicians interested in participating in MIPS through MVP reporting would be required to complete an annual registration process described in section IV.A.3.b.(4)(f) of this rule. At the time of registration, MVP participants would need to select a specific MVP, a population health measure and if administrative claims measures are included in the selected MVP, the MVP participants would also need to choose an applicable administrative claims measure in the MVP. We refer readers to section IV.A.3.b.(4)(f) of this rule for additional details on MVP registration requirements.

Due to the delay in implementation of MVPs to the CY 2023 performance period/2025 MIPS payment year, we anticipate that there is an adequate amount of time for clinicians that historically participate in MIPS to determine if the measures and activities in an MVP are applicable to the scope of care provided. In Table 97, we estimate that the registration process for clinicians choosing to submit MIPS data for the measures and the activities in an MVP would require 0.25 hours of a computer systems analyst's time, similar to the currently approved burden of group registration process for CMS Web Interface finalized in the CY 2021 PFS final rule (85 FR 84983) for the CY 2023 performance period/2025 MIPS payment year. We assume that the staff involved in the MVP registration process will mainly be computer systems analysts or their equivalent, who have an average labor cost of $95.22/hour.

As discussed above, based on data from the CY 2019 performance period/2021 MIPS payment year, we assume that approximately 10 percent of the clinicians that currently participate in MIPS would submit data for the measures and activities in an MVP. Note that we apply this 10 percent calculation after adding the clinicians who begin submitting though the CQM and eCQM collection types due to the sunset of Web Interface in the CY 2023 performance period/2025 MIPS payment year. For the CY 2023 performance period/2025 MIPS payment year, we assume that a total of 25,798 submissions will be received for the measures and activities included in MVPs. This total includes our estimate of 20 subgroup reporters that would also be reporting MVPs in addition to MVP reporters who currently participate in MIPS. Therefore, we assume that the total number of individual clinicians, groups, subgroups and APM Entities to complete the MVP registration process is 12,917. We estimate that the total cost to clinicians participating as individuals and groups associated with the MVP registration process would be approximately $307,465. Table 97 includes our burden assumptions related to the MVP registration process for clinicians participating in MIPS for

reporting MVPs as individuals, groups, subgroups, and APM Entities.

TABLE 97: Total Estimated Burden for MVP Registration (Individual clinicians, Groups, Subgroups and APM Entities)

Burden and Respondent Descriptions	CY 2023 Burden Estimate
Estimated # of Individual clinicians, groups, subgroups and APM Entities Registering (a)	12,917
Estimated Total Annual Burden Hours Per Registration (b)	0.25
Estimated Total Annual Burden Hours for MVP Registration (c) = (a) * (b)	**3,229***
Estimated Cost Per MVP (@ computer systems analyst's labor rate of $95.22/hr. (d)	95.22
Estimated Total Annual Burden Cost for MVP Registration (e) = (c) * (d)	**$307,465***

*Due to burden being estimated in fractions of minutes and hours, totals may reflect impact of rounding.

(ii) Burden for Subgroup Registration

We are finalizing the proposal to add a separate ICR to estimate the burden associated with subgroup registration to capture the subgroup registration requirements in section IV.A.3.b.(4)(f)(ii)(D) of this rule. In section IV.A.3.b.(3)(b)(ii) of this rule, we finalized the definition of a subgroup at § 414.1305 as a subset of a group, as identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI. In addition to the burden for MVP registration process described above, clinicians who choose to form subgroups for reporting the MVPs or the APP will need to submit a list of each TIN/NPI associated with the subgroup and a plain language name for the subgroup in a manner specified by CMS, described in section IV.A.3.b.(4)(f)(ii)(D) of this rule.

As discussed above, we estimate that clinicians will choose to form 20 subgroups for reporting the measures and activities in MVPs. Additionally, we estimate that clinicians who choose to participate as subgroups for reporting MVPs will require a minimum of 0.5 hours per subgroup respondent to submit the finalized requirements for subgroup registration. We assume that the staff involved in the subgroup registration process will mainly be computer systems analysts or their equivalent, who have an average labor cost of $95.22/hr.

We assume that all subgroups would report MVPs, the burden associated with subgroup quality reporting will be included with the MVP quality reporting ICR. The burden associated with subgroup submissions for Promoting Interoperability and improvement activities will be included with those ICRs.

TABLE 98: Total Estimated Burden for Subgroup Registration CY 2023 Performance Period/2025 MIPS Payment Year

Burden and Respondent Descriptions	CY 2023 Burden Estimate
Estimated # of Subgroups Registering(a)	20
Estimated Total Annual Burden Hours Per Subgroup (b)	0.5
Estimated Total Annual Burden Hours for Subgroup Reporting (c) = (a) * (b)	**10**
Estimated Cost Per Subgroup (@ computer systems analyst's labor rate of $95.22/hr. (d)	$95.22
Estimated Total Annual Burden Cost for Subgroup Registration (e) = (a) * (d)	**$952**

(iii) Burden for MVP Quality Performance Category Submission

In the CY 2017 PFS final rule (81 FR 77100 through 77114), we established the submission criteria for quality measures (excluding the CMS Web Interface measures and the CAHPS for MIPS survey measure) at § 414.1335, which requires a MIPS eligible clinician, group, or virtual group that is reporting on Qualified Clinical Data Registry (QCDR) measures, MIPS clinical quality measures (MIPS CQMs), electronic CQMs (eCQMs), or Medicare Part B claims measures to submit data on at least six measures, including at least one outcome measure. As discussed in section IV.A.3.b.(4)(d)(ii) of this final rule, we finalized the proposal that except as provided in paragraph

§ 414.1365(c)(1)(i), an MVP Participant must select and report 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure, included in the MVP. The decrease in the number of required measures in the quality performance category from 6 to 4 is a two-thirds reduction in the number of measures needed for eligible clinicians to submit data for the quality performance category in MVPs described in Appendix 3: MVP Inventory of this final rule. Therefore, we estimate that the time for submitting the measures in the MVP quality performance category would, on average, take two-thirds of the currently approved burden per respondent for the quality performance category as it does to complete a MIPS quality submission through the CQM, eCQM, and Claims submission types.

As described above in this section of the final rule, we estimate that 10 percent of the clinicians who participated in MIPS for the CY 2019 performance period/2021 MIPS payment year would submit data for the quality performance category of MVPs beginning with the CY 2023 performance period/2025 MIPS payment year. We anticipate that there would be 20 subgroups reporters in the CY 2023 performance period/2025 MIPS payment year. As shown in Table 99, we estimate that approximately 2,825 clinicians would submit data for the MVP quality performance category using the Medicare Part B claims collection type; approximately 5,210 clinicians and 10 subgroups would submit data using MIPS CQM and QCDR collection type; and approximately 4,862 clinicians and 10 subgroups would submit data using eCQMs collection type. We want to note that we used the same methodologies used in sections V.B.8.e.(4), V.B.8.e.(5) and V.B.8.e.(6) to estimate the quality submission burden for each collection type. As shown in Table 99, for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 26,670 hours (9.44 hr × 2,825 clinicians) at a cost of $2,691,329 (2,825 respondents × 952.68/respondent) for the Medicare Part B claims collection type, 31,163 hours [5.97 hr × 5,220 (5,210 + 10)] at a cost of $3,211,216 (5,220 × 615.18/respondent) for the MIPS CQM and QCDR collection type, and 25,822 hours [5.3 hr × 4,872 (4,862 + 10) respondents] at a cost of $2,662,191 (4,872 × 546.43/respondent) for the eCQM collection types.

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TABLE 99: Estimated Burden for Quality Performance Category: Clinicians Submitting Data for MVPs in CY 2023

Burden and Respondent Descriptions	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from pre-existing collection types (a)	4,862	5,210	2,825
# of Subgroup reporters (b)	10	10	0
Total MVP participants (c) = (a) + (b)	4,872	5,220	2,825
Hours Per Clinician to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) * (j)	**25,822**	**31,163**	**26,688**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr @ varying times) (k)	$126.64	$190.44	$457.06
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr) (l)	$151.94	$151.94	$228.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr) (m)	$62.85	$62.85	$62.85
Cost to Review Measure Specifications (@ LPN's labor rate of $48.16/hr) (n)	$31.79	$31.79	$31.79
Cost to Review Measure Specifications (@ billing clerk's labor rate of $40.02/hr) (o)	$26.41	$26.41	$26.41
Cost to Review Measure Specifications (@ physician's labor rate of $217.32/hr) (p)	$144.88	$144.88	$144.88
*Total Annual Cost Per Clinician (q) = (k) + (l) + (m) + (n) + (o) + (p)	$546.43	$615.18	$952.68
***Total Annual Cost (r) = (c) * (q)**	**$2,662,191**	**$3,211,216**	**$2,691,329**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

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(8) Quality Data Submission via CMS Web Interface

The finalized requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Background

In the CY 2021 PFS final rule, we finalized our policy to sunset the CMS Web Interface measures as a collection type/submission type starting with the CY 2022 performance period/2024 MIPS payment year. As a result of this provision, for the CY 2022 performance period/2024 MIPS payment year, we estimated a burden of zero due to our assumption that all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types (85 FR 84981).

In section IV.A.3.d.(1)(d) of this rule, we are finalizing to continue the CMS Web Interface measures as a collection type for the CY 2022 performance period/2024 MIPS payment year. Additionally, we are finalizing to sunset the CMS Web Interface measures as a collection type for the CY 2023 performance period/2025 MIPS payment year. For this final rule, we estimate burden for the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years.

For the CY 2022 performance period/2024 MIPS payment year, we assume that 114 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the CY 2019 performance period/2021 MIPS payment year. This is an increase of 114 groups from the currently approved number of 0 groups provided in the CY 2021 PFS final rule (85 FR 84981 due to the provision to continue with the CMS Web Interface as a collection type for the CY 2022 performance period/2024 MIPS payment year. We estimate that 44,385 clinicians will submit as part of groups via this method, an increase of 44,385 from our currently approved estimate of 0 clinicians.

The estimated burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is

prepopulated in the CMS Web Interface. Our burden estimate for submission includes the time (61 hours and 40 minutes or 61.67 hours) needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate a burden for the CY 2022 performance period/2024 MIPS payment year of 7,030 hours (114 groups × 61.67 hr) at a cost of $669,433 (114 groups × $5,872.21/group). For the CY 2023 performance period/2025 MIPS payment year, we are finalizing to revise our estimated burden to zero due to our assumption that with the finalized policy to sunset the CMS Web Interface as a collection type, all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types. Based on the assumptions discussed in this section, Table 100 summarizes the finalized estimated burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 100: Estimated Burden for Quality Data Submission via the CMS Web Interface

Burden and Respondent Descriptions	CY 2022 MIPS Performance Period	CY 2023 MIPS Performance Period
# of Eligible Group Practices (a)	114	0
Total Annual Hours Per Group to Submit (b)	61.67	0
Total Annual Hours (c) = (a) * (b)	7,030	0
Cost Per Group to Report (@ computer systems analyst's labor rate of $95.22/hr) (d) = ($95.22/hr) * (b)	$5,872.21	0
Total Annual Cost (e) = (a) * (d)	$669,433	0

TABLE 101: Change in Estimated Burden for Quality Data Submission via the CMS Web Interface

Burden and Respondent Descriptions	CY 2021 MIPS Performance Period	CY 2022 MIPS Performance Period	CY 2023 MIPS Performance Period
Total Currently Approved Annual Hours (a)	6,845	0	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (see Table 100, row (c))	0	7,030	0
Difference (c) = (b)-(a)	**-6,845**	**+7,030**	**0**
Total Currently Approved Annual Cost (d)	$651,816	$0	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (see Table 100, row (e))	0	$669,433	0
Difference (f) = (e)-(d)	**-$651,816**	**+$669,433**	**0**

(9) Beneficiary Responses to CAHPS for MIPS Survey

This rule is not implementing any new or revised collection of information requirements or burden related to the CAHPS for MIPS survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any changes to the CAHPS for MIPS Survey process under that control number.

(10) Group Registration for CMS Web Interface

The finalized requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2021 PFS final rule, we finalized to sunset the CMS Web Interface measures as a collection type/submission type starting with the CY 2022 performance period/2024 MIPS payment year. As a result, we estimated that there will be zero hours and $0 burden for group registration for the CMS Web Interface for the CY 2022 performance period/2024 MIPS payment year (85 FR 84984). As discussed in section IV.A.3.d.(1)(d) of this final rule, we are finalizing to continue the CMS Web Interface measures as a collection type for the CY 2022 performance period/2024 MIPS payment year. We are also finalizing to sunset the CMS Web Interface as a collection type starting with the CY 2023 performance period/2025 MIPS payment year.

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an online registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 102, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $95.22/hr for a computer systems analyst (or their equivalent) to register the group.

Because we are finalizing to sunset the CMS Web Interface beginning with the CY 2023 performance period/2025 MIPS payment year, it is possible that fewer groups will elect to register to submit quality data for the first time in the performance year prior to the collection type/submission type no longer being available; however, we currently have no data with which to estimate what the associated reduction may be. Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84983), we continue to assume that approximately 90 groups will elect to use the CMS Web Interface for the first time during the CY 2022 performance period/2025 MIPS payment year based on the estimated number of new registrations during the CY 2021 performance period/2023 MIPS payment year. As shown in Table 102, we estimate a burden of 23 hours (90 new registrations × 0.25 hr/registration) at a cost of $2,190 (22.5 hr × $95.22/hr).

TABLE 102: Estimated Burden for Group Registration for CMS Web Interface

Burden and Respondent Descriptions	Burden Estimate
Number of New Groups Registering for CMS Web Interface (a)	90
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a) * (b)	23
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (a) * (d)	$2,190

As shown in Table 103, the estimated increase in the number of groups registering for the CMS Web Interface collection type to submit the MIPS data and the estimated increase in burden per respondent results in adjustment to the total time burden of +23 hours (+90 respondents × 0.25 hr/respondent) at a cost of $2,190 for the CY 2022 performance period/2024 MIPS payment year. For the CY 2023 performance period/2025 MIPS payment year, our finalized burden estimate is zero hours and $0.

TABLE 103: Change in Estimated Burden for Group Registrations for the CMS Web Interface

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	22.5	0	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 102, row (c))	0	23	0
Difference (c) = (b) - (a)	**-22.5**	**+23**	**0**
Total Currently Approved Annual Cost (d)	$2,142	0	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 102, row (e))	0	$2,190	0
Difference (f) = (e) - (d)	**-$2,142**	**+$2,190**	**0**

(11) Group Registration for CAHPS for MIPS Survey

This rule is not implementing any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any changes to the CAHPS for MIPS Survey registration process under that control number.

f. ICRs Regarding the Call for MIPS Quality Measures

This rule is not implementing any new or revised collection of information requirements or burden related to the call for MIPS quality measures. However, outside of the rulemaking process we replaced the existing tool for stakeholders beginning with the 2021 Annual Call for Measures. As described below, to account for the updated tool (MERIT), we are finalizing to revise our currently approved burden estimates. The updated tool and revised burden will be submitted to OMB under control number 0938–1314 (CMS–10621).

Beginning with the 2021 Annual Call for Measures, we replaced the customary Office of the National Coordinator (ONC) Issue Tracking System Jira platform that stakeholders

used to submit candidate quality measure specifications and all supporting data files for CMS review with the MUC Entry/Review Information Tool (MERIT). For the ONC Issue Tracking System Jira platform used by stakeholders, the approved estimated time for a practice administrator to identify, propose, and link to a quality measure is 0.9 hours and for a clinician to identify, propose, link to quality measure, and complete the Peer Review Journal Article form is 4.6 hours (0.6 hours to identify, propose, and link to quality measure (84 FR 63132) and 4 hours to complete the Peer Review Journal Article Form (84 FR 63133), with a total estimated time of 5.5 hours per quality measure submission. Based on the stakeholder experience with the updated tool and additional information collected at the time of submission, we estimate that it will add approximately 1.5 hours for the practice administrator at $114.24/hr and 0.5 hours at $217.32/hr for a clinician to identify, propose, and link the quality measure, and reduce approximately 2 hours at $217.32/hr for a clinician to complete the Peer Review Journal Article Form, resulting in a new estimated time of 2.4 hours for a practice administrator and 3.1 hours for a clinician, and an unchanged total estimated time of 5.5 hours per quality measure submission. In order to account for the implementation of the MERIT tool starting with the 2021 Annual Call for Measures, we are revising the estimated time required for a practice administrator to identify, propose, and link to a quality measure to 2.4 hours (from 0.9 hr) and a clinician to identify, propose, link to quality measure, and complete the Peer Review Journal Article Form to 3.1 hours (from 4.6 hr), resulting in a total estimated time of 5.5 hours per quality measure submission. Based on the number of submissions received during the CY 2020 Call for Quality Measures process, we anticipate receiving the same number of 28 submissions during the CY 2021 Call for Quality Measures process (84 FR 63132).

Although the total estimated time of 5.5 hours for completing a quality measure submission using the MERIT tool (see Table 104) is the same estimated time as the ONC Issue Tracking System Jira platform, we need to account for the changes to the individual components of the estimated time required by a practice administrator and clinician using the MERIT tool. Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84984), we estimate an annual burden of 154 hours (28 submissions × 5.5 hr/measure). Thus, we are finalizing to adjust our estimated annual burden from $30,197 (28 submissions × [(0.9 hr × $110.74/hr) + (4.6 hr × $212.78/hr)) to $26,541 (28 measures × [(2.4 hr × $114.24/hr) + (3.1 hr × $217.32/hr)]) a difference of −$4,329 for the CY 2022 performance period/2024 MIPS payment year.

TABLE 104: Estimated Burden for Call for Quality Measures

	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	28
# of Hours per Practice Administrator to Identify, Propose and Link Measure (b)	2.4
# of Hours per Clinician to Identify and Link Measure (c)	1.1
# of Hours per Clinician to Complete Peer Review Article Form (d)	2
Annual Hours Per Response (e) = (b) + (c) + (d)	5.5
Total Annual Hours (f)=(a)*(e)	**154**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $114.24/hr) * 2.4 hr = (g)	$274.20
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ clinician's labor rate of $217.32/hr) * 3.1 hr = (h)	$673.69
Total Annual Cost Per Submitted Measure (i)	$947.89
***Total Annual Cost (j)=(a)*(i)**	**$26,541**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 105, using our currently approved burden estimates, the redistribution of the estimated time needed for the clinician and practice administrator as discussed above, we are estimating an adjustment of 0 hours at a cost of −$4,329 for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of $26,541 (28 measures × $947.89/respondent).

TABLE 105: Change in Estimated Burden for Call for Quality Measures

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	154	154	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 104, row (c))	0	154	154
Difference (c) = (b) - (a)	**-154**	**0**	**+154**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$30,870	$30,870	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 104, row (e))	0	$26,541	$26,541
Difference (f) = (e) - (d)	**-$30,870**	**-$4,329**	**+$26,541**

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2022 performance period/2024 MIPS payment year, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis, and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The finalized requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), CY 2019 PFS final rule (83 FR 60011 through 60012), CY 2020 PFS final rule (84 FR 63134 through 63135), and the CY 2021 PFS final rule (85 FR 84984 through 84985) for our previously finalized requirements and burden for reweighting applications for Promoting Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting of the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting of the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

Table 106 summarizes the burden for clinicians to apply for reweighting of the Promoting Interoperability performance category to zero percent due to a significant hardship exception or as a result of a decertification of an EHR. Based on the number of reweighting applications received by March, 2021 for the CY 2020 performance period/2022 MIPS payment year, we assume 20,192 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship or EHR decertification and an additional 22,635 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activities performance categories due to an extreme or uncontrollable circumstance. For the CY 2022 performance period/2024 MIPS payment year, we estimate that a total of 42,797 reweighting applications will be submitted. This is a decrease of 9,302 respondents compared to our currently approved estimate of 52,099 respondents (85 FR 84984). This decrease is likely due to the provision in section IV.A.3.e.(2)(b)(iv)(A) of this rule to automatically reweight the Promoting Interoperability performance category for small practices who previously had to apply for reweighting. For the CY 2020 performance period/2024 MIPS payment year, 13,894 respondents requested reweighting due to significant hardship for small practices. Similar to the data used to estimate the number of respondents in the CY 2021 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. Similar to our assumptions in the CY 2021 PFS final rule (85 FR 84984), our respondent estimate does not include reweighting

applications submitted during the extended period ending November 29, 2021 due to the PHE for COVID–19, as we do not believe it would be an accurate basis of future estimates for reweighting application submissions. We assume that, out of our total respondent count of 42,797 above, we estimate that 22,605 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR.

In the CY 2021 PFS final rule (85 FR 84984) we discussed that, beginning with the CY 2019 performance period/2021 MIPS payment year, APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. As discussed in this section of this final rule, due to data limitations and our inability to determine who will use the APP versus the traditional MIPS submission mechanism for the CY 2022 performance period/2024 MIPS payment year, we assume ACO APM Entities will submit data through the APP and non-ACO APM Entities will participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. Therefore, we limited our analysis to ACOs that were eligible for an exception due to extreme and uncontrollable circumstances during the CY 2020 performance period/2022 MIPS payment year and elected not to report quality data. Based on this data, we estimate that 30 APM Entities will submit an extreme and uncontrollable circumstances exception application for the CY 2022 performance period/2024 MIPS payment year. Combined with our aforementioned estimate of 42,797 eligible clinicians and groups, the total estimated number of respondents for the CY 2022 performance period/2024 MIPS payment year is 42,827.

Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84984–84985), we continue to estimate it will take 0.25 hours for a computer system analyst to complete and submit the application. As shown in Table 106, we estimate an annual burden of 10,707 hours (42,827 applications × 0.25 hr/application) and $1,019,521 (10,707 hr × $95.22/hr).

TABLE 106: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	42,797
# APM Entities requesting Extreme and Uncontrollable Circumstances exception (b)	30
Total Applications Submitted (c)	42,827
Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	**10,707**
Labor Rate for a computer systems analyst (f)	$95.22/hr
Total Annual Cost (g) = (e) * (f)	**$1,019,521**

As shown in Table 107, using our currently approved burden estimates, the decrease in the estimated number of respondents (from 52,099 to 42,827 respondents) results in an adjustment of minus 2,318 hours (9,272 respondents × 0.25 hr/respondent) and minus $220,720 for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 10,707 hours (42,827 respondents × 0.25 hr/respondent) and $1,019,521 (10,707 hours × $95.22/respondents).

TABLE 107: Adjusted Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	13,025	13,025	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 106, row (c))	0	10,707	10,707
Difference (c) = (b) - (a)	**-13,025**	**-2,318**	**+10,707**
Total Currently Approved Annual Cost (d)	$1,240,241	$1,240,241	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 106, row (e))	0	$1,019,521	$1,019,521
Difference (f) = (e) - (d)	**-$1,240,241**	**-$220,720**	**+$1,019,521**

(3) Submitting Promoting Interoperability Data

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509 through 77511), CY 2018 Quality Payment Program final rule (82 FR 53919 through 53920), CY 2019 PFS final rule (83 FR 60013 through 60014), CY 2020 PFS final rule (84 FR 63135 through 63137), and the CY 2021 PFS final rule (85 FR 84985 through 84987) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In section IV.A.3.d.(4)(d)(ii) of this final rule, we are finalizing the additional requirement that MIPS eligible clinicians must attest to conducting an annual assessment of the High Priority Guides of the SAFER Guides beginning with the CY 2022 performance period/2024 MIPS payment year. Clinicians will complete this attestation by checking a box when they submit their Promoting Interoperability performance category data. We estimate that this requirement will add an additional minute to the current estimated time it takes to complete the submission of Promoting Interoperability data. In the CY 2022 PFS proposed rule, we assumed no change in estimates as result of the proposal to modify the Provide Patients Electronic Access to Their Health Information measure to require MIPS eligible clinicians to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely (86 FR 39509). As discussed in section IV. of this final rule, this policy is not being finalized as proposed at this time.

As shown in Table 108, based on data from the CY 2019 performance period/ 2021 MIPS payment year, we estimate that a total of 51,647 respondents consisting of 40,172 individual MIPS eligible clinicians and 11,475 groups and virtual groups will submit Promoting Interoperability data. Since our CY 2021 PFS final rule estimated 53,636 respondents, this represents a decrease of 1,989 respondents (51,647 respondents − 53,636 active respondents).

We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APP. As a result, we do not anticipate any change in burden. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 through 59823). Burden estimates for this final rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants.

TABLE 108: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians in CY 2022

Burden and Respondent Descriptions	# of Respondents
Number of individual clinicians to submit Promoting Interoperability (a)	40,172
Number of groups to submit Promoting Interoperability (b)	11,475
Total Respondents in CY 2022 performance period (CY 2022 PFS Final Rule) (c) = (a) + (b)	51,647
*Total Respondents in CY 2021 performance period (CY 2021 PFS Final Rule) (d)	53,636
Difference (e) = (c) – (d)	-1,989

As discussed in section IV.A.3.b.(2)(c)(ii) of this final rule, we will be introducing subgroup reporting in CY 2023 performance period/2025 MIPS payment year. As we discussed above in this section of the final rule, we estimate that there will be 20 subgroup submissions in CY 2023 performance period/2025 MIPS payment year, each of which will have burden related to the submission of Promoting Interoperability data. We have included this burden in Table 109.

TABLE 109: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians in CY 2023

Burden and Respondent Descriptions	# of Respondents
Number of individual clinicians to submit Promoting Interoperability in CY 2023 (a)	40,172
Number of groups to submit Promoting Interoperability in CY 2023 (b)	11,475
# of Subgroups to submit Promoting Interoperability in MVPs during the CY 2023 MIPS performance period (c)	20
Total Respondents in 2023 MIPS performance period (CY 2022 PFS Final Rule) (d) = (a) + (b) + (c)	51,667
*Total Respondents in 2021 MIPS performance period (CY 2021 PFS Final Rule) (e)	0
Difference (f) = (d) – (e)	+51,667

With the inclusion of the additional minute (0.02 hr) to attest to conducting an annual assessment of the High Priority Guides of the SAFER Guides, we are adjusting our estimate of the time required for an individual or group to submit Promoting Interoperability data from 2.67 hours to 2.69 hours (2.67 hr + 0.02 hr). As shown in Table 110, the total burden estimate for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 138,930 hours (51,647 respondents × 2.69 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $13,228,915 (138,930 hr × $95.22/hr)).

TABLE 110: Estimated Burden for Promoting Interoperability Performance Category Data Submission in CY 2022

Burden and Respondent Descriptions	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	40,172
Number of groups to submit Promoting Interoperability (b)	11,475
Total (c) = (a) + (b)	51,647
Total Annual Hours Per Respondent (d)	2.69
Total Annual Hours (e) = (c) * (d)	**138,930**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (f)	$95.22/hr
Total Annual Cost (g) = (e) * (f)	**$13,228,915**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 111, with the introduction of subgroup reporting in CY 2023 performance period/2025 MIPS payment year, the total burden for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 138,984 hours (51,667 respondents × 2.69 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $13,234,078 (138,984 hr × $95.22/hr)).

TABLE 111: Estimated Burden for Promoting Interoperability Performance Category Data Submission in CY 2023

Burden and Respondent Descriptions	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	40,172
Number of groups to submit Promoting Interoperability (b)	11,475
Number of subgroups to submit Promoting Interoperability (c)	20
Total (d) = (a) + (b) + (c)	51,667
Total Annual Hours Per Respondent (e)	2.69
Total Annual Hours (f) = (d) * (e)	**138,984**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (g)	$95.22/hr
Total Annual Cost (h) = (f) * (g)	**$13,234,078**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

Table 112, using our updated per respondent burden estimate (+0.02 hr/response), the decrease in number of respondents and SAFER guide attestation requirement results in a total adjustment of −4,278 hours at a cost of −$407,351 for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 138,984 hours (51,667 respondents × 2.69 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $13,234,078 (138,984 hours × $95.22/hour).

TABLE 112: Change in Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance period
Total Currently Approved Annual Hours (a)	143,208	143,208	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (see Table 111, row (f))	0	138,930	138,984
Difference (c) = (b) - (a)	**-143,208**	**-4,278**	**+138,984**
Total Currently Approved Annual Cost (d)	$13,636,266	$13,636,266	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (see Table 111, row (h))	0	$13,228,915	$13,234,078
Difference (f) = (e) - (d)	**-$13,636,226**	**-$407,351**	**+$13,234,078**

h. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule is not implementing any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the process for nomination of Promoting Interoperability measures under that control number.

i. ICR Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

The finalized requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512), CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922), CY 2019 PFS final rule (83 FR 60015 through 60017), CY 2020 PFS final rule (84 FR 63138 through 63140) and the CY 2021 PFS final rule (85 FR 84987 through 84989) for our previously finalized requirements and burden for submission of data for the improvement activities performance category.

In section IV.A.3.d.(3) of this rule, we are finalizing to: (1) Revise group reporting requirements for the 50 percent threshold to address subgroups; (2) add 7 new improvement activities, modify 15 existing improvement activities, and remove 6 previously adopted improvement activities for the CY 2022 performance period/2024 MIPS payment year and future years; (3) revise the ''Drug Cost Transparency to include requirements for use of real-time benefit tools'' improvement activity; and (4) add the COVID–19 ''Clinical Data Reporting with or without Clinical Trial'' improvement activity for CY 2022 performance period/2024 MIPS payment year and future years. Additionally, we are finalizing to adjust our currently approved burden estimates based on more recent data.

Specifically, we are finalizing to revise § 414.1360(a)(2) to state that, beginning with the CY 2023 performance period/2025 MIPS payment year, each improvement activity for which groups and virtual

groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year. In section IV.A.3.d.(3)(b) of this rule, we discussed stakeholder requests through the Quality Payment Program help desk to apply the 50 percent threshold to a portion of clinicians in a group. We anticipate that clinicians will find applicable and meaningful activities specific to practice size, specialty, or practice setting. Therefore, we assume that the provision to apply the 50 percent minimum threshold to clinicians who submit for the improvement activity performance category as part of groups, virtual groups, or choose to participate as subgroups beginning with the CY 2023 performance period/2025 MIPS payment year will not present additional complexity or burden.

We do not believe the changes to the improvement activities inventory will impact time or financial burden on stakeholders because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. Therefore, we are not adjusting the estimated time of 5 minutes (per response) currently approved for improvement activities submission.

As represented in Table 113, based on data from the CY 2019 performance period/2021 MIPS payment year, we estimate that a total of 81,562 respondents consisting of 63,845 individual clinicians and 17,717 groups will submit improvement activities during the CY 2022 performance period/2024 MIPS payment year. Since our currently approved burden sets out 79,927 respondents, this represents an increase of 1,635 respondents (81,562 respondents − 79,927 active respondents). This is an increase of 1,242 individuals and 393 groups from the estimates of 62,603 individuals and 17,324 groups provided in the CY 2021 PFS final rule (85 FR 50362).

As discussed in sections V.B.8.e. and V.B.8.g.(3) of this final rule regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we are finalizing to update our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or participating in an ACO in the CY 2019 performance period/2021 MIPS payment year but will be QPs in the CY 2022 performance period/2024 MIPS payment year, and will therefore not be required to submit improvement activities data.

TABLE 113: Estimated Number of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians in CY 2022

Burden and Respondent Descriptions	Count
# of clinicians to participate in improvement activities data submission as individuals during the CY 2022 MIPS performance period (a)	63,845
# of Groups to submit improvement activities on behalf of clinicians during the CY 2022 MIPS performance period (b)	17,717
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2022 MIPS performance period (CY 2022 Final Rule) (c) = (a) + (b)	81,562
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2020 MIPS performance period (CY 2021 PFS Final Rule) (d)	79,927
Difference (e) = (c) - (d)	**+1,635**

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

As discussed in section IV.A.3.b.(2)(c)(ii) of this final rule, we are finalizing subgroup reporting in the CY 2023 performance period/2025 MIPS payment year. As we discussed in section V.B.8.e.(7)(a) of this final rule, we estimate that there will be 20 subgroup reporters in the CY 2023 performance period/2025 MIPS payment year, each of which will have burden related to the submission of improvement activities. We have included this burden in Table 114.

TABLE 114: Estimated Number of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians in CY 2023

Burden and Respondent Descriptions	Count
# of clinicians to participate in improvement activities data submission as individuals during the CY 2023 MIPS performance period (a)	63,845
# of Groups to submit improvement activities on behalf of clinicians during the CY 2023 MIPS performance period (b)	17,717
# of Subgroups to submit improvement activities in MVPs during the CY 2023 MIPS performance period (c)	20
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 MIPS performance period (CY 2022 PFS Final Rule) (d) = (a) + (b) + (c)	81,582
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2020 MIPS performance period (CY 2021 PFS Final Rule) (e)	0
Difference (f) = (d) - (e)	**+81,582**

Consistent with the CY 2021 PFS final rule, we continue to estimate that the per response time required per individual or group is 5 minutes for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials (84 FR 63140).

As shown in Table 115, we estimate an annual burden of 6,770 hours (81,562 responses × 0.083 hr) at a cost of $644,639 (6,770 hr × $95.22/hr)) for the CY 2022 performance period/2024 MIPS payment year.

TABLE 115: Estimated Burden for Improvement Activities Submission in CY 2022

Burden and Respondent Descriptions	Burden Estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2022 performance period (a)	81,562
Total Annual Hours Per Respondent (b)	0.083
Total Annual Hours (c) = (a) * (b)	**6,770**
Labor rate for a computer systems analyst to submit improvement activities (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$644,639**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 116, with the introduction of subgroup reporting in the CY 2023 performance period/2025 MIPS payment year, we estimate an annual burden of 6,771 hours (81,582 responses × 0.083 hr) and $644,735 (6,771 hr × $95.22/hr).

TABLE 116: Estimated Burden for Improvement Activities Submission in CY 2023

Burden and Respondent Descriptions	Burden Estimate
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 performance period (a)	81,582
Total Annual Hours Per Respondent (b)	0.083
Total Annual Hours (c) = (a) * (b)	**6,771**
Labor rate for a computer systems analyst to submit improvement activities (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$644,735**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 117, using our unchanged currently approved per respondent burden estimate, the increase in the number of respondents results in an adjustment of 109 hours at a cost of $10,379 (109 hr × $95.22/hr) for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 6,771 hours (81,582 responses × 0.083 hr) at a cost of $644,735 (6,771 hr × $95.22/hr).

TABLE 117: Change in Estimated Burden for Improvement Activities Submission

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	6,661	6,661	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 116, row (c))	0	6,770	6,771
Difference (c) = (b) - (a)	**-6,661**	**+109**	**+6,771**
Total Currently Approved Annual Cost (d)	$634,221	$634,260	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 116, row (e))	0	$644,639	$644,735
Difference (f) = (e) - (d)	**-$634,221**	**+10,379**	**+$644,735**

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53922), CY 2019 PFS final rule (83 FR 60017 through 60018), CY 2020 PFS final rule (84 FR 63141) and the CY 2021 PFS final rule (85 FR 84989 through 85 FR 84990) for our previously finalized requirements and information collection burden for the nomination of improvement activities.

In section IV.A.3.d.(3)(c)(i)(B) of this rule, we are finalizing: (1) To revise the required criteria for improvement activity nominations received through the Annual Call for Activities; (2) changes to the timeline for improvement activities nomination during a PHE; and (3) to suspend activities that become obsolete or impacted by clinical practice guideline changes from the program when this occurrence happens outside of the rulemaking process.

In section IV.A.3.d.(3)(c)(i)(B)(cc) of this rule, we are finalizing 2 new criteria that beginning with the CY 2022 Annual Call for Activities MIPS improvement activities: (1) Should not duplicate other improvement activities in the Inventory; and (2) should drive improvements that go beyond purely common clinical practices.

Additionally, we are finalizing to increase the number of criteria stakeholders are required to meet when submitting an activity provision from a minimum of 1 to all 8 criteria, which includes the two new provision criteria. We believe that this provision will provide clearer guidance to stakeholders when submitting a nomination for an improvement activity. In the CY 2021 PFS final rule, we estimated that it would require 0.6 hours for a medical and health services manager or equivalent and 0.4 hours for a physician to link the nominated improvement activity to existing and related cost and quality measures (85 FR 84989). Given that our current approved estimated time per respondent to nominate an improvement activity is 3 hours (1.8 hours for a medical and health services manager or equivalent and 1.2 hours for a physician), we assume that the new requirement to meet all 8 criteria will require approximately 1 hour at $114.24/hr for a medical and health services manager to identify and submit an activity and 0.4 hours at a rate of $217.32/hr for a clinician to review each activity. Combined with our currently approved burden estimate, we are finalizing to revise our estimate to 2.8 hours at $114.24/hr for a medical and health services manager or equivalent and 1.6 hours at $217.32/hr for a physician to nominate an improvement activity. This represents a change of +1

hours (2.8 hr − 1.8 hr) for a medical and health services manager or equivalent and +0.4 hours (2 hr − 1.6 hr) for a physician and an overall increase of 1.4 hours. We considered whether we should double our estimates for nomination of an improvement activity to 6 hours. Since only 2 of the required 8 criteria are new, we assume that stakeholders are familiar with the existing criteria and will not need additional time to review but will need the additional time to verify and confirm if the considered activity meets all the 8 criteria. We solicited comment on our estimate to revise the time for nomination of an improvement activity to 4.4 hours and if there are additional burden implications that we should consider for above provisions to revise the criteria.

We did not receive public comments on the proposed burden estimates for this information collection. We are finalizing as proposed. The burden estimates have not been updated from the CY 2021 PFS proposed rule (86 FR 39514 through 39516).

In the CY 2021 PFS final rule, we finalized an exception stating that during the PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe (85 FR 84989). Instead of only accepting nominations and modifications submitted February 1st through July 1 each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). In section IV.A.3.d.(3)(c)(i)(B)(aa) of this rule, we are finalizing to clarify that in order to implement a new improvement activity for a PHE during the same year as the nomination, the nomination will need to be received no later than January 5th of the nomination year to be included in a rule for notice-and-comment rulemaking during that fiscal or calendar year, a necessary precursor to implementation if it were to be finalized, as described above.

We believe this provision will not affect our currently approved burden estimates since we assume that the number of nominations will not change, but it will make an activity available for reporting to clinicians in the same performance year it was intended to be implemented. Similar to our assumptions in the CY 2021 PFS final rule (85 FR 84989), we expect additional nominations may be received as a result of this change. However, we do not have any data with which to estimate what the additional number may be. As a result, we are not making any changes our currently approved burden estimate.

In section IV.A.3.d.(3)(c)(i)(C)(aa) of this rule, we are finalizing that beginning with the CY 2022 performance period/2024 MIPS payment year, for each improvement activity that is in the Inventory, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline, it will be removed from the program as soon as possible. In the CY 2020 PFS final rule (84 FR 62988 through 62990), we finalized the factors for consideration in removing improvement activities. Following the publication of the CY 2021 PFS proposed rule, the improvement activities team became aware that clinicians could no longer complete the activity from April 1 through December 31, 2020, because one of the improvement activities in the Inventory had expired on March 31, 2020. We do not anticipate any burden for stakeholders because of the above provision as described, the policy does not change requirements for the nomination of improvement activities. This provision will help avoid stakeholder confusion and ensure the accuracy of the available activities in the Inventory. Therefore, we are not making any changes to our estimated burden due to the above policy.

Additionally, consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84990) we continue to use our currently approved assumption that we will receive 31 nominations of new or modified activities which will be evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2023 Improvement Activities Inventory as we believe this estimate is more realistic than basing our estimate on the number of nominations received during the 2021 Annual Call for Activities.

As shown in Table 118, accounting for the change in burden per respondent estimate due to the provision to require all the 8 criteria for nomination of an improvement activity as described above in this section, we are adjusting our estimated annual information collection burden to 136 hours (31 nominations × 4.4 hr/nomination) at a cost of $20,695 (31 × [(2.8 hr × $114.24/hr) + (1.6 hr × $217.32/hr)]).

TABLE 118: Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
# of Nominations of New Improvement Activities (a)	31
# of Hours Per Medical and Health Services Manager to Identify and Nominate Activity (b)	2.8
# of Hours Per Physician to Identify Activity (c)	1.6
Annual Hours Per Respondent (d)= (b) + (c)	4.4
Total Annual Hours (e) = (a) * (d)	**136**
Cost to Identify and Submit Activity (@ medical and health services manager's labor rate of $114.24/hr) (f) = $114.24/hr * (b)	$319.87
Cost to Identify Improvement Activity (@ physician's labor rate of $210.44/hr) (g) = $217.32/hr * (c)	$347.71
Total Annual Cost Per Respondent (h)=(f)+(g)	$667.58
Total Annual Cost (i) = (a) * (h)	**$20,695**

As shown in Table 119, using our unchanged estimate of the number of activities nominated, the increase in the burden per nomination results in a change of 43 hours (31 nominations × 1.4 hr/nomination) at a cost of $6,492 (31 activities × [(1 hr × $114.24/hr) + (0.4 hr × $217.32/hr)]) for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 136 hours (31 nominations × 4.4 hr) at a cost of $20,695 (31 × [(2.8 hr × $114.24/hr) + (1.6 hr × $217.32/hr)]).

TABLE 119: Change in Estimated Burden for Nomination of Improvement Activities

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	93	93	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 118, row (c))	0	136	136
Difference (c) = (b) - (a)	**-93**	**+43**	**+136**
Total Currently Approved Annual Cost (d)	$14,203	$14,203	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 118, row (e))	0	$20,695	$20,695
Difference (f) = (e) - (d)	**-$14,203**	**+$6,492**	**+$20,695**

k. Nomination of MVPs

This rule is not implementing any new or revised collection of information requirements or burden related to the nomination of MVPs for inclusion in the Quality Payment Program. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the MVP nomination process under that control number.

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the policies in this rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not making any changes to this information collection under that control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule is not implementing any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we are finalizing to adjust our currently approved burden estimates based on updated projections for the CY 2022 performance period/2024 MIPS payment year. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As shown in Table 120, based on our predictive QP analysis for the 2022 QP performance period/2024 MIPS payment year, which accounts for historical response rates in the CY 2020 performance period/2022 MIPS payment year, we are revising our estimate that 150 APM Entities and 100 eligible clinicians (representing approximately 9,000 Partial QPs) will make the election to participate as a Partial QP in MIPS, a total of 250 elections which is a decrease of 50 from the 300 elections that are currently approved by OMB under the aforementioned control number. We continue to estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we are revising our estimated annual burden to 63 hours (250 respondents × 0.25 hr/election) and $5,999 (63 hr × $95.22/hr).

TABLE 120: Estimated Burden for Partial QP Election

Burden and Respondent Description	Burden Estimate
# of respondents making Partial QP election (150 APM Entities, 100 eligible clinicians) (a)	250
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a) * (b)	**63**
Labor rate for computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$5,999**

As shown in Table 121, using our unchanged currently approved per respondent burden estimate (85 FR 84991), the decrease in the number of Partial QP elections results in an adjustment of 12.5 hours (−50 elections × 0.25 hr) at a cost of −$1,191 (−12.5 hr × $95.22/hr) for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 63 hours (250 respondents × 0.25 hr/election) at a cost of $5,999 (63 hr × $95.22/hr).

TABLE 121: Change in Estimated Burden for Partial QP Election

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	75	75	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 120, row (c))	0	63	63
Difference (c) = (b) - (a)	**-75**	**-12**	**+63**
Total Currently Approved Annual Cost (d)	$7,142	$7,142	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 120, row (e))	0	$5,999	$5,999
Difference (f) = (e) - (d)	**-$7,142**	**-$1,143**	**+$5,999**

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician Initiated Process (§ 414.1445)

The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1445)

This rule is not implementing any new or revised collection of information requirements related to the Payer-Initiated Process. However, we are adjusting our currently approved burden estimates based on updated projections for the CY 2022 performance period/2024 MIPS payment year.

As shown in Table 122, based on the actual number of requests received in the 2020 QP performance period, we are revising our estimate that for the 2023 QP performance period, 15 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (6 Medicaid payers, 6 Medicare Advantage Organizations, and 3 remaining other payers), a decrease of 65 from the 80 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We are revising our estimated annual burden to 150 hours (15 submissions × 10 hr/submission) and $14,283 (150 hr × $95.22/hr).

TABLE 122: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
# of other payer payment arrangements (3 Medicaid, 3 Medicare Advantage Organizations, 1 remaining other payers) (a)	15
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	**150**
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$14,283**

As shown in Table 123, using our unchanged currently approved per respondent burden estimate (85 FR 84992), the decrease in the number of payer-initiated requests from 800 to 150 results in an adjustment of −650 hours (−65 requests × 10 hr) at a cost of −$61,893 (−650 hr × $95.22/hr) for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 150 hours (15 requests × 10 hr) at a cost of $14,283 (150 hr × $95.22/hr).

TABLE 123: Estimated Change in Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	800	800	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 122, row (c))	0	150	150
Difference (c) = (b) - (a)	**-800**	**-650**	**+150**
Total Currently Approved Annual Cost (d)	$76,176	$76,176	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 122, row (e))	0	$14,283	$14,283
Difference (f) = (e) - (d)	**-$76,176**	**-$61,893**	**+$14,283**

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule is not implementing any new or revised collection of information requirements or burden related to the Eligible-Clinician Initiated Process. As described below, we are adjusting our currently approved burden estimates based on updated projections for the CY 2022 performance period/2024 MIPS payment year. As mentioned above, the new and adjusted burden will be submitted to OMB for approval.

As shown in Table 124, based on the actual number of requests received in the 2020 QP performance period, we estimate that in CY 2022 for the 2023 QP performance period, 15 Eligible-Clinician Initiated request for Other Payer Advanced APM determinations will be submitted, a decrease of 135 from the 150 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We are adjusting our estimated annual burden to 150 hours (15 submissions × 10 hr/submission) and $14,283 (150 hr × $95.22/hr).

TABLE 124: Estimated Burden for Other Payer Advanced APM Identification Determinations: Eligible Clinician Initiated Process

	Burden Estimate
# of other payer payment arrangements from APM Entities and eligible clinicians	15
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	**150**
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$14,283**

As shown in Table 125, using our unchanged currently approved per respondent burden estimate (85 FR 84993), the decrease in the number of eligible clinician-initiated requests from 150 to 15 results in an adjustment of −1,350 hours (−135 requests × 10 hr) at a cost of −$128,547 (−1,350 hr × $95.22/hr) for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 150 hours (15 submissions × 10 hr/submission) at a cost of $14,283 (150 hr × $95.22/hr).

TABLE 125: Estimated Change in Burden for Other Payer Advanced APM Identification Determinations: Eligible Clinician Initiated Process

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	1,500	1,500	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 124, row (c))	0	150	150
Difference (c) = (b) - (a)	**-1,500**	**-1,350**	**+150**
Total Currently Approved Annual Cost (d)	$142,830	$142,830	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 124, row (e))	0	$14,283	$14,283
Difference (f) = (e) - (d)	**-$142,830**	**-$128,547**	**+$14,283**

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule is not implementing any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule is not implementing any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. As described below, we are adjusting our currently approved burden estimates based on data from the CY 2019 performance period/2021 MIPS payment year. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53924 through 53925), CY 2019 PFS final rule (83 FR 60022), CY 2020 PFS final rule (84 FR 63145 through 63146) and the CY 2021 PFS final rule (85 FR 84993) for our previously finalized requirements and burden for voluntary participants to opt-out of public reporting on Physician Compare.

In the CY 2021 PFS final rule (85 FR 84993), we estimated that 10 percent of the clinicians and groups who voluntarily participate in MIPS would opt out of public reporting. Based on the number of opt-out eligible clinicians that chose to opt-out of public reporting in the CY 2019 performance period/2021 MIPS payment year, we are revising our estimates. We anticipate that 0.1 percent of the total clinicians and groups who will voluntarily participate in the CY 2022 performance period/2024 MIPS payment year will also elect not to participate in public reporting. This results in a total of 38 (0.001 × 37,934 voluntary MIPS participants) clinicians and groups, a decrease of 3,448 from the currently approved estimate of 3,486. Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the RIA section of the CY 2019 PFS final rule, we continue to estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

Table 126 shows that for these voluntary participants, we continue to estimate it will take 0.25 hours for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 10 hours (38 requests × 0.25 hr/request) and $952 (10 hr × $95.22/hr).

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TABLE 126: Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	38
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours (c) = (a) * (b)	**10**
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$952**

As shown in Table 127, using our unchanged currently approved per respondent burden estimate, the decrease of 3,448 opt outs by voluntary participants results in an adjustment of −862 hours (−3,448 requests × 0.25 hr) at a cost of $−82,079 (−862 hr × $95.22/hr) for the CY 2022 performance period/2024 MIPS payment year. We are setting forth new burden estimates for the CY 2023 performance period/2025 MIPS payment year, which results in an increase of 10 hours (38 requests × 0.25 hr/request) at a cost of $952 (10 hr × $95.22/hr).

TABLE 127: Estimated Change in Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

Burden and Respondent Descriptions	CY 2021 Performance Period	CY 2022 Performance Period	CY 2023 Performance Period
Total Currently Approved Annual Hours (a)	872	872	N/A
Total Annual Hours for Respondents in CY 2022 PFS Final Rule (b) (See Table 126, row (c))	0	10	10
Difference (c) = (b) - (a)	**-872**	**-862**	**+10**
Total Currently Approved Annual Cost (d)	$82,984	$82,984	N/A
Total Annual Cost for Respondents in CY 2022 PFS Final Rule (e) (See Table 126, row (e))	0	$952	$952
Difference (f) = (e) - (d)	**-$82,984**	**-$82,032**	**+$952**

p. Summary of Annual Quality Payment Program Burden Estimates

Table 128 summarizes this final rule's total burden estimates for the Quality Payment Program for the CY 2021, CY 2022 and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years.

As discussed earlier, for this final rule, we are subtracting the currently approved burden for the CY 2021 performance period/2023 MIPS payment year. As shown in table 128, this represents a decrease in burden of 1,479,672 hours and $144,576,960.

In the CY 2021 PFS final rule, the total estimated burden for the CY 2022 MIPS performance period/2024 MIPS payment year was 1,473,741 hours at a cost of $144,034,968 (85 FR 84994). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2021 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2021 PFS final rule into the CY 2022 performance period/2024 MIPS payment year is 1,468,566 hours at a cost of $148,078,846. These represent a decrease of 5,175 hours and an increase of $4,043,878. To understand the burden implications of the policies in this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2021 PFS final rule into the CY 2022 performance period/2024 MIPS payment year. This burden estimate of 1,424,586 hours at a cost of $143,651,994 reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflect the exclusion of QPs from all MIPS performance categories, a decrease of 43,980 hours and $4,426,813. This burden estimate is lower than the burden approved for information collection related to the CY 2021 PFS final rule due to updated data and assumptions. Our total burden estimate for the CY 2022 performance period/2024 MIPS payment year is 1,428,391 hours and $144,014,757, which represents a decrease of 40,175 hours and $4,068,418 from the CY 2021 PFS final rule. The difference of +3,805 hours (43,980 hours − 40,175 hours) and +$358,395 ($4,426,813 − $4,068,418) between this estimate and the total burden shown in Table 128 is the increase in burden associated with impacts of the policies for the CY 2022 performance period/2024 MIPS payment year, which includes the re-introduction of the CMS Web Interface measures as a collection type/submission type.

Table 128 also offers a comparison between the total currently approved estimated burden from the CY 2021 PFS final rule and our estimated burden for the CY 2023 performance period/2025 MIPS payment year. As discussed above, we are setting forth our estimates for the CY 2023 performance period/2025 MIPS payment year as new burden with no currently approved estimate. Our total burden estimate for the CY 2023 MIPS performance period/2025 MIPS payment year is 1,383,049 hours and $139,501,770.

We have included Table 128 to assist in understanding these differences. Note that the difference between the burden estimates for the CY 2022 and 2023 MIPS performance periods/2024 and 2025 MIPS payment years is entirely due to the policies to introduce MVP and subgroup reporting and sunset the CMS Web Interface measures as a collection type/submission type beginning in the CY 2023 MIPS performance period/2025 MIPS payment year.

TABLE 128: Summary of Burden Estimates and Requirements from the CY 2022 PFS Final Rule

CY 2021 Performance Period/2023 MIPS Payment Year		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2021 PFS Final Rule (a)	1,479,672	$144,576,960
CY 2022 PFS Final Rule Total Burden (b)	0	0
Total change in burden (c) = (b) – (a)	**-1,479,672**	**-$144,576,960**
CY 2022 Performance Period/2024 MIPS Payment Year		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2021 PFS Final Rule (d)	1,473,741	$144,034,968
CY 2022 PFS Final Rule w/ updated wage rates and ICRs (e)	1,468,566	$148,078,846
CY 2022 PFS Final Rule w/ updated data and assumptions (f)	1,424,586	143,652,033
Change in burden due to updated data and assumptions (g) = (f) – (e)	**-43,980**	**-4,426,813**
CY 2022 PFS Final Rule Total Burden (h)	1,428,391	$144,014,757
Total change in burden (i) = (h) – (e)	**-40,175**	**-4,068,418**
Change in burden associated with policies (j) = (i) – (g)	**3,805**	**358,395**
CY 2023 Performance Period/2025 MIPS Payment Year		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2021 PFS Final Rule (k)	N/A	N/A
CY 2022 PFS Final Rule w/ updated wage rates and ICRs (l)	N/A	N/A
CY 2022 PFS Final Rule w/ updated data and assumptions (m)	N/A	N/A
Change in burden due to updated data and assumptions (n) = (m) – (l)	N/A	N/A
CY 2022 PFS Final Rule Total Burden (o)	1,383,049	$139,501,770
Total change in burden (as shown in Table 131) (p) = (o) – (l)	+1,383,049	+$139,501,770
Change in burden associated with policies (q) = (p) – (n)	+1,383,049	+$139,501,770

TABLE 129: Summary of Quality Payment Program Burden Estimates and Requirements for the CY 2022 Performance Period/ 2024 MIPS Payment Year CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses*	Responses	Change in Responses	Currently Approved Total Time (Hours)*	Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR self-nomination (see section V.B.8.c.(2) * (See Table 84)	82	84	2	826	1,176	350
§ 414.1400 Registry self-nomination (see section V.B.8.c.(3) * (See Table 86)	183	147	-36	1,139	841	-298
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section V.B.8.e.(4)): 2022 Performance Period (See Table 92)	29,273	28,252	-1,021	415,677	401,178	-14,499
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section V.B.8.e.(5)): 2022 Performance Period (See Table 94)	52,944	52,036	-908	480,890	472,643	-8,247
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section V.B.8.e.(6)): 2022 Performance Period (See Table 96)	50,475	48,573	-1,902	403,800	388,584	-15,216
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section V.B.8.e.(8)): 2022 Performance Period (See Table 101)	0	114	+114	0	7,030	+7,030
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section V.B.8.e.(10)): 2022 Performance Period (See Table 103)	0	90	+90	0	23	+23
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section V.B.8.g.(2)) (See Table 107)	52,099	42,827	-9,272	13,025	10,707	-2,318
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section V.B.8.g.(3)): 2022 performance period (See Table 112)	53,636	51,647	-1,989	143,208	138,930	-4,278
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section V.B.8.i): 2022 (See Table 117)	79,927	81,562	+1,635	6,661	6,770	+109
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see section V.B.8.j) (See Table 119)	31	31	0	93	136	+43
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section V.B.8.m) (See Table 121)	300	250	-50	75	63	-12
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process (see section V.B.8.n.(1)) (See Table 123)	80	15	-65	800	150	-650
§ 414.1445 Eligible Clinician Initiated Process (see section V.B.8.n.(2)) (See Table 125)	150	15	-135	1,500	150	-1,350
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see section V.B.8.o) (See Table 127)	3,486	38	-3,448	872	10	-862
TOTAL	322,666	305,681	-16,985	1,468,566	1,428,391	-40,175

*Total Responses is equal to the number of self-nomination applications plus the number of Corrective Action Plans submitted.

TABLE 130: Summary of Quality Payment Program Burden Estimates and Requirements for the CY 2023 Performance Period/ 2025 MIPS Payment Year CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses	Responses	Change in Responses	Currently Approved Total Time (Hours)*	Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR self-nomination (see section V.B.8.c.(2)) * (See Table 84)	N/A	84	+84	N/A	1,176	+1,176
§ 414.1400 Registry self-nomination (see section V.B.8.c.(3)) * (See Table 86)	N/A	147	+147	N/A	841	+841
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section V.B.8.e.(4)): 2023 Performance Period (See Table 92)	N/A	25,427	+25,427	N/A	361,061	+361,061
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section V.B.8.e.(5)): 2023 Performance Period (See Table 94)	N/A	46,890	+46,890	N/A	425,902	+425,902
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section V.B.8.e.(6)): 2023 Performance Period (See Table 96)	N/A	43,773	+43,773	N/A	350,186	+350,186
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section V.B.8.e.(8)): 2023 Performance Period (See Table 101)	N/A	0	0	N/A	0	0
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section V.B.8.e.(10)): 2023 Performance Period (See Table 103)	N/A	0	0	N/A	0	0
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section V.B.8.g.(2)) (See Table 107)	N/A	42,827	+42,827	N/A	10,707	+10,707
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section V.B.8.g.(3)): 2023 Performance Period (See Table 112)	N/A	51,667	+51,667	N/A	138,984	+138,984
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section V.B.8.i): 2023 Performance Period (See Table 117)	N/A	81,582	+81,582	N/A	6,771	+6,771
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see section V.B.8.j) (See Table 119)	N/A	31	+31	N/A	136	+136
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section V.B.8.m) (See Table 121)	N/A	250	+250	N/A	63	+63
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process (see section V.B.8.n.(1) (See Table 123)	N/A	15	+15	N/A	150	+150
§ 414.1445 Eligible Clinician Initiated Process (see section V.B.8.n.(2)) (See Table 125)	N/A	15	+15	N/A	150	+150
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see section V.B.8.o) (See Table 127)	N/A	38	+38	N/A	10	+10
MVP Registration (see section V.B.8.e.(7)(a)(i)): 2023 Performance Period (See Table 97)	N/A	12,917	+12,917	N/A	3,229	+3,229

Requirement	Currently Approved Responses	Responses	Change in Responses	Currently Approved Total Time (Hours)*	Total Time (Hours)	Change in Total Time (Hours)
Subgroup Registration (see section V.B.8.e.(7)(a)(ii)): 2023 Performance Period (See Table 98)	N/A	20	+20	N/A	10	+10
MVP Quality Submission (see section V.B.8.e.(7)(a)(iii)): 2023 Performance Period (See Table 99)	N/A	12,917	+12,917	N/A	83,673	+83,673
TOTAL	N/A	318,600	+318,600	N/A	1,383,049	+1383,049

*Total Responses is equal to the number of self-nomination applications plus the number of Corrective Action Plans submitted.

Table 131 represents averages for the estimated changes in burden for the CY 2021, 2022, and 2023 performance periods/2023, 2024, and 2025 MIPS payment years.

TABLE 131: Calculating Average Total Change in Burden

Changes Under §§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
CY 2021 Performance Period/2023 MIPS Payment Year	123,619	-327,126	Varies	-1,479,672	Varies	-144,576,960
CY 2022 Performance Period/2024 MIPS Payment Year	119,890	-16,995	Varies	-40,175	Varies	-4,068,418
CY 2023 Performance Period/2025 MIPS Payment Year	119,910	+323,039.00	Varies	+1,383,049	Varies	+139,501,770
TOTAL	+363,419	-21,082	Varies	-136,798	Varies	-9,143,608
AVERAGE	+121,140	-7,027	Varies	-45,599	Varies	-3,047,869

Table 132 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this final rule. We have divided the reasons for our change in burden into those related to new policies and those related to adjustments in burden from continued Quality Payment Program Year 5 policies that reflect updated data and revised methods.

TABLE 132: Reasons for Change in Burden Compared to the Currently Approved CY 2021 Information Collection Burden

Quality Payment Program Table	Changes in burden due to CY 2022 Final Rule policies	Adjustments in burden from continued CY 2021 PFS Final Rule policies due to revised methods or updated data
Section V.B.8.c.(2): QCDR Self-Nomination and other Requirements (See Table 84)	Increase in burden due to the policy requiring submission of participation plans, as necessary (3 hours per plan). Increase in burden due to current policies not previously having a burden estimate. (QCDR pre-existing measures)	Increase in number of hours required for simplified and full self-nomination process.
Section V.B.8.c.(3): Qualified Registry Self-Nomination and other Requirements (See Table 86)	Increase in burden due to the policy requiring submission of participation plans, as necessary (3 hours per plan).	Decrease in the estimated number of hours required for full-self nomination process
Section V.B.8.e.(4): Quality Performance Category Medicare Part B Claims Collection Type (See Table 92)	(CY 2023 Performance Period/2025 MIPS Payment Year) Decrease in burden due to estimated 10% of submitters reporting through MVPs. This decrease is offset slightly by the addition of Web Interface submitters due to the sunset of the CMS Web Interface collection type.	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Decrease in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year and updated QP projections for the CY 2022 MIPS performance period/2024 MIPS payment year.
Section V.B.8.e.(5): Quality Performance Category QCDR/ MIPS CQM Collection Type (See Table 94)	(CY 2022 Performance Period/2024 MIPS Payment Year) Decrease in the number of respondents due to the policy to extend the CMS Web Interface measures as a collection type/submission type for the CY 2022 performance period/2024 MIPS payment year. (CY 2023 Performance Period/2025 MIPS Payment Year) Increase in the number of respondents due to the policy to sunset the CMS Web Interface measures as a collection type/submission type and decrease in respondents due to MVP implementation.	Decrease in number of respondents due to updated projections from the CY 2022 MIPS performance period/2024 MIPS payment year and updated QP projections for the CY 2022 MIPS performance period/2024 MIPS payment year.

Quality Payment Program Table	Changes in burden due to CY 2022 Final Rule policies	Adjustments in burden from continued CY 2021 PFS Final Rule policies due to revised methods or updated data
Section V.B.8.e.(6): Quality Performance Category eCQM Collection Type (See Table 96)	(CY 2022 Performance Period/2024 MIPS Payment Year) Decrease in the number of respondents due to the policy to extend the CMS Web Interface measures as a collection type/submission type for the CY 2022 performance period/2024 MIPS payment year. (CY 2023 Performance Period/2025 MIPS Payment Year) Increase in number of respondents due to the policy to sunset the CMS Web Interface measures as a collection type/submission type and decrease in respondents due to MVP implementation.	Decrease in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year and updated QP projections for the CY 2022 performance period/2024 MIPS payment year.
SectionV.B.8. e.(7)(a)(i): MVP Registration (See Table 97)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) New information collection request	Not applicable
Section V.B.8.e.(7)(a) (ii): Subgroup Registration (See Table 98)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) New information collection request	Not applicable
Section V.B.8.e.(7)(a) (iii): MVP Quality Performance Category Submission (See Table 99)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) New information collection request	Not applicable
Section V.B.8.e.(8): Quality Performance Category CMS Web Interface Collection Type (See Table 101)	(CY 2022 Performance Period/2024 MIPS Payment Year) Addition of information collection due to the policy to extend the CMS Web Interface measures as a collection type/submission type. (CY 2023 Performance Period/2025 MIPS Payment Year) Removal of information collection due to the policy to sunset the CMS Web Interface measures as a collection type/submission type.	(CY 2022 Performance Period/2024 MIPS Payment Year) Increase in number of respondents (+114) due to policy to extend the CMS Web Interface measures as a collection type/submission type.
Section V.B.8.e.(10): Registration for CMS Web Interface (See Table 103)	(CY 2022 Performance Period/2024 MIPS Payment Year) Addition of information collection due to the policy to extend the CMS Web Interface measures as a collection type/submission type. (CY 2023 Performance Period/2025 MIPS Payment Year) Removal of information collection due to the policy to sunset the CMS Web Interface measures as a collection type/submission type.	(CY 2022 Performance Period/2024 MIPS Payment Year) Increase in number of respondents (+90) due to policy to extend the CMS Web Interface measures as a collection type/submission type.
Section V.B.8.g.(2): Reweighting Applications for Promoting Interoperability and Other Performance Categories (See Table 107)	Decrease in the number of respondents due to the policy to allow automatic reweighting of the Promoting Interoperability performance category for small practices	None

Quality Payment Program Table	Changes in burden due to CY 2022 Final Rule policies	Adjustments in burden from continued CY 2021 PFS Final Rule policies due to revised methods or updated data
Section V.B.8.g.(3): Promoting Interoperability Performance Category Data Submission (See Table 112)	(CY 2022 Performance Period/2024 MIPS Payment Year) Increase in per response burden (+0.02 hours) due to the policy for annual assessment SAFER Guides requirement (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Increase in number of respondents (+20) due to the implementation of subgroup reporting for MVPs and APP.	Decrease in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year and updated QP projections for the CY 2022 performance period/2024 MIPS payment year.
Section V.B.8.i: Improvement Activities Submission (See Table 117)	(CY 2023 Performance Period/2025 MIPS Payment Year) Increase in number of respondents (+20) due to the implementation of subgroup reporting for MVPs and APP.	Increase in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year
Section V.B.8.j: Nomination of Improvement Activities (See Table 119)	Increase in per response burden (+1.4 hours) due to the revised criteria for nomination of improvement activities	None.
Section V.B.8.m: Partial QP Election (See Table 121)	None	Decrease in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year.
Section V.B.8.n.(1): Other Payer Advanced APM Identification: Other Payer Initiated Process (See Table 123)	None.	Decrease in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year.
Section V.B.8.o: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare (See Table 127)	None.	Decrease in number of respondents due to updated projections for the CY 2022 performance period/2024 MIPS payment year.

C. Summary of Annual Burden Estimates for Changes

TABLE 133: Annual Requirements and Burden Estimates

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.806 (Requiring Certain Manufacturers to Report Drug Pricing Information for Part B) *	0938-0921	740	2,960	13	38,480	38.86	1,495,333
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan) *	0938-1396	100	100	0.1667	16.67	210.44	3,508
Part 403 (Open Payments Provisions included in the CY 2022 PFS)	0938-1237	2,398	2,398	Varies	1,263	Varies	64,561
§§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program) **	0938-1314	121,140	-7,027	Varies	-45,599	Varies	-3,047,869
TOTAL		123,138	1,739	varies	-22,647.33	varies	-$4,752,038

*The finalized requirements and burden will be submitted to OMB using the standard PRA process.
**Averages the CY 2021, CY 2022, and CY 2023 MIPS performance period burden changes over the 3-year 2023, 2024, and 2025 MIPS payment years.

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VI. Regulatory Impact Analysis

A. Statement of Need

In this final rule, we are finalizing payment and policy changes under the Medicare PFS and required statutory changes under the Consolidated Appropriations Act, 2021 and sections 2003 and 2005 of the SUPPORT for Patients and Communities Act of 2018. We also are finalizing changes to payment policy and other related policies for Medicare Part B. In addition, this final rule will make modest revisions to certain Medicare provider and supplier enrollment regulatory provisions and add already existing provider and supplier requirements pertaining to prepayment and post-payment review activities.

This final rule is necessary to make policy changes under Medicare FFS and to address various provider and supplier enrollment issues. Therefore, we included a detailed Regulatory Impact Analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explain the selection of these regulatory approaches that we believe adhere to statutory requirements and, to the extent feasible, maximize net benefits

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this final rule will redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities.

The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, the PFS pays for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This final rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this final rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this final rule, we discussed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement provisions of the statute. We provide information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve BN.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2021 with payment rates for CY 2022 using CY 2020 Medicare utilization. The payment impacts described in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2022, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments. In addition, section 101 of Division N of the CAA provided a 3.75 percent increase in PFS payment amounts for services furnished on or after January 1, 2021, and before January 1, 2022 and required that the increase shall not be taken into account in determining PFS payment rates for subsequent years. The expiration of this 3.75 percent increase in payment amounts will result in the CY 2022 conversion factor being calculated as though the 3.75 percent increase for the CY 2021 conversion factor had never been applied.

To calculate the CY 2022 PFS conversion factor (CF), we took the CY 2021 conversion factor without the 1-year 3.75 percent increase provided by the CAA and multiplied it by the BN adjustment required as described in the preceding paragraphs. We estimate the CY 2022 PFS CF to be 33.5983 which reflects the BN adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the expiration of the 3.75 percent increase for services furnished in CY 2021, as provided in the CAA. We estimate the CY 2022 anesthesia CF to be 20.9343 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 134: Calculation of the CY 2022 PFS Conversion Factor

CY 2021 Conversion Factor		34.8931
Conversion Factor without CY 2021 Consolidated Appropriations Act Provision		33.6319
Statutory Update Factor	0.00 percent (1.0000)	
CY 2022 RVU Budget Neutrality Adjustment	-0.10 percent (0.9990)	
CY 2022 Conversion Factor		**33.5983**

TABLE 135: Calculation of the CY 2022 Anesthesia Conversion Factor

CY 2021 National Average Anesthesia Conversion Factor		21.5600
Conversion Factor without CY 2021 Consolidated Appropriations Act Provision		20.7807
Statutory Update Factor	0.00 percent (1.0000)	
CY 2022 RVU Budget Neutrality Adjustment	-0.10 percent (0.9990)	
CY 2022 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.84 percent (1.0084)	
CY 2022 Conversion Factor		**20.9343**

Table 136 shows the payment impact of the policies contained in this final rule on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 136 (CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 136.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2020 utilization and CY 2021 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2022 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2022 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2022 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2022 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 136: CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$213	0%	0%	0%	0%
Anesthesiology	$1,626	0%	1%	0%	1%
Audiologist	$56	0%	0%	0%	0%
Cardiac Surgery	$197	0%	-1%	0%	0%
Cardiology	$5,926	0%	-1%	0%	-1%
Chiropractic	$600	0%	0%	0%	0%
Clinical Psychologist	$791	0%	0%	0%	0%
Clinical Social Worker	$849	0%	0%	0%	0%
Colon and Rectal Surgery	$140	0%	0%	0%	0%
Critical Care	$353	0%	0%	0%	0%
Dermatology	$3,336	0%	0%	0%	1%
Diagnostic Testing Facility	$664	0%	6%	0%	6%
Emergency Medicine	$2,445	0%	0%	0%	0%
Endocrinology	$489	0%	0%	0%	0%
Family Practice	$5,557	0%	0%	0%	1%
Gastroenterology	$1,428	0%	0%	0%	0%
General Practice	$361	0%	0%	0%	1%
General Surgery	$1,688	0%	0%	0%	0%
Geriatrics	$170	0%	1%	0%	1%
Hand Surgery	$214	0%	1%	0%	1%
Hematology/Oncology	$1,679	0%	-1%	0%	-1%
Independent Laboratory	$537	0%	0%	0%	0%
Infectious Disease	$620	0%	0%	0%	0%
Internal Medicine	$9,618	0%	0%	0%	0%
Interventional Pain Mgmt	$865	0%	2%	0%	1%
Interventional Radiology	$465	0%	-5%	0%	-5%
Multispecialty Clinic/Other Phys	$133	0%	0%	0%	0%
Nephrology	$2,231	0%	0%	0%	0%
Neurology	$1,313	0%	0%	0%	0%
Neurosurgery	$687	0%	0%	0%	0%
Nuclear Medicine	$48	0%	-1%	0%	-1%
Nurse Anes / Anes Asst	$1,036	0%	1%	0%	0%
Nurse Practitioner	$5,130	0%	0%	0%	0%
Obstetrics/Gynecology	$541	0%	0%	0%	0%
Ophthalmology	$4,218	0%	0%	0%	0%
Optometry	$1,075	0%	0%	0%	0%
Oral/Maxillofacial Surgery	$70	0%	-1%	0%	-1%
Orthopedic Surgery	$3,167	0%	0%	0%	0%
Other	$52	0%	0%	0%	0%
Otolarngology	$1,003	0%	0%	0%	0%
Pathology	$1,030	0%	0%	0%	0%
Pediatrics	$54	0%	0%	0%	0%
Physical Medicine	$999	0%	0%	0%	0%
Physical/Occupational Therapy	$3,850	0%	-1%	0%	-1%
Physician Assistant	$2,723	0%	0%	0%	0%
Plastic Surgery	$311	0%	0%	0%	1%
Podiatry	$1,797	0%	1%	0%	1%
Portable X-Ray Supplier	$83	0%	2%	0%	2%
Psychiatry	$1,015	0%	0%	0%	0%
Pulmonary Disease	$1,424	0%	0%	0%	0%
Radiation Oncology and Radiation Therapy Centers	$1,605	0%	-1%	0%	-1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Radiology	$4,257	0%	-1%	0%	-1%
Rheumatology	$523	0%	0%	0%	-1%
Thoracic Surgery	$293	0%	-1%	0%	-1%
Urology	$1,623	0%	0%	0%	1%
Vascular Surgery	$1,107	0%	-5%	0%	-5%
Total	$84,285	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

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2. CY 2021 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including diagnostic testing facilities, portable x-ray, podiatry, hand surgery, and geriatrics, reflect increases relative to other physician specialties. These increases can be attributed largely to the update to clinical labor pricing as the services that these specialties furnish involve a higher proportion of clinical labor cost that is reflected in their PE RVUs. These increases are also due to increases in value for particular services after considering the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC), and CMS review and increased payments resulting from updates to supply and equipment pricing.

The estimated impacts for several specialties, including interventional radiology, vascular surgery, radiation oncology, and cardiology, reflect decreases in payments relative to payment to other physician specialties which are largely the result of the redistributive effects of the clinical labor pricing update. The services furnished by these specialties involve proportionally higher supply or equipment item costs, and therefore are affected negatively by the updates to clinical labor pricing. Since PE is budget neutralized within itself, increased pricing for clinical labor holds a corresponding relative decrease for other components of PE such as supplies and equipment. These decreases are also due to the revaluation of individual procedures based on reviews by the AMA RUC and CMS, as well as decreases resulting from the continued phase-in implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreases due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 2 percent decrease for CY 2021 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 136), including comments received in response to the valuations. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 136 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2020 utilization data, Total RVUs change between −1 percent and 1 percent for more than 90 percent of practitioners, representing more than 81 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Many specialties, such as chiropractic, clinical social worker, family practice, internal medicine and emergency medicine, exhibit little variation in changes in total RVUs per practitioner. For these specialties, more than 90 percent of these practitioners will experience a change in Total RVUs between −1 percent and 1 percent. Other specialties exhibit more variation in changes in total RVUs per practitioner. For example, for diagnostic testing facilities, 39 percent of IDTFs will experience a 2 percent or more decrease in Total RVUs, but these suppliers represent only 33 percent of Total RVUs for this specialty. Meanwhile, one percent of IDTFs will experience 10 percent or more increases in Total RVUs and these suppliers account for 33 percent of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule.

Many commenters requested that CMS maintain the 3.75 percent increase in PFS payment amounts that was specified under section 101 of the CAA for services furnished during CY 2021. We remind commenters that this increase was provided through a time-limited amendment to the statute, which CMS does not have legal authority to alter. The expiration of this 3.75 percent increase in payment amounts will result in the CY 2022 conversion factor being calculated as though the 3.75 percent increase for the CY 2021 conversion factor had never been applied. Several commenters requested clarification regarding whether the specialty impacts displayed in Table 136 reflected the expiration of the 3.75 percent CAA provision for CY 2022. We can clarify for the commenters that the specialty impacts displayed in Table 136 reflect changes that take place within the pool of total RVUs. The specialty impacts table therefore includes any changes in spending which result from finalized policies within BN (such as the revaluation of E/M codes in CY 2021 or the clinical labor

pricing update in CY 2022) but does not include any changes in spending which result from finalized policies outside of BN. The expiration of the 3.75 percent CAA provision for CY 2022 is a statutory change that takes place outside of BN, and therefore, is not captured in the specialty impacts displayed in Table 136.

b. Impact

Column F of Table 136 displays the estimated CY 2022 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2022 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/.* We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/.*

D. Effect of Changes Related to Telehealth Services

Before the PHE for COVID–19, approximately 15,000 FFS Medicare beneficiaries received a Medicare telemedicine service each week. According to a report prepared by the Assistant Secretary for Planning and Evaluation (ASPE),[267] in the last week of April 2020, nearly 1.7 million beneficiaries received telehealth services. By April 2020, nearly half of all Medicare primary care visits were telehealth encounters, a level consistent with health care encounters more broadly. There are approximately 271 services currently included on the list of Medicare telehealth services, including more than 165 that were added on a temporary basis during the PHE for COVID–19 (including service categories such as emergency department visits, initial inpatient and nursing facility visits, and discharge day management services) that are covered through the end of the PHE. Preliminary data show that between mid-March and mid-October 2020, over 24.5 million out of 63 million Medicare beneficiaries and enrollees have received a Medicare telemedicine service during the PHE. It is important to note that preliminary data reflect that the largest increases in services furnished via telehealth communications systems, by beneficiary access/volume, were for services that were already on the Medicare telehealth services list before the PHE.

As discussed in section II.D. of this final rule, we are finalizing our proposal to amend the regulatory definition of interactive telecommunications system for purposes of Medicare telehealth services to include audio-only communication technology under certain circumstances for mental health services furnished to established patients in their homes. We anticipate that this policy will increase utilization of Medicare telehealth mental health services relative to utilization that will occur without the change. The estimated cost impact on overall Medicare services is unclear, though these changes will largely maintain current policies and access to the specific mental health services that are available to beneficiaries during the PHE. By requiring that a modifier be appended to the claim to identify that the service was furnished via audio-only communication technology, we will be able to closely monitor utilization and address any potential concerns regarding overutilization through future rulemaking.

Comment: Commenters were very supportive of our proposal to allow for mental health services to be furnished using audio-only communications technology. A few commenters, while supportive of the use of audio-only communications technology during the PHE, urged CMS to further study and evaluate the safety and effectiveness of the audio-only modality for various levels of care and treatments to determine appropriateness of continuing payment after the PHE expires. Commenters supported the proposal to create a service-level modifier to identify mental health telehealth visits ''furnished to a beneficiary in their home using audio-only communications technology.''

Response: We are finalizing creation of a service-level modifier that would identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. We anticipate that our policy of allowing mental health services to be furnished using audio-only communications technology this will have a positive impact on access to care for mental health services and contribute to overall health equity.

Section 123 of the CAA removed the geographic and site of service restrictions for telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, and required as a condition of payment for these telehealth services furnished in the patient's home that a physician or practitioner furnish an in-person, non-telehealth service to a beneficiary within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at intervals as specified by the Secretary. Section 125 of the CAA created a new Medicare provider type—the rural emergency hospital, effective beginning in CY 2023—and added rural emergency hospitals to the list of eligible telehealth originating sites at section 1834(m)(4)(C)(ii) of the Act. As discussed in section II.D. of this final rule, we will require, as a condition of payment for a telehealth service described in section 1834(m)(7) of the Act, that the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of service of a telehealth service as specified in section 1834(m)(7)(B)(i) of the Act, and proposed in this final rule that an in-person, non-telehealth service to the beneficiary must occur at 12-month intervals for subsequent care, with the possibility for exceptions that must be documented by the practitioner in the medical record.

We solicited comment on whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service, and we are finalizing a policy to allow this. Given that the removal of the geographic and site of service restrictions for telehealth will expand the availability of mental health services, we anticipate that utilization of these mental health services will be comparable to observed utilization for mental health services during the COVID–19 PHE.

We received public comments on whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service. The following is a summary of the comments we received and our responses.

Comment: Many commenters agreed with the alternative policy we considered to allow the required in-

[267] Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the Covid–19 Pandemic (*hhs.gov*).

person, non-telehealth service to be furnished by another physician or practitioner of the same specialty and subspecialty in the same group as the practitioner who furnishes the mental health telehealth services to the beneficiary if the practitioner who furnishes the telehealth services is unavailable.

Response: We are adopting the alternative policy discussed in the proposed rule to allow a clinician's colleague in the same subspecialty in the same group to furnish the in-person, non-telehealth service to the beneficiary if the original practitioner is unavailable. This is also consistent with longstanding policy, which defines an established patient as an individual who receives professional services from the physician/NPP or another physician of the same specialty and subspecialty who belongs to the same group within the previous 3 years, for purposes of billing for E/M services. While the language in the CAA states that the physician or practitioner furnishing the in-person, non-telehealth service must be the same person as the practitioner furnishing the telehealth service, we believe this policy would be consistent with statutory requirements, because we have historically treated the billing practitioner and other practitioners of the same specialty or subspecialty in the same group as if they were the same individual.

After consideration of public comments, we are finalizing our alternative policy that a practitioner in the same subspecialty and the same group may furnish the in-person, non-telehealth service to the same beneficiary, if the original practitioner is unavailable.

With regard to our policy to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023, we believe the establishment of this certain end date will provide clarity to the stakeholder community but will have a negligible impact on PFS expenditures. For example, services that have already been added to the permanent telehealth services list are furnished via telehealth, on average, less than 0.1 percent of the time they are reported. Further, although data is still being collected, in our initial review of the data, we have not noticed an increase in the overall utilization trend for these services suggesting that practitioners may be furnishing these services via telehealth as replacement for in person encounters. The statutory conditions on payment for Medicare telehealth services under section 1834(m) of the Act, such as the originating site requirements related to geographic location and site of service, have limited increases in telehealth service utilization outside of the PHE for COVID–19; however, we believe there is value in allowing physicians to furnish services added to the Medicare telehealth services list on a Category 3 basis, and for patients to receive broader access to this care through telehealth, through the end of CY 2023 in order to ease the transition from the PHE. Additionally, for services added to the Medicare telehealth list on a Category 3 basis, outside of the circumstances of the PHE for COVID–19, all of the statutory restrictions under section 1834(m) of the Act will also apply to these services; therefore, we do not anticipate any significant increase in utilization.

E. Effect of Changes Related to Services Furnished in Whole or in Part by PTAs and OTAs

As discussed in section II.H.1., we are finalizing proposed revisions to the current *de minimis* policy for services furnished in whole or in part by PTAs/OTAs that we finalized in CY 2020 PFS final rule (84 FR 62702 through 62708) under which the CQ or CO modifier applies when the PTA or OTA furnished more than 10 percent of a service or a 15-minute unit of service. Beginning January 1, 2022, CMS will apply a 15 percent reduction to the payment amount for a physical or occupational therapy service when the CQ/CO modifier is applied to the service. Our revision to the *de minimis* policy will allow the PT/OT to bill without the CQ/CO modifier for the final 15-minute unit (in a multi-unit billing scenario) when the PT/OT meets the billing threshold of 8 minutes, which is when the minutes are greater than the midpoint (7.5 minutes) of the 15-minute unit, regardless of any minutes provided by the PTA/OTA for that final unit.

Under the policy we are finalizing, the PT/OT services will not be discounted as the result of any ''left-over'' minutes provided by the PTA/OTA when the therapist provides enough minutes on his or her own to meet the billing threshold amount. In these scenarios, the PTA's/OTA's minutes are considered immaterial for the purposes of billing. For example, if the PT/OT provided 23 minutes of a 15-minute service and the PTA/OTA provided another 20 minutes of the same service—three units of service can be billed for the 43 total minutes (38 minutes through 52 minutes). Here, one full 15-minute unit of service is billed without the CQ/CO modifier for the PT/OT service with 8 minutes remaining, and one full unit of service is billed with the CQ/CO modifier for the service provided by the PTA/OTA with 5 minutes remaining. Under the policy, the third unit is billed without the CQ/CO modifier because the 8 minutes provided by the PT/OT meets the billing threshold amount. However, under our current *de minimis* policy, the 5 minutes provided by the PTA/OTA is more than 10 percent (it is 38 percent of the total service − PTA/OTA minutes divided by the total of PTA/OTA + PT/OT minutes: 5 divided by 13 = 38 percent) meaning the CQ/CO modifier is applied to the third and final unit of service.

Under our current *de minimis* policy, under which the CQ/CO modifier is applied whenever the PTA/OTA provides more than 10 percent of a service whether or not the PT/OT furnishes enough of the service to bill for it without the portion furnished by the PTA/OTA, stakeholders have expressed concern that the PT/OT has a financial incentive not to have the PTA/OTA provide any additional minutes, regardless of the individual patient's needs, when those minutes of service lead to a reduced payment for a unit of a service. There may be a cost implication to this policy as fewer billing scenarios may result in application of the CQ/CO modifiers and consequent payment reduction. However, we believe that basing our policy on a ''midpoint rule'' in which the PT/OT provides enough minutes on their own (8 or more minutes) to bill for the final unit of a billing scenario could eliminate the PT's/OT's financial incentive to not provide appropriate therapy to an individual patient when it is furnished by the PTA/OTA. On the other hand, if we were to continue with our *de minimis* standard to apply to all billing scenarios for PTA/OTA services that exceed the 10 percent standard, we are uncertain how to gauge the overall costs of this policy because of the possible altered PT/OT behavioral change that is due to the financial incentives built into that policy as discussed above.

F. Other Provisions of the Regulation

1. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.A. of this final rule, we make multiple provisions related to RHCs and FQHCs. In terms of estimated impacts to the Medicare program, Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients as required by section 132 of the CAA, 2021 and Concurrent Billing for CCM and

Transitional Care Management TCM Services for RHCs and FQHCs will have negligible impact to Medicare spending.

Section 130 requires that all independent RHCs are now subject to the per-visit limit (which is also referred to as ''cap'') and phases in an increase in the statutory payment cap over an 8-year period. The cap in CY 2021, for services furnished after March 31, is set at $100 per visit, then at $126 per visit in 2022; at $139 per visit in 2023; at $152 per visit in 2024; at $152 per visit in 2025; at $165 per visit in 2026; at $178 per visit in 2027; and at $190 per visit in 2028. Beyond 2028, the limit is updated by the applicable Medicare Economic Index (MEI).

This provision also controls the annual rate of growth in payments to certain provider-based RHCs whose payments are currently higher than the payment limit. Each year, but for services provided after March 31 in 2021, the payment limit shall be set at the greater of: (1) The RHC per visit amount from the prior year, increased by the percentage increase in the applicable MEI; and (2) the cap limits applicable to each year as described above. In order to be eligible for this ''grandfathering'' policy, the RHC must have been based in a hospital with fewer than 50 beds and enrolled in Medicare as of December 31, 2019.

Section 2 of Public Law 117–7, enacted on April 14, 2021, made technical corrections to section 130. First, for an RHC that is hospital-based and whose parent hospital has fewer than 50 beds, the date by which the RHC must be Medicare-certified, in order to be grandfathered, was changed from December 31, 2019 to December 31, 2020. Next, a clinic that is owned by a hospital with fewer than 50 beds and that submitted certain applications (received by Medicare) for certification as a Medicare RHC prior to the end of 2020 can be grandfathered, and its clinic-specific cap is to be set based on its 2021 cost per visit. Lastly, a grandfathered RHC must continue to be owned by a hospital with fewer than 50 beds; if the parent hospital exceeds 50 beds, the RHC will lose its grandfathered status.

Table 137 are the FY estimates (in millions) for the impact of section 130, which improves payments to RHCs. These providers are currently paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services, and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, except for certain provider-based RHCs that have an exception to the payment limit. The RHC payment limit per visit for CY 2021 is $87.52, which is 1.4 percent higher than the CY 2020 payment limit of $86.31.

TABLE 137: Fiscal Year Estimates for the Impact of Section 130 of the CAA

Medicare (Part B)	2021	2022	2023	2024	2025	2026	2026	2028	2029	2030	2031	2022-26	2022-31
Part B benefits	10	180	160	230	310	390	490	580	640	700	750	1,270	4,430
Premium offset	–	-40	-40	-60	-80	-100	-120	-140	-160	-170	-190	-320	-1,100
Net Part B	10	140	120	170	230	290	370	440	480	530	560	950	3,330

In section III.B. of this final rule, we discuss that we proposed to revise the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time telecommunications technology, but only when furnishing services for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.

According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth under the PFS during the PHE, use of telehealth for many professional services spiked in utilization around April 2020 and diminished over time, but not to pre-pandemic levels. In contrast, Medicare claims data suggests that for mental health services both permanently and temporarily added to the Medicare Telehealth list, subsequent to April 2020, the trend is toward maintaining a steady state of usage over time. Given the expanded availability of mental health services at RHCs and FQHCs, we do anticipate that this policy will increase spending; however, we are not certain of the magnitude of this increase, since it is not clear at this time how or whether trends related to utilization of communication technology during the PHE will continue after such a time that the PHE were to end. While the estimated cost impact of this provision is unclear, the requirement that a modifier be appended to the claim to identify that the service was furnished via audio-only communication technology will allow us to closely monitor utilization and address any potential concerns regarding overutilization through future rulemaking.

2. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802 and 414.806)

This provision implements new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of the CAA (for the purposes of this section of this final rule, hereinafter is referred to as ''section 401''). These new requirements will improve the accuracy of reported payment limits and limit the use of WAC-based pricing.

As described in section III.D.1. of this final rule, in considering whether to exclude repackagers from the reporting requirements at section 1847A(f)(2) of the Act, we conducted two analyses to estimate: (1) The proportion of repackaged products in our existing ASP data; (2) the number of new ASP submissions we can expect as a result of the new reporting requirements under section 401; and (3) the proportion of those (new) submissions that involve repackaged products.

Additionally, while we believe it will impact reporting volume and payment limits under section 1847A of the Act for many billing and payment codes, we are unable to estimate the magnitude of these effects for the following reasons. We estimate: (1) 361 non-reporting manufacturers (of either single source or multiple source drugs) will now be required to report ASP data under section 1847A(f)(2) of the Act; and (2) 6114 products payable under Part B that these non-reporting manufacturers sell. However, we do not know which Healthcare Common Procedure Coding System (HCPCS) code payment limits will be impacted by these 6114 products, nor do we know the sales volume of these 6114 products. Because this information is used to calculate volume-weighted ASP payment limits, we are unable to quantitatively estimate the economic impacts of this provision (that is, the likely costs or savings) on beneficiaries, the government, and other

stakeholders. (We note that the economic impacts on manufacturers, as a result of the information collection requirements of this provision is discussed in section V. of this final rule.)

For single source drugs, these changes may result in lower payment limits because, typically, the WAC-based pricing is higher than ASP plus 6 percent. This then translates to cost savings for both the government and beneficiaries, who will pay coinsurance on a lesser amount. However, for the reason stated previously, we are unable to predict the magnitude of this effect.

Similarly, payment limits for multiple source drugs could increase or decrease, and we are unable to predict the direction or magnitude of specific or aggregate effects at this time.

We do not anticipate that this provision of this final rule will necessitate the revision of existing Medicaid Drug Rebate Agreements.

We welcomed comment on (1) the likely costs or savings to beneficiaries, the government, and other stakeholders and (2) other related impacts of this provision.

We received public comments on the likely costs or savings to beneficiaries, the government, and other stakeholders, and other related impacts of this provision. The following is a summary of the comments we received and our responses.

Comment: One commenter suggested that CMS exclude repackagers from the proposed ASP reporting requirements. They stated that requiring all repackagers to report would likely be duplicative and increase the burden on all parties without providing tangible benefit. They recommend repackagers who already report ASP data continue to do so, but that CMS not require repackagers, as a group, to be subject to the reporting requirements at this time.

Response: We are not persuaded that repackagers should be excluded at this time. In order to maintain consistency and integrity of the ASP data for those manufacturers with and without Medicaid drug rebate agreements, and for operational reasons, we do not believe it is appropriate to exclude repackagers from the ASP reporting requirements. If warranted, we could revisit this in future rulemaking.

Comment: One commenter concluded that CMS' analysis and proposal not to exclude repackagers without a rebate agreement from reporting ASP data is reasonable. The commenter stated given that repackagers with a rebate agreement are required to report ASP data, it is reasonable not to exclude repackagers without a rebate agreement from the requirements of section 401. They added that having ASP data from repackagers with and without rebate agreements could also permit future analysis of the effect of repackagers' ASP submissions on Medicare Part B payment rates.

Response: We agree it is reasonable not to exclude repackagers without a Medicaid drug rebate agreement and thank the commenter for their feedback.

After consideration of public comments, we are finalizing as proposed.

3. Determination of ASP for Certain Self-Administered Drug Products

a. Anticipated Effects

This provision implements new statutory requirements under section 1847A(g) of the Act, as amended by section 405 of the CAA 2021, (for the purposes of this section of this final rule, hereinafter is referred to as ''section 405''). As identified by the OIG studies discussed in section III.D.2. of this final rule, the CMS payment-limit determination under section 1847A of the Act includes all versions of a product marketed under a single FDA approval, and consistent with section 1847A(b)(5) of the Act, the payment-limit determination does not exclude products based on packaging. Thus, the volume-weighted, average-ASP determination can include self-administered versions that may lead to increased program and beneficiary costs because of distorted ASP-based payment limits. In particular, the OIG studies identified two billing and payment codes that included self-administered NDCs. The OIG study determined that as a result of the inclusion of these NDCs in the calculation of the ASP payment limit, Medicare payment amounts remained inflated in 2017 and 2018, causing the program and its beneficiaries to pay an additional $497 million during this period. Since 2014, current payment methodology has resulted in an additional $173 million in Medicare beneficiary coinsurance for these two NDCs. (See OIG's July 2020 report titled, ''Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars,'' available at *https://oig.hhs.gov/oei/reports/OEI–BL–20–00100.asp*.)

Implementation of the regulatory changes has the potential to result in decreased payment limits for identified billing and payment codes that could, in turn, substantially reduce Medicare and beneficiary expenditures, as described in the OIG study. Since section 1847A(g)(3) of the Act requires CMS to implement the required payment changes beginning on July 1, 2021, these potential savings may be observed within the year.

By adding sections 1847A(g)(1) and (2) of the Act, section 405 also directs the OIG to conduct future studies with same or similar methodologies to those in the July 2020 report and directs CMS to apply the lesser of payment methodology to the applicable billing and payment codes. This has the potential to result in additional savings to the program and beneficiaries if additional products are identified by these periodic OIG studies.

b. Expected Benefits

Codifying the provisions set forth by section 405 will permit to CMS to apply the lesser of payment methodology at section 1847(g)(2) of the Act to billing and payment codes identified by future OIG studies (described in section III.D.2. of this final rule). This provision addresses distorted payment limits for these products and may result in payment amounts that are better aligned with versions of these products that are payable under Part B (for example, versions that are usually not self-administered). Although we are unable to quantify the total magnitude of the potential savings, these changes have the potential to substantially reduce program expenditures and beneficiary coinsurance.

4. Appropriate Use Criteria

Section 1834(q)(2) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (PAMA), established a program to promote the use of appropriate use criteria (AUC) for applicable imaging services furnished in an applicable setting.

In the CY 2019 PFS final rule (83 FR 59452), we performed an RIA for this program. In this final rule, we are finalizing our proposal to begin the payment penalty phase of the program on the later of January 1, 2023 or the January 1 of the year after the year in which the PHE for COVID–19 ends. Because, under our provisions, the payment penalty phase will be further delayed, we are updating the estimates for incremental changes from the RIA from the CY 2019 PFS final rule. Since we did not propose new policy requirements nor do we have sufficient reason to change any of the assumptions made in the RIA finalized in the CY 2019 PFS (83 FR 60034 through 60044), we are only updating the analysis to reflect 2019 Medicare claims data (updated from 2014). We identify four incremental changes from the CY 2019

PFS final rule estimates due to updated claims data: (1) Impact of required AUC consultations by ordering professionals; (2) impact to Medicare beneficiaries; (3) process efficiencies to potentially offset the estimated burden on Medicare beneficiaries; and (4) impact on transmitting orders for advanced diagnostic imaging services. Each of these incremental changes results in a lower estimate.

a. Impact of Required AUC Consultations by Ordering Professionals

As discussed in detail in the CY 2019 PFS final rule (83 FR 60035 through 60037), the annual impact estimate of consultations by ordering professionals was $70,001,700. In our estimates, we calculated the burden for auxiliary personnel to consult AUC under the direction of an ordering professional and the burden for ordering professionals to perform the consultation directly. We estimated that 90 percent of consultations will be performed by a medical assistant (occupation code 31–9092) and 10 percent of consultations will be performed by a general practitioner (occupation code 29–1062). We estimated that 43,181,818, 2-minute consultations occur annually.

Using 2019 Medicare claims data as our basis for the analysis, we proposed to change the methodology used to determine the volume of consultations and proposed to use more granular data that will reduce potential double-counting of advanced diagnostic imaging services. For example, an imaging service furnished in an outpatient hospital department could have two claims associated with that service. There could be a claim from the facility and a claim from the physician that interprets that imaging service. In the CY 2019 RIA (83 FR 60034 through 60044) we were concerned that the estimate of 43,181,818 consultations may be an overestimate because it took into account total claims. For this CY 2022 RIA, we proposed to change the method of counting the total number of advanced diagnostic imaging services that will be furnished under the AUC program which will correspond to the total number of consultations.

Using the Integrated Data Repository we identified Medicare claims using the following parameters: (1) 2019 date of service; (2) claim lines containing one of the procedure codes identified in CR10481 and CR11268 at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R2040OTN.pdf* and *https://www.cms.gov/files/document/r2404otn.pdf,* respectively; and (3) claims types of outpatient or practitioner. Claims were then separated based on the setting in which the imaging service was furnished and further by claim type. Using only services billed on the professional claim type, the total number of claim lines containing one of the identified procedure codes was included to total 30,359,901 advanced diagnostic imaging services estimated to be subject to the AUC program. By using this combination, we believe we can reduce the risk of double-counting services to obtain a more accurate estimate of total number of diagnostic imaging services subject to the AUC program. Therefore, this analysis will use the estimate of 30,359,901 AUC consultations.

Using the May 2020 BLS mean hourly wages, we update our estimates for a medical assistant (occupation code 31–9092) with mean hourly wage of $17.75 and 100 percent fringe benefits for 90 percent of consultations (910,797 hours) to be $30,511,701 (910,797 hours × $33.50/hour). The occupation for general practitioner is no longer listed on the BLS so, instead, we update our estimate using the occupation code for general internal medicine physician (29–1216) with mean hourly wage of $101.42 and 100 percent fringe benefits for 10 percent of consultations (101,200 hours) to be $20,527,408 (101,200 hours × $202.84/hour). The updated total annual estimated impact of consultations is $51,039,109, for an incremental change (reduction) of $18,962,591.

b. Impact to Medicare Beneficiaries

In the CY 2019 PFS final rule, we estimated that the additional 2-minute consultation would impact the Medicare beneficiary when their advanced diagnostic imaging service is ordered by the ordering professional by introducing additional time to their office visit. For this update, we used the updated number of consultations calculated above from claims data, as well as the May 2020 BLS mean hourly wage. To estimate this annual cost, we multiplied the annual burden of 1,011,997 hours by the BLS occupation code that represents all occupations in the BLS (00–0000) as mean hourly wage plus 100 percent fringe ($54.14/hr) for a total estimate of $54,789,518 per year for an incremental change (reduction) of $13,211,482. We also estimated that, over time, process efficiencies may be implemented. We assumed that 50 percent of practices implemented an improvement process that streamlined AUC consultation so Medicare beneficiaries spent the same amount of time in the physician's office regardless of whether an advanced diagnostic imaging service was ordered. The updated estimate that such an improvement process could offset the estimated burden on Medicare beneficiaries by $27,394,759 annually for an incremental change (reduction) of $6,605,741.

c. Impact on Transmitting Orders for Advanced Diagnostic Imaging Services

In the CY 2019 PFS final rule, we estimated that including AUC consultation information on the order for an advanced diagnostic imaging service to the furnishing professional or facility is estimated as the additional 5 minutes spent by a medical secretary (occupation code 43–6013). To update this estimate, we use the May 2020 mean hourly wage of $18.75 plus 100 percent fringe benefits to transmit the order for the advanced diagnostic imaging service. In aggregate, we assumed in the CY 2019 PFS final rule that 40,000,000 advanced diagnostic imaging services are ordered annually. We proposed to update that number to match the total number of AUC consultations proposed earlier in this RIA to 30,359,901, so the updated total annual burden to communicate additional information in the order is estimated as $94,495,192 ($18.75/hr × 2 × 0.083 hr × 30,359,901 orders) for an incremental change (reduction) of $20,044,808.

d. Impact on Furnishing Professionals and Facilities

As described in the CY 2019 PFS final rule, we identified an estimated 174,064 furnishing professionals (comprising radiologists, ASCs, IDTFs and hospitals) and assumed that every identified furnishing professional will choose to update their processes for the purposes of the AUC program in the same way by purchasing an automated solution to report AUC consultation information which was estimated to cost $10,000 for each furnishing professional. We update this cost to account for inflation and therefore the updated estimated cost is $10,636.07 ($10,000 adjusted for inflation to 2021 dollars) for a total estimated one-time update cost of $1,851,356,888.48 (174,064 × $10,636.07).

e. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

As described in the CY 2019 PFS final rule, we assumed that there may be some savings to the Medicare program due to the AUC program requirements and potential decreases in inappropriate utilization of advanced diagnostic imaging services. This assumption was based on literature describing prior

experiences with clinical decision support in a pilot project conducted in Minnesota, a retrospective cohort study on evidence-based clinical decision support for lumbar MRI, brain MR and sinus CT and local implementation of clinical decision support, and we estimated that savings may account for $700,000,000 savings per year.

f. Summary of Delay-Attributable Changes and Discounted Rates

Table 138 summarizes the substantive changes from the CY 2019 PFS final rule to the CY 2022 PFS final rule impact estimates. The effect of a 3-year delay is approximated by applying 3 years' worth of discounting at 7 percent or 3 percent discount rates (Circular A–4, *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/regulatory_matters_pdf/a-4.pdf*).

TABLE 138: AUC Program Related Activities with Changes in Impact Estimates Resulting from a 3-Year Delay

AUC Program Related Activity	CY 2022 PFS Rule Impact Estimate	Change from CY 2019 PFS Final Rule (as a function of the discount rate)
Impact of required AUC consultations by ordering professional	$51,039,109	- $4.3 million (3%) - $9.4 million (7%)
Impact to Medicare beneficiaries	$54,789,518	- $4.6 million (3%) - $10.1 million (7%)
Impact on transmitting orders for advanced diagnostic imaging services	$94,495,192	- $8.0 million (3%) - $17.4 million (7%)
AUC automated solution	$1,851,356,888	- $157.1 million (3%) - $340.1 million (7%)
Medicare program impacts associated with advanced diagnostic imaging services	$700,000,000	- $59.4 million (3%) - $128.6 million (7%)
Total Change Attributable to a 3-Year Delay		- $174.1 million (costs, 3%) - $376.9 million (costs, 7%) - $59.4 million (transfers, 3%) - $128.6 million (transfers, 7%)

5. Removal of Selected National Coverage Determinations (NCDs)

We proposed to remove two older NCDs that no longer contain clinically pertinent and current information or that involve items or services that are used infrequently by beneficiaries. Generally, proactively removing obsolete or unnecessary NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. The two NCDs fall into two impact categories. First, eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). Second, if the previous national coverage determination barred coverage for an item or service under title XVIII, MACs will now be able to cover the item or service if the MAC determines that such action is appropriate under the statute. We believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries since we believe the future utilization for items and services within these policies will be limited, each affecting less than one percent of the Medicare FFS population.

For the one NCD where NCD removal changes coverage from limited national coverage to MAC discretion, claims data from 2019 shows that less than one percent of the Medicare population is affected. Specifically, NCD 180.2 Enteral and Parenteral Nutrition Therapy provided coverage with limitations. Where in 2019 CMS paid 1,643,739 Medicare FFS claims for 83,551 unique beneficiaries totaling CMS payments of $356,228,606. While we have claims data available for 2020, the data shows a decrease in claims, unique beneficiaries and total amount paid by CMS. We believe this may be due in part to the COVID–19 pandemic; however, we do not have any information to be able to say that conclusively. The change could be due to other factors not examined here. We estimate there will be *de minimis* change to 2022 payments, compared to 2019 or 2020 because, as discussed in section III.F. of the final rule, local contractors have finalized two LCDs, effective for dates of service on or after September 5, 2021 that will continue to provide parenteral and enteral nutrition coverage for Medicare beneficiaries, after removal of NCD 180.2. Therefore, we believe that removing this NCD will not result in significant changes to payments.

For the one non-covered NCD to be eliminated, Positron Emission Tomography (PET) Scans under NCD 220.6, we did not expect to find historical claims data for the non-oncologic uses of PET at issue. We broadly noncover non-oncologic indications of PET, in other words, we required that every non-oncologic indication for PET must have its own NCD in order to receive coverage. Because this NCD provides for noncoverage on non-oncologic indications, we do not have accurate claims data to estimate total impact. However, based on the service, we expect future claims to affect less than one percent of Medicare FFS beneficiaries. As discussed in section III.F. of this final rule, the NCD allows coverage for diagnostic PET imaging for oncologic uses not already determined by an NCD, to be made at the discretion of local MACs. We believe that extending local contractor discretion for non-oncologic indications of PET provides an immediate avenue to potential coverage in appropriate

candidates and provides a framework that better serves the needs of the Medicare program and its beneficiaries. For clarity, we did not propose to change any other subsections of 220.6. Thus, the NCDs listed at 220.6.1 through 220.6.20 will not be changed by this provision.

6. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation

As discussed in section III.H., Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR), of this final rule, we proposed largely conforming changes throughout §§ 410.47 (PR) and 410.49 (CR/ICR). These changes are intended to ensure consistency and accuracy in terminology, definitions and requirements where appropriate across PR and CR/ICR conditions of coverage. Specific to PR, we proposed to remove the requirement for direct physician-patient contact related to the periodic review of the patient's treatment plan because such interaction within the PR program is not necessary for all patients and can be specified, as needed, in individualized treatment plans (ITPs). We also proposed to add coverage of PR for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge. After considering public comments and additional clinical evidence, we are finalizing the revisions to improve consistency and accuracy across PR and CR/ICR conditions of coverage as proposed. We are also finalizing the removal of the PR requirement for direct physician-patient contact. We are expanding upon our proposal to cover PR for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge. We are removing the proposed hospitalization requirement and finalizing coverage of PR for beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks. We did not receive public comments on the proposed impact so we use the same methodology in estimating the impact of the final expansion of coverage for PR below.

In assessing the impact of these provisions, we note that the expansion of PR coverage may increase utilization. Based on the low utilization rate discussed below, we do not believe the other revisions will significantly impact utilization and the Medicare program.

To estimate the potential increase from the expansion of coverage for PR, we searched the literature for articles that evaluated the utilization rate of PR for the currently eligible diagnosis of chronic obstructive pulmonary disease (COPD) in order to determine the historical utilization trends of this service.

Nishi et al. (2016) investigated the number of Medicare beneficiaries with COPD who received PR from January 1, 2003 to December 31, 2012. Their results included both individuals who had experienced hospitalizations for COPD and those who were outpatients only. The number of unique patients with COPD who initially participated in PR during the study period was 2.6 percent in 2003 (before conditions of coverage at § 410.47 were established) and 2.88 percent in 2012 (after conditions of coverage at § 410.47 were established).[268] In 2019, Spitzer, et al. published an article based on Medicare claims data from 2012, finding that 2.7 percent of eligible Medicare beneficiaries received PR within 12 months of hospitalization with COPD.[269] Using claims data from FFS Medicare beneficiaries hospitalized for COPD in 2014, Lindenauer et al. (2020) reported that only 3 percent initiated PR within 1 year of their hospital discharge.[270] Taken together, this data informs us that utilization of PR in the Medicare population is very low, and that the majority of patients who avail themselves of this service do so, post hospitalization.

There are limitations to applying this data to identify the utilization rate of PR to the conditions of coverage specified at § 410.47. Most notably, some of these studies included patients whose services were billed with non-PR respiratory therapy codes (G0237, G0238 and G0239), instead of only patients whose services were billed with the PR code (G0424). But the authors also limited patient inclusion to those with a principal or secondary COPD diagnosis, so we believe this suggests that 3 percent is an upper bound for the utilization of PR currently in Medicare beneficiaries. Given that participation in PR has remained steady for many years, we do not expect this pattern to change. As such, for the purposes of this analysis, we assume that 3 percent of eligible beneficiaries under the expansion of coverage (beneficiaries who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks) will participate in PR.

To identify the eligible beneficiaries under our provision, we first identify the number of beneficiaries who had COVID–19 using the Preliminary Medicare COVID–19 Data Snapshot.[271] At the time of writing, the Snapshot included data from January 1, 2020 to July 24, 2021, and identified 4,656,553 total COVID–19 cases for Medicare beneficiaries. Using Medicare FFS data from February 24, 2020 to September 27, 2020 as compared to the same time frame in 2015 through 2019, Tarazi et al. (2021) found that the COVID–19 related mortality rate, defined as death within 60 days of COVID–19 diagnosis, was 17.5 percent.[272] To calculate the number of beneficiaries that survive COVID–19 to be eligible for PR under our coverage expansion, we reduced 4,656,553 by 17.5 percent (814,897) to 3,841,656 beneficiaries. A paper published by the Tony Blair Institute for Global Change [273] states that the Covid Symptom Study led by King's College London indicated that about 10 percent of survey participants reported symptoms (including shortness of breath and other symptoms like fatigue, headache and loss of smell) beyond a four-week recovery period. Using this information, we estimate that the patient population we are expanding PR coverage to, those who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks, to be 384,166 beneficiaries (3,841,656 × 0.10). Based on our assumption of utilization above, 3 percent, for the newly covered patient population, we estimate 11,525

[268] Nishi SP, Zhang W, Kuo YF, Sharma G. Pulmonary Rehabilitation Utilization in Older Adults With Chronic Obstructive Pulmonary Disease, 2003 to 2012. J Cardiopulm Rehabil Prev. 2016;36(5):375–382. doi:10.1097/HCR.0000000000000194.

[269] Spitzer KA, Stefan MS, Priya A, et al. Participation in pulmonary rehabilitation after hospitalization for chronic obstructive pulmonary disease among Medicare beneficiaries. Ann Am Thorac Soc. 2019;16:99–106.DOI: 10.1513/AnnalsATS.201805–332OC. PMID: 30417670; PMCID: PMC6344454.

[270] Lindenauer PK, Stefan MS, Pekow PS, et al. Association Between Initiation of Pulmonary Rehabilitation After Hospitalization for COPD and 1-Year Survival Among Medicare Beneficiaries. JAMA. 2020;323(18):1813–1823. doi:10.1001/jama.2020.4437.

[271] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[272] Tarazi WW, Finegold K, Sheingold SH, et al. COVID–19-Related Deaths And Excess Deaths Among Medicare Fee-For-Service Beneficiaries. Health Affairs 40, No. 6 (2021): 879–885. doi: 10.1377/hlthaff.2020.02521.

[273] Published at https://institute.global/sites/default/files/articles/Long-Covid-Reviewing-the-Science-and-Assessing-the-Risk.pdf on October 5 2020.

beneficiaries will receive PR (384,166 × 0.03).

Medicare covers PR for a maximum of 72 sessions. Using 2018 and 2019 Medicare claims data from the Chronic Conditions Data Warehouse (CCW), beneficiaries on average completed 14 sessions of PR. If we assume patients eligible based on our expansion of coverage will participate, on average, in the same number of sessions, we estimate the expansion of coverage will increase PR utilization by 161,350 sessions annually (11,525 beneficiaries × 14 average sessions completed per beneficiary).

Claims for PR are submitted using CPT code G0424. Our analysis of Medicare claims data indicates that 97.54 percent of PR sessions are billed under the Hospital OPPS at $55.66 (national average price) for an estimated total of $8,759,815 (161,350 PR sessions × 0.9754 × $55.66). The remaining 2.46 percent of PR sessions are billed under the PFS, with 2.12 percent of PR sessions furnished in a physician's office which has a national average price of $30.36 and 0.34 percent billed by a physician when PR was furnished in a HOPD which has a national average price of $13.96. Taken together, the estimated total for this remaining 2.46 percent of PR sessions is $111,508 ((161,350 PR sessions × 0.0212 × $30.36) + (161,350 PR sessions x 0.0034 × $13.96)). We estimate the total added cost to the Medicare program of this expansion of coverage to be $8,871,323 ($8,759,815 + $111,508) annually during and immediately following the PHE for COVID–19. The impact of our final rule increases the final estimate by $6,709,876 which reflects the larger patient population that will be eligible for PR. Removing the proposed hospitalization requirement increased the number of eligible beneficiaries by 290,555. As COVID–19 cases decline, we expect the annual impact to decrease because eligible patient populations will likely decrease; however, we are unable to estimate the longer term impact of our provisions due to the unpredictable nature of the PHE and the lack of long term data on COVID–19.

7. Medical Nutrition Therapy

As discussed in section III.I., Medical Nutrition Therapy (MNT), of this final rule, we proposed to remove the restriction that patients only be referred to MNT by the treating physician and update the glomerular filtration rate (GFR) eligibility for patients with chronic kidney disease. We do not anticipate any significant increase in utilization of MNT services resulting from our revisions. Despite various policy changes that could have improved use, such as increasing payment via adding work RVUs to MNT codes in 2006, approving MNT for telehealth coverage in 2005 and including registered dieticians (RDs) and nutrition professionals as telehealth distant site providers, and waiving out-of-pocket costs to beneficiaries, MNT participation remains under 2 percent of eligible beneficiaries. Based on an analysis of Medicare claims data from 2018, 2019, 2020, we identify the utilization rate of MNT services among eligible beneficiaries to be between 1.5 and 1.8 percent.

Although MNT is covered by many State Medicaid programs and private insurers, use is low in the US.[274] [275] [276] The Academy of Nutrition and Dietetics recognizes that research specific to the underuse of MNT services is scant.[277] Anecdotal reports and related research on diabetes self-management training point to a multitude of reasons why utilization of the MNT services benefit have remained low. These potential barriers include lack of awareness of MNT by patients and clinicians, inconsistent coverage for MNT services by non-Medicare payers, patient travel and time issues to receive the services and lack of availability of services from RDs who may perceive the process of Medicare enrollment/insurance credentialing and billing as being burdensome and complex.[278] Of about 100,000 RDs in the US, only 1,589 submitted Medicare FFS MNT claims in 2017. One study revealed that less than half of RDs providing MNT services in an ambulatory care setting indicated they were not Medicare providers due to reasons such as perceived low reimbursement rates, not providing MNT to Medicare eligible patients, not knowing how to become a Medicare provider, and providing MNT to Medicare patients for diagnoses not covered by Medicare.[279]

Our revisions may increase beneficiary access to the MNT benefit and reduce primary care physician burden since we proposed that referrals can come from other physicians and not only from the physician treating the patient for their diabetes or kidney disease; although, as discussed above, we do not expect the changes to make a significant impact on the Medicare program. We do not anticipate increased administrative burden as documentation in the medical record of any referred service is already a part of discharge planning in the hospital setting. The changes to the GFR requirements are to conform our regulation to updated clinical standards and also do not pose a significant change.

8. Medicare Shared Savings Program

a. Modifications to the Shared Savings Program Quality Reporting Requirements Under the APP and the Quality Performance Standard

In section IV.A.3.d.(1)(d) of this final rule, we are extending the use of the CMS Web Interface as a collection type for the Quality Payment Program for performance years 2022, 2023, and 2024 for Shared Savings Program ACOs reporting under the APP. In section III.J.1.c. of this final rule, we are finalizing that in order for ACOs to meet the quality reporting requirements under the Shared Savings Program for performance year 2022 and subsequent performance years, ACOs must meet the following requirements:

For performance years 2022, 2023, and 2024: An ACO must report on either:

(a) The ten CMS Web Interface measures and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP, or

(b) The three eCQMs/MIPS CQMs and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP.

If an ACO chooses to report the three eCQMs/MIPS CQMs, its performance on all three eCQMs/MIPS CQMs will be used for purposes of MIPS scoring under the APP. If an ACO decides to report both the ten CMS Web Interface measures and the three eCQMs/MIPS CQMs, it will receive the higher of the

[274] *https://www.eatrightpro.org/payment/nutrition-services/medicaid/medicaid-and-rdns.*

[275] Kramer, H., Jimenez, E.Y., Brommage, D., Vassalotti, J., Montgomery, E., Steiber, A., & Schofield, M. (2018). Medical nutrition therapy for patients with non–dialysis-dependent chronic kidney disease: barriers and solutions. *Journal of the Academy of Nutrition and Dietetics,* 118(10), 1958–1965.

[276] Jimenez, E.Y., Kelley, K., Schofield, M., Brommage, D., Steiber, A., Abram, J.K., & Kramer, H. (2021). Medical nutrition therapy access in CKD: A cross-sectional survey of patients and providers. *Kidney medicine*, 3(1), 31–41.

[277] Kramer, H., Jimenez, E.Y., Brommage, D., Vassalotti, J., Montgomery, E., Steiber, A., & Schofield, M. (2018). Medical nutrition therapy for patients with non–dialysis-dependent chronic kidney disease: Barriers and solutions. *Journal of the Academy of Nutrition and Dietetics*, 118(10), 1958–1965.

[278] Ibid.

[279] Parrott JS, White JV, Schofield M, Hand RK, Gregoire MB, Ayoob KT, Pavlinac J, Lewis JL, Smith K. Current coding practices and patterns of code use of registered dietitian nutritionists: The Academy of Nutrition and Dietetics 2013 coding survey. J Acad Nutr Diet. 2014;114(10):1619–1629.

two quality scores for purposes of the MIPS Quality performance category. For performance year 2025 and subsequent years: The ACO must report the three eCQMs/MIPS CQMs and administer a CAHPS for MIPS survey and CMS will calculate the two claims-based measures included under the APP.

Absent the related provision analyzed below to reduce the quality performance standard for PY 2023 to the 30th percentile MIPS Quality performance category score, the changes to the quality reporting requirements, including the accommodation to continue the availability of the CMS Web Interface as a reporting mechanism under the APP will likely provide an easier path for a meaningful subset of ACOs that would otherwise have faced difficulty meeting the quality performance threshold previously established in rulemaking for PY 2023. However, we estimate that nearly all such ACOs would already have met the lower 30th percentile performance standard in PY 2023 without the additional reporting flexibility. Of the relatively few, remaining ACOs that we estimate would have failed to meet the lower 30th percentile performance standard without the additional reporting flexibility, we estimate that about half (on average) will meet the quality performance standard as a result of the quality reporting flexibility adopted in this final rule, and thereby further increase shared savings payments to ACOs by about $20 million in PY 2023.

In section III.J.1.d. of this final rule, we are finalizing, with modifications, the proposal to freeze the quality performance standard at the 30th percentile across all MIPS Quality performance category scores for performance year 2023, and to establish incentives to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in performance year 2022 and performance year 2023. The quality performance standard will increase to the 40th percentile across all MIPS Quality performance category scores for performance years 2024 and subsequent performance years. The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions.

We are finalizing that, with the exception of an ACO in the first performance year of its first agreement period, an ACO will meet the quality performance standard under the Shared Savings Program by reporting quality data via the APP established under § 414.1367 according the method of submission established by CMS and for:

- Performance years 2022 and 2023:

++ Achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ If the ACO reports the three eCQMs/MIPS CQMs, meeting the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three measures, and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least 1 of the 5 remaining measures in the APP measure set. Consequently, the ACO would be required to meet the performance benchmark on either 2 outcome measures (one measure at the 10th percentile and the other at the 30th percentile), or 1 outcome measure at the 10th percentile and any other measure in the APP measure set at the 30th percentile.

If the ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

- Performance year 2024 and subsequent performance years:

Achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

If the ACO (1) does not report any of the 10 CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and (2) does not administer a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

Our analysis of quality performance data reported by ACOs for performance years starting during 2019 indicates that about 20 percent of ACOs would have failed a quality performance standard defined as the 40th percentile across all MIPS Quality performance category scores. There is significant uncertainty whether PY 2023 will play out similarly to the baseline data. The fraction of ACOs that would ultimately fail to meet a higher standard in PY 2023 could change significantly if the universe of MIPS Quality performance category scores improves relative to ACOs' quality performance scores, or alternatively if ACOs, particularly ACOs at risk of failing, respond to the increased quality performance standard by boosting their performance. Utilizing a Monte Carlo approach, assuming that the simulated poor performing ACOs have a 50 percent chance of improving their quality performance beyond the 40th percentile, if CMS kept the quality performance standard at the 40th percentile, then the cost of reducing to the 30th percentile in 2023 will be $190 million (range $10 million to $370 million). There is a wide range because slight changes in quality scoring at the low end of the distribution could render the 40th percentile more or less of an effective point of discrimination among ACOs earning shared savings.

b. Modifications to Other Shared Savings Program Requirements

We do not anticipate a material aggregate impact for the other changes we are finalizing as proposed related to the Shared Savings Program, specifically: Revisions to the definition of primary care services used in the Shared Savings Program's beneficiary assignment methodology (section III.J.2. of this final rule); revisions to the repayment mechanism arrangement policy, including changes to the calculation and recalculation of repayment mechanism amounts (section III.J.3. of this final rule); revision of the requirements concerning disclosure of prior participation in the Shared Savings Program by the ACO, ACO participants, and ACO providers/suppliers, and revisions to Shared Savings Program requirements to reduce the frequency and circumstances under which ACOs submit sample ACO participant agreements and executed ACO participant agreements to CMS (section III.J.4. of this final rule); and revisions to the beneficiary notification requirement as it applies to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation (section III.J.5. of this final rule).

However, as we note in section III.J.3. of this final rule, lower required repayment mechanism amounts could reduce costs for ACOs in fees charged by financial institutions for letters of credit and by insurance companies for surety bonds. We estimate that such relief, in total for all participating ACOs, could be worth $2 to $4 million annually under the approach we are finalizing (assuming a reduction of approximately $196 million in repayment mechanism amounts, in aggregate).

We also note that the revisions we are finalizing to the definition of primary care services used in the assignment methodology may have differing effects on a subset of participating ACOs, for example, by leading a beneficiary to be assigned to a competing ACO, for a small subset of beneficiaries. We do not anticipate such ACO-level changes will result in a net impact on program spending overall.

9. Medicare Ground Ambulance Data Collection System

In section III.K. of this final rule, we finalized our proposed changes to the Medicare Ground Ambulance Data Collection System including the proposed change to the data collection period and data reporting period for selected ground ambulance organizations in year 3, proposed revisions to the timeline for when the payment reduction for failure to report will begin and when the data will be publicly available, and proposed revisions to the Medicare Ground Ambulance Data Collection Instrument.

We stated in the proposed rule that while we believed that these changes and clarifications will be well received by the ground ambulance stakeholders, we did not believe that these changes will have any substantive impact on the cost or time associated with completing the Medicare Ground Ambulance Data Collection Instrument. We also noted in the proposed rule that the overall length of the Medicare Ground Ambulance Data Collection Instrument would be the same as previously finalized (84 FR 62888) with these changes. Additionally, some of the instructions which we proposed to add were intended to improve clarity and may therefore reduce the time the ground ambulance organizations spend addressing the questions. We did not receive any public comments on our estimated impact on the cost or time associated with completing the Medicare Ground Ambulance Data Collection Instrument. As we discussed in section III.K of this final rule, we are finalizing our proposed changes to the Medicare Ground Ambulance Data Collection System.

10. Medicare Diabetes Prevention Program Expanded Model

a. Effects of Provisions Relating to the Medicare Diabetes Prevention Program Expanded Model

(1) Effects on Beneficiaries

We proposed to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) Allow CMS to remove the ongoing maintenance phase (months 13–24) of the MDPP set of services for those beneficiaries who started their first core session on or after January 1, 2022; (2) update the performance payments for the MDPP set of services in the core and core maintenance performance periods; and (3) waive the Medicare provider enrollment application fee for all organizations enrolling as MDPP suppliers on a prospective basis. These changes will have a positive impact on beneficiaries' health by increasing the capacity of MDPP eligible organizations to enroll in Medicare as MDPP suppliers and increasing access to the MDPP set of services for beneficiaries. Eligible beneficiaries receive these services as preventive services, which require no copays or cost sharing. These changes address MDPP supplier and beneficiary needs based upon all available monitoring and evaluation data. The changes are also responsive respond to stakeholder comments.

(2) Effects on the Market

Currently, more than 1,000 organizations nationally are eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) status. However, only 27 percent of eligible organizations are participating in MDPP. We anticipate that the removal of the second year of the MDPP set of services will make MDPP attractive and feasible to more MDPP eligible organizations. Not only does a 12-month MDPP services period align with that of the CDC's National DPP and the DPP model test, our data show that only 10 percent of enrolled MDPP participants continue with the Ongoing Maintenance phase sessions (Year 2), and the majority are reaching their weight loss milestone within the first 6 months of the set of MDPP services. Stakeholders report that the second year of MDPP, or the ongoing maintenance phase, is cost prohibitive due to the costs to retain beneficiaries in year 2 of the expanded model as well as the costs to deliver an additional year of the expanded model that is not supported by the CDC National DPP curriculum. The CDC's National DPP curriculum supports a 1-year program and suppliers have found it difficult to extrapolate the curriculum to a second year. Additionally, MDPP suppliers commented that they have an increasingly difficult time making the business case for MDPP given the costs associated with the ongoing maintenance phase and the low performance payments associated with the second year. Given the low volume of participants continuing in the second year of MDPP, delivering the MDPP ongoing maintenance period creates an undue burden to MDPP suppliers. The cost to offer and deliver the sessions to a small cohort of individuals outweigh the maximum payments available from Medicare.

Stakeholders have consistently commented that CMS should shorten the MDPP expanded model to 1 year, with payment levels at least equivalent to the levels provided in the DPP model test. For example, during the DPP model test, suppliers were paid an average of $462 per beneficiary for the 1-year model test. The second year has made delivering MDPP both financially unattractive and unstainable for many of the current and eligible MDPP suppliers. Suppliers have reported that it is very difficult to engage and retain beneficiaries in a second year, and the reimbursement levels for a second year are inadequate to cover supplier costs. We proposed to shorten the MDPP service period to 1 year and increase the performance payments in the first year. These changes respond to stakeholder feedback and may alleviate some of the difficulty retaining MDPP participants during the core maintenance phase of the expanded model.

(3) Burden Related to Information Collection Requirements—No impact

(a) Supplier Standards

MDPP suppliers may encounter the Medicare enrollment fee during the following Medicare provider enrollment transactions: initial enrollment; revalidation (every 5 years for MDPP); or the addition of a new practice location. The provider/supplier enrollment fee for Calendar Year 2021 is $599. Although MDPP suppliers may submit a written request to CMS for a hardship exception to the application fee in accordance with § 424.514, many will not qualify and the hardship application process will simply add more burden on the organization. We have heard from the CDC as well as other stakeholders that the enrollment fee is a potential barrier to eligible MDPP suppliers who will not otherwise enroll in Medicare except for MDPP. Approximately 39 percent of our current suppliers are non-traditional suppliers that serve their local communities and play a critical role in enrolling more diverse, equitable, and inclusive cohorts of Medicare beneficiaries to MDPP. These non-traditional suppliers include, but are not limited to YMCAs, county health departments, community health centers, and non-profit organizations that focus on health education, and otherwise will neither enroll nor be able

to enroll as a Medicare supplier at all if it were not for MDPP. They often serve as trusted sources of health information for their communities. However, they also represent a large number of eligible organizations who have not enrolled in Medicare as MDPP suppliers. We anticipate that waiving the enrollment fee on a prospective basis along with the other programmatic adjustments are likely to result in more MDPP suppliers, increased beneficiary access to MDPP services, and an ongoing reduction of the incidence of diabetes in eligible Medicare beneficiaries, in both urban and rural communities.

In April 2020, CMS waived all provider enrollment application fees as part of the COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers. As a result, we saw an increase in MDPP supplier enrollment. We believe that granting a waiver of the fee for MDPP suppliers to extend beyond the COVID–19 Emergency Declaration Blanket Waiver, along with the other change to MDPP, may stimulate MDPP supplier enrollment and enhance the MDPP evaluation. We proposed waiving the Medicare provider enrollment fee beyond COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers because the enrollment fee creates a potential barrier to MDPP supplier enrollment, beneficiary access to the program, and subsequently, our ability to evaluate MDPP. Specifically, we proposed, to waive the enrollment fee as described in section 1866(j)(2)(C)(i) and (ii) of the Act during the MDPP expanded model test phase.

(b) Payment for MDPP Services

Our regulations at § 414.84 specify the payments MDPP suppliers may be eligible to receive, payments for furnishing MDPP services, and meeting performance targets related to beneficiary weight loss and/or attendance. MDPP suppliers are paid by CMS by submitting claims for MDPP beneficiaries using claim form CMS–1500 (*https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf*). As a condition for payment, claims submitted by MDPP suppliers must be for services furnished to eligible beneficiaries in accordance with § 414.84(b) and (c). We have streamlined the performance payments so that they are easier to understand and suppliers receive larger payments for participants reaching attendance and weight loss performance-based milestones. For example, the attendance-based performance payments are based on a standardized per-session rate, paid after the 1st, 4th, and 9th sessions attended during the core sessions interval, and after attending the two (2) sessions during each of the core maintenance intervals. We have redistributed all the Year 2 ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments in Year 1. As finalized, the maximum payment of $705 over a 1-year service period is $1 more than the current maximum payment of $704 under the original 2-year payment structure. We believe eliminating the second year and its associated payments while increasing the first-year payments will result in a more financially sustainable expanded model.

Increasing the first year MDPP payment amounts should not negatively affect a supplier's performance (for example, participants' weight loss). As finalized, we increased the per session payments to $35, with suppliers receiving $53 more per beneficiary who attends the 4th core session compared to current payments and $27 more than proposed. We increased the attendance-based payments in response to stakeholder comments and maintained the 5 percent weight loss payments. Although some of the largest payments to suppliers are still driven by weight loss achievement, the maximum payment for attendance only is finalized at $455 compared to $338 proposed and $205 current. Further, in order to maintain CDC Diabetes Prevention Recognition Program (DPRP) recognition status, which is required to be an MDPP supplier, certain levels of performance metrics (for example, weight loss) must be satisfied. There is no evidence that eliminating the second-year maintenance sessions, shortening the MDPP services period to 1 year, will have any negative effects on performance of the expanded model.

(4) Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

Table 140 shows an updated estimate (in millions) for the impact on Medicare spending of two changes to the Medicare Diabetes Prevention Program (MDPP) to be implemented in 2022, with corrected assumptions:

- Waiving the Medicare enrollment fee for all new MDPP suppliers; and
- Shortening the MDPP services period to 1 year and shifting all of the Ongoing Maintenance reimbursement amounts to year one.

TABLE 140: Estimated 10-Year Impact of MDPP on Medicare Spending for CYs 2022 through 2031

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
Impact on Medicare Spending	$0.3	$0.2	$0.2	$0.1	-$0.0	-$0.1	-$0.2	-$0.3	-$0.3	-$0.4	-$0.6

These estimates by the CMS Office of the Actuary do not consider waiving the Medicare enrollment fee as a direct cost and assume there will be an additional 500 beneficiaries per year participating in MDPP. The average payment for an MDPP participant will increase by $150. While the maximum payment available to an MDPP supplier is only slightly greater than the maximum payment available under the original 2-year payment structure, the second year set of MDPP services have historically been far less utilized than the first year set of services. Therefore, eliminating the second-year payments has a minimal negative effect to the assumed costs of the expanded model. In the most recent year prior to the PHE, 747 Medicare FFS beneficiaries entered MDPP. Increasing the first-year payment amounts to suppliers and waiving the Medicare enrollment fee should increase access to MDPP, resulting in more utilization of the MDPP set of services. Starting in 2022, we can assume that 750 beneficiaries will have entered the expanded model each year without including the finalized changes. After including these changes, we will now

assume 1,250 beneficiaries will enter the expanded model each year. This assumption has a high level of uncertainty and we revisit it in the Sensitivity Analysis section.

Increasing the first year MDPP payment amounts should not negatively affect a supplier's performance (for example, participants' weight loss). Almost all of the increases to the payment amounts are applied after the 4th core session. Even though most of the payment increases are not tied to weight loss achievement, in order to maintain CDC Diabetes Prevention Recognition Program recognition status, which is required to be an MDPP supplier, certain levels of performance metrics (for example, weight loss) must be satisfied.

There is no evidence that eliminating the second-year maintenance sessions, shortening the MDPP services period to one year, will have any negative effects on performance of the expanded model.

(b) Sensitivity Analysis

Since the cost to suppliers for delivering the MDPP set of services is generally unknown, how utilization of the expanded model will be affected by the changes is highly uncertain. Table 141 shows the 10-year impact estimates (in millions) for different levels of additional beneficiary participation as a result of the changes:

TABLE 141: 10 Year Impact Estimates

Additional Beneficiaries Per Year	10-year Estimated Impact
0	$0.5
250	$0.3
500 (assumption used in best estimate)	-$0.6
1,000	-$2.3

Finally, higher projected savings are associated with increases in beneficiary participation, while no additional beneficiaries will result in an estimated cost.

The financial impacts we provided for the previously proposed payment schedule changes included errors that impacted our estimates: additional costs resulting from payment increases were not applied to the baseline participants; the count of 1,742 participants used to estimate future baseline participation included Medicare Advantage beneficiaries, which should have been excluded; and since there were only 747 new FFS participants in the most recent year prior to the start of the PHE, our best estimate would have assumed 250 additional FFS participants per year resulting from the previously proposed changes.

TABLE 142: Estimated 10-Year Impact of Previously Proposed MDPP Payment Schedule Changes on Medicare Spending for CYs 2022 through 2031, Corrected

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
Impact on Medicare Spending (previous)	$0.2	$0.2	$0.1	$0.0	-$0.1	-$0.2	-$0.2	-$0.3	-$0.3	-$0.4	-$0.9
Impact on Medicare Spending (corrected)	$0.2	$0.1	$0.1	$0.0	$0.0	-$0.1	-$0.1	-$0.1	-$0.2	-$0.2	-$0.2

b. Alternatives Considered

No alternatives were considered. The 2-year MDPP service period has depressed interest in MDPP among would-be MDPP suppliers. These actions address stakeholder comments on the barriers to MDPP expanded model success. If we do not take action, we will not be able to scale MDPP as intended, impacting Medicare beneficiary access to this expanded model. Reducing the MDPP from a 24- to a 12-month services period, increasing the year 1 performance payments, and waiving the Medicare provider enrollment application fee not only better aligns the expanded model with the evidence that helped certify the DPP model test initially, but it will encourage eligible organizations to enroll as MDPP suppliers.

c. Impact on Beneficiaries

This change will have a positive impact on eligible MDPP beneficiaries, as it better aligns with the CDC's National DPP, giving both the participants and the coaches similar messaging regarding this expanded model, regardless of payer. MDPP suppliers often offer the MDPP set of services to mixed cohorts, or classes with participants who are not eligible for MDPP, but who are enrolled in a National DPP cohort. Since MDPP generally follows the CDC's National DPP and aligns its expanded model with the CDC's DPRP Standards, it is confusing to participants, coaches, and staff when talking about a 2-year set of services to its eligible Medicare participants when the non-Medicare participants have a 1-year program. Finally, reducing the MDPP service period from 2 years to 1 year allows more cohorts to start and finish MDPP during the expanded model initial period of performance, which is expected to end in March 2023.

d. Estimating Regulatory Familiarization Costs

Given that we tried to align this rule as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rule impacts only enrolled MDPP suppliers and eligible beneficiaries who

have started the MDPP expanded model or are interested in MDPP.

11. Vaccine Administration Services

In section II.J.1. of this final rule, we are finalizing that effective January 1, 2022, CMS will pay $30 per dose for the administration of the influenza, pneumococcal and hepatitis B virus vaccines. In addition, CMS will maintain the current payment rate of $40 per dose for the administration of the COVID–19 vaccines through the end of the calendar year in which the ongoing PHE ends. Effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID–19 vaccine administration will be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines.

We estimate that the policy to increase the administration cost for influenza/pneumococcal/HBV vaccine services to $30 in 2022 will increase Medicare spending by roughly $250 million in CY 2022. This estimate doesn't reflect the impact of induced utilization of the vaccine, or any offsetting savings resulting from averted hospitalizations for those who would now get the vaccine. This policy may encourage more health care providers to offer these services or encourage those that already offer these services to proactively identify and vaccinate more beneficiaries compared to what they might under the lower rates, which would result in further additional vaccine costs. However, if more beneficiaries were vaccinated then Medicare costs associated with the treatment of influenza, pneumonia, and hepatitis B could be reduced. In order to offset the costs associated with this policy roughly 10–11K influenza-related hospitalizations would have to be averted.

12. Medicare Provider and Supplier Enrollment Changes—Provider Enrollment

As explained in section III.N. of this final rule, we proposed changes to three of our existing revocation reasons:

- We proposed to expand § 424.535(a)(2) to permit revocation based on the OIG exclusion of administrative or management services personnel furnishing services payable by a Federal health care program, such as a billing specialist, accountant, or human resources specialist.
- We proposed to expand § 424.535(a)(13) to permit revocation of a physician's or other eligible professional's enrollment if he or she surrenders his/her Drug Enforcement Administration (DEA) certificate of registration in response to an order to show cause.
- We proposed to revise the factors in § 424.535(a)(8)(ii) (which permits revocation based on a pattern or practice of submitting non-compliant claims) to better enable CMS to target shorter periods of non-compliant billing.

We believe that all three of these changes will result in an increase in the number of revocations that CMS imposes. However, we believe this number will be rather small. We currently impose only a limited number of revocations under §§ 424.535(a)(2), (a)(13), and (a)(8)(ii). Accordingly, since our expansion of these three revocation reasons will be fairly modest, we do not foresee more than a very slight increase in revocations.

Table 143 outlines the number of revocations we estimate will ensue under our revocation expansions. These numbers only account for additional revocations stemming from our changes:

TABLE 143: Additional Revocations

Revocation Reason	Number
§ 424.535(a)(2)	5
§ 424.535(a)(13)	5
§ 424.535(a)(8)(ii)	5
Total	**15**

Internal CMS data indicates that the average provider/supplier that will be affected by these regulatory expansions receives roughly $50,000 in Medicare payments each year. (We used a similar $50,000 annual payment estimate for our provider enrollment provisions in the CY 2020 PFS final rule) (84 FR 62568)). Providers/suppliers revoked under our revocation expansions will thus not receive these payments. Hence, multiplying our $50,000 estimate by the revocation totals in Table 143 results in a projected transfer from these providers/suppliers to the Federal Government of $750,000 ($50,000 × 15 revocations).

We did not receive public comments on these estimates and are therefore finalizing them as proposed.

13. Provider/Supplier Medical Review Requirements—Prepayment and Post-Payment Reviews

In section III.N.2. of this final rule, we proposed to: (1) Define key terms including ''additional documentation,'' ''additional documentation request,'' ''post-payment medical review,'' and ''prepayment medical review;'' (2) codify contractors' authority to request additional documentation for prepayment and post-payment review within established timeframes; (3) codify timeframes for response to requests for documentation; and (4) codify result of a failure to comply with prepayment or post-payment documentation request(s) by a provider or supplier, specifically denial of payment. We do not believe these provisions involve any additional impact or burden on providers, suppliers, or States; however, we welcomed feedback from stakeholders regarding the potential costs of these provisions.

The regulations will incorporate already established key terms and definitions as well as processing requirements pertaining to prepayment and post-payment medical review into regulation. Placing this information in regulation will improve provider and supplier understanding of the medical review process and their responsibilities in complying with our review contractor's requests. Further, the regulations represent no change to medical review requirements. As such, we did not anticipate any change in the number of prepayment medical reviews, post-payment medical reviews or the number of additional documentation requests made by contractors.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

14. Effect of Modifications to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.O of this final rule, we are finalizing our proposal to allow OTPs to continue to furnish the therapy and counseling portions of the weekly bundles, as well as any additional counseling or therapy that is billed using the add-on code, using audio-only telephone calls rather than via two-way interactive audio-video communication technology in cases where audio/video communication is not available to the beneficiary after the conclusion of the PHE for COVID–19, provided all other applicable requirements are met. We believe this change will facilitate broader access to these services for beneficiaries. We are also finalizing our proposal to require that when these services are furnished using audio-only technology, practitioners certify that they had the capacity to furnish the services using two-way audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary.

We believe the Part B cost impact of these final policies will be minimal, since payment for therapy and counseling is included in the bundled payment regardless of the modality used to deliver it and we do not expect that this provision will increase the frequency at which medically necessary counseling and therapy services are billed using the counseling and therapy add-on code (HCPCS code G2080).

Additionally, as discussed in section III.O. of this final rule, the FDA recently announced the approval of a new, higher dose naloxone hydrochloride nasal spray product used to treat opioid overdose and that the newly approved product delivers 8mg of naloxone. In the CY 2021 PFS final rule (85 FR 84683 through 84685), we finalized payment for HCPCS code G2215 (Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure). HCPCS code G2215 was priced based on an assumption of a typical case in which the beneficiary will be provided with a box of two 4mg nasal spray products. At the time of drafting the proposed rule, we did not yet have any available pricing information for this newly approved product. However, in order to be able to make payment to OTPs under Medicare for this product, we proposed to create a new G-code describing a take-home supply of this higher dose naloxone hydrochloride nasal spray product. After considering the comments received, we are finalizing our proposal to establish a new code for a higher-dose of naloxone hydrochloride nasal spray. We will price this code as proposed; the drug component is based on the methodology at § 410.67(d)(2)(i) and the amount of the non-drug component of the code is based on the CY 2020 Medicare payment rate for CPT code 96161, as updated by the MEI. Based on utilization of the existing naloxone codes under the OTP benefit, we believe that the cost impact of finalizing this new code will be minimal.

15. Physician Self-Referral Update

The physician self-referral law provisions are discussed in section III.P. of this final rule.

As discussed in section III.P.2. of this final rule, we are amending the provisions of § 411.354(c)(2) identifying unbroken chains of financial relationships that constitute ''indirect compensation arrangements'' to ensure that a longstanding prohibition on certain per unit of service-based compensation formulas for determining charges for the rental of office space and equipment remains within the ambit of the law. This provision, which was inadvertently omitted when the definition of ''indirect compensation arrangement'' was revised in the December 2, 2020 final rule entitled ''Modernizing and Clarifying the Physician Self-Referral Regulations'' (85 FR 77492), is necessary to protect against potential abuses such as overutilization and anti-competitive behavior. We believe that most parties have continued to comply with the regulatory provisions on per unit of service-based compensation formulas for the rental (or lease) of office space and equipment as they have done since the requirements became effective on October 1, 2009. We are also adding provisions to assist stakeholders in identifying the individual unit to be analyzed under the provisions of § 411.354(c)(2)(ii)(A)(2)(i) through (iv). We believe that the clarity provided by these provisions will facilitate compliance without adding burden.

As discussed in section III.P.3. of this final rule, we are finalizing our proposal to permit the use of the exception for preventive screening tests and vaccines at § 411.355(h) for COVID–19 vaccines during such period as the vaccines are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. We believe that this provision will ensure that the physician self-referral law will not impede the availability of critically important COVID–19 vaccines for Medicare and other patients.

As discussed in section III.P.4. of this final rule, we are finalizing our proposal to publish the Code List for Certain Designated Health Services (Code List) solely on the CMS website. Commencing after the publication of the January 1, 2022 Code List in this final rule, the Code List will be updated annually and published on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.* No less than 30 consecutive calendar days prior to the effective date of a Code List update, we will provide advance notice of the updated Code List on the CMS website. We will also provide for a 30-day public comment period for each update using *www.regulations.gov,* and publish instructions for submitting comments on the CMS website. We will address all public comments that we receive through this process on the CMS website. Finally, we are revising the definition of ''List of CPT/HCPCS Codes'' at § 411.351 by updating the URL that indicates where the Code List is published on the CMS website. We believe that these provisions will facilitate compliance with the physician self-referral law and allow easier access to the most up-to-date Code List.

16. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act)

In addition to the cost reflected in the Collection of Information section of this final rule, we expect that there will be an additional burden for CMS to award and work with a CMS contractor to develop a process for reviewing the PDE data to assess prescriber compliance with the regulatory provision and review and process prescriber attestations. Based on similar contracts, and conversations with the industry, in the CY 2022 PFS proposed rule, we estimated the costs of (A) development of operational strategy for the new program, (B) reviewing PDE data, and (C) prescriber case work. We solicited stakeholder feedback on our estimate and all our assumptions.

(A) Development of policy: We estimated that it would take our contractor a week of work, 40 hours, to develop the strategy for how the contractor will process the prescriber attestations. We estimated that it would take an operations manager and compliance officer working together at a combined hourly wage of $193.60/hr

($120.90/hr + $72.70/hr) a full 40-hour work week to operationalize this aspect of it. Therefore, we estimated the aggregate cost to be $7,744 (40hr * $193.60/hr).

(B) Since systems already exist to collect the appropriate PDE data, in our proposed rule, we stated that our contractor would only have to review the data for compliance with the EPCS mandate. Therefore, we estimated that it would take 2 computer systems analysts each working at $95.22/hr, a week and a half of work, 60 hours. Therefore, the aggregate cost would be $5,713.20 (60 hr * $95.22/hr).

(C) We estimated that it would take 4 administrative support workers each working at $36.82/hr, 60 hours to generate the letters and disseminate them to the appropriate prescriber, which means that it would cost our contractor $2,209.20/year (60 hr * $36.82/hr) in administrative support costs. We estimated that it would be the full-time job of a customer service representative working at $37.02/hr to field prescriber inquiries about the disseminated letters. Thus, we estimated that our contractor would spend $77,001.60 ($37.02/hr * 40 * 52) on the salary of the customer service representative for this task.

The aggregate impact for our contractor is 200 hours at a cost of $92,668. We solicited comment on the accuracy of this burden estimate and on any measures that CMS can take to decrease the impact of this provision, while maintaining its utility and implementing the statutory mandate. We did not receive public comments on the burden estimates for this provision, and therefore, we are finalizing as proposed.

17. Open Payments

a. Payment Context Field for Teaching Hospitals

This provision is for a mandatory freeform text context field. We have created this provision at the request of stakeholders, particularly after conversations with teaching hospitals. The teaching hospitals confirmed that the majority of their disputes arise because of a lack of information within the record and an inability to associate the payment to the correct area within their large organization, not the inaccuracy of the record itself. The benefit of this field is to give better context to the records attributed to teaching hospitals and thereby reduce the number of disputes. For this reason, we also believe it will increase goodwill between the program's stakeholders. The cost is that reporting entities will need to collect an additional piece of information, which will increase burden. We do not believe this burden will be great because the volume of reported teaching hospital payments is much lower than the volume of physician covered recipient payments. In addition, we have created flexibility with this field so that the reporting entity can choose which piece of information is most appropriate and can be something that they already collect, such as a check number or name of the department in the hospital.

b. Optional Annual Recertification

The optional annual recertification is at the request of reporting entities and will increase the availability of communication to CMS. The burden associated with this action is low because it will be a low-effort process only completed by the entities who choose to do so.

c. Defining a Physician-Owned Distributorship

Since the program began in 2013, we have heard feedback that physician-owned distributorship (PODs) should be better represented in the data because the conflict of interest potentially created by PODs is at the heart of the program. We created this new definition due to the lack of an existing POD definition that would be appropriate for the program's needs. Although this is a new definition, it will only be a subset of the existing definitions of applicable manufacturer and applicable group purchasing organization. ''Applicable manufacturer—POD'' and ''Group purchasing organization—POD'' are already ''business type'' choices when registering in the Open Payments system. Therefore, this definition will not alter existing regulations beyond requiring PODs to identify themselves as such.

d. Disallowing Record Deletion Without Reason

We believe there is not currently language to prevent an applicable manufacturer or applicable group purchasing organization from submitting and attesting to records, then deleting the records to prevent publication. This action would be contrary to the spirit of transparency of the program. To help ensure compliance with this requirement, we are also adding a new field that will allow entities to communicate the reason for the deletion to CMS. Since the entities will have attested to the accuracy and completeness of these records, we believe it is appropriate to confirm the reason for the deletion. We have not perceived the behavior of inappropriate deletions within the data and do not believe it will increase burden beyond the additional field when deleting a record. We are preemptively closing a potential loophole.

e. Disallow Publication Delays of General Payments

The statute requires that delays are ''made pursuant to product research or development agreements and clinical investigations'' (1128G(c)(1)(E) of the Act). A small number of general payments are delayed annually, which we are unable to verify meet this requirement. Research payments contain the appropriate fields to ensure that the statutory provisions are being met. We do not believe that it will be a burden for the small number of general payments to either be reported as research payments or not delayed.

f. Short-Term Loans

Short-term loans are not required to be reported, but they must be shorter than 91 days to meet the exception. This provision does not create burden because it only clarifies that those 90 days must be the cumulative total for a year, which is already outlined in subregulatory guidance. We do not anticipate that this will change reporting behavior but want to explain the exception more clearly within the text of the final rule.

g. Remove General Ownership Records

Ownership records have special rules for reporting outlined in the statute (section 1128G(a)(2) of the Act), which are not included in the format for general records. However, there is currently a general record for reporting ownership and investment interest (Nature of Payment = 11). We anticipate a small burden for the approximately 92 reporting entities who have previously used the general nature of payment category in order to fill out the different fields in the ownership record. This burden will allow the records to meet statutory mandates.

h. Updated Contact Information

Open Payments conducts regular compliance-related outreaches to reporting entities when it encounters data that may not meet program requirements. We have found that the two contacts provided by applicable manufacturers and group purchasing organizations often become obsolete, especially if a company has not updated its contact information during the recertification process. It is crucial for the integrity of the data that we have the ability to contact entities in the case of

irregularities. Additionally, we believe that ensuring informal communications from CMS will reduce burden since it may prevent more formal compliance actions if the entity is unresponsive due to outdated contact information. However, we do not believe this is an issue for the majority of reporting entities, nor do we believe that keeping the contact information updated will create a large burden.

18. Updates to the Quality Payment Program

In section IV.A. of this final rule, we include our finalized policies for the Quality Payment Program. In this section, we first present the overall and incremental impacts to the number of expected QPs and associated APM Incentive Payments. In the following sections, we estimate the overall and incremental impacts to the total MIPS eligible population and the payment impacts by practice size for the CY 2022 performance period/2024 MIPS payment year based on various finalized policies, including policies to modify MIPS eligibility, the MIPS final score and the performance threshold and additional performance threshold as discussed in sections IV.A.3.a., IV.A.3.d., IV.A.3.e., and IV.A.3.f. of this final rule.

For the MIPS payment adjustment, we ran two RIA models: A baseline and a final policies model. The aim of the baseline model is to model the status of our population of clinicians for the CY 2022 performance period/2024 MIPS payment year if this final rule does not take effect. It therefore reflects previously finalized policies for the CY 2022 performance period/2024 MIPS payment year. Select examples of the baseline policies scheduled to start in the CY 2022 performance period/2024 MIPS payment year include the removal of the Web Interface as a collection type and the change in the performance category weights. There was no defined performance threshold or additional performance threshold, so our baseline model assumed the performance threshold and additional performance threshold used for the previous period (CY 2021 performance period/2023 MIPS payment year).

The aim of the final policies model is to estimate the incremental effect of the final policies for the CY 2022 performance period/2024 MIPS payment year on MIPS eligibility, MIPS final scores, and payment adjustments. In other words, by comparing the difference between our baseline model and our final policies model we can estimate the incremental impact of finalizing the policies contained in this final rule. Select examples of the finalized policies include, the inclusion of new MIPS eligible clinician types, the inclusion of the Web Interface as a collection type, the change in performance threshold and additional performance threshold, and the changes to the complex patient bonus. Refer to section VI.F.18.e.(2) of this final rule for the detailed methods on how we integrated the policies into the baseline and final policies models.

a. Assessing Use of 2020 Data for Estimating Future MIPS Performance

In the 2022 PFS proposed rule (86 FR 39546), we stated that the RIA used the 2019 MIPS performance period data because the data for the 2020 MIPS performance period were not available in time to incorporate into the proposed rule model. We noted we would evaluate whether it is appropriate to use the 2020 performance period data to predict performance in CY 2022 for the final rule and whether adjustments would need to be made if CY 2020 performance period data are used. We have already acknowledged some data from the CY 2020 performance period is not usable. For example, we have stated that based on our analysis of the 2020 performance period data, we could not reliably calculate scores for the cost measures that would adequately capture and reflect the performance of MIPS eligible clinicians. As a result, we reweighted the cost performance category for all MIPS eligible clinicians for the CY 2020 MIPS performance period.[280] Additionally, in section IV.A.3.f.(2) of this final rule, we noted we have final score data for the CY 2020 performance period/2022 MIPS payment year available to use in our assessment of whether to use the mean or median for the performance threshold, but the data for the CY 2020 performance period/2022 MIPS payment year may be subject to change as a result of the targeted review process. However, we have also indicated that for certain purposes 2020 performance period data could be beneficial too. As discussed in section IV.A.3.e.(1)(c)(ii) of this final rule, we believe 2020 performance period data is appropriate to use for historic benchmarks in part because it is the most recent available dataset and it reflects a performance period in which clinicians were facing the PHE.

To evaluate whether the 2020 MIPS performance period data is appropriate to use to predict future performance, we considered whether the extreme and uncontrollable circumstances policy impacted submissions and data, and whether the COVID–19 PHE impacted services provided (for example, quality measures, the number of MIPS eligible clinicians, claims). For the 2020 performance year, we applied the MIPS automatic extreme and uncontrollable circumstances policy to all individual MIPS eligible clinicians and allowed for extreme and uncontrollable applications due to the COVID–19 PHE (*https://qpp.cms.gov/resources/covid19?py=2020*). Due to these extreme and uncontrollable circumstances policies, not all clinicians or groups may have submitted data for the 2020 MIPS performance period.

When we evaluated whether the 2020 MIPS performance period data is appropriate to use to estimate 2022 MIPS performance period performance for MIPS eligible clinicians, we compared the 2020 MIPS performance period data to the 2019 MIPS performance period data on key metrics. Overall, we observed a decrease in the number of MIPS eligible clinicians at the individual level who exceed the low-volume threshold. We also observed a decline in data submitted by individual and group. Finally, when examining actual scores and payment information for the 2020 performance period/2022 MIPS payment year compared to the 2019 performance period/2021 MIPS payment year, we found an increase in the number of MIPS eligible clinicians receiving a neutral score. However, our initial findings suggest the extreme and uncontrollable circumstances policy combined with the COVID–19 PHE limit the data needed to simulate future MIPS eligible population and associated performance. Therefore, this RIA uses the 2019 MIPS performance period submissions which were used for the CY 2021 PFS final rule RIA (85 FR 85011 through 85023) and CY 2022 PFS proposed rule RIA (86 FR 39545 through 39556). We note that the findings are specific for purposes of estimating future performance for the entire population of MIPS eligible clinicians.

b. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years 2019 through 2024, through the Medicare Option, eligible clinicians with a sufficient percentage of Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs in the applicable QP performance period for a year. These QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of

[280] *https://qpp.cms.gov/mips/cost?py=2020.* Last accessed October 20, 2021.

their estimated aggregate paid amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs but meet a lower threshold to become Partial QPs for the year may elect to report to MIPS and, if they elect to report, will then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status and does not meet any other exemption category, the eligible clinician will be subject to MIPS, will report to MIPS, and will receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year is 0.75 percent, while the update to the PFS CF for services that are furnished by clinicians who do not achieve QP status for a year is 0.25 percent. In addition, MIPS eligible clinicians will receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although the statute establishes overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the 2024 MIPS payment year of the Quality Payment Program.

Overall, we estimate that for the 2022 QP Performance Period between 225,000 and 290,000 eligible clinicians will become QPs. Therefore, they will be excluded them from MIPS and will qualify for the lump sum APM incentive payment in Payment Year 2024 based on 5 percent of their Part B paid amounts for covered professional services in the preceding year. These paid amounts for QPs are estimated to be between approximately $12,000 million and $15,000 million in total for the 2022 performance year. The analysis for this final rule used the 2020 third snapshot participation file. We based APM Incentive Payment Amounts on paid amounts with service dates of January 1, through September 30, 2020. We multiplied the calculated amounts by 1.5 to approximate payment amounts for the full calendar year. We estimate that the total lump sum APM Incentive Payments will be approximately $600–750 million for the 2024 Quality Payment Program payment year.

In section VI.F.18.a. of this final rule, we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2022 QP Performance Period as well as some Advanced APMs anticipated to be operational during the 2022 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that will attain QP status through the All-Payer Combination Option. We note that the Kidney Care Choices Model and the Radiation Oncology model have been included in our analysis as we anticipate that the model will be Advanced APMs in 2022. Additionally, we anticipate that the Maryland Primary Care Program will not be an Advanced APMs in 2022. The following APMs are expected to be Advanced APMs for the 2022 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Global and Professional Direct Contracting Model;
- Kidney Care Choices Model (Kidney Care First; Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program);
- Medicare Shared Savings Program (Basic Track Level E, and the ENHANCED Track);
- Oncology Care Model (Two-Sided Risk Arrangements);
- Primary Care First (PCF) Model;
- Radiation Oncology model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see 81 FR 77444 through 77445 for information on the APM Participant Lists and QP determinations) on the 2020 third snapshot participation file to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2022 QP Performance Period. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

c. Impact for the CY 2021 Performance Period/2023 MIPS Payment Year

In section IV.A.3.e.(2)(a)(ii) of this final rule, we finalize our proposal to double the complex patient bonus, and to increase its cap to 10 points for the CY 2021 Performance Period/2023 MIPS Payment Year. We expect this policy to result in an increase of 3 points in the median bonus thus increasing MIPS final scores at the median by 3 points. We do not know the effects of the PHE for COVID–19 and its effect on MIPS performance in 2021, so we did not recreate the analysis and payment distributions with the updated bonus for the CY 2021 performance period/2023 MIPS payment year (85 FR 85012 through 85019). The increase in complex patient bonus points will result in smaller payment adjustments for three reasons. First, the resulting increase in final scores will reduce the budget neutral pool. Second, the increase in complex patient bonus points will increase the number of clinicians with scores above the performance threshold or additional performance threshold, meaning more clinicians will share in the budget neutral pool and additional $500 million for exceptional performance and potentially lower the scaling factor that is applied to the MIPS payment adjustment and additional payment adjustment. Third, the average scores of those receiving a positive or additional adjustment will be higher, which means the adjustment rates for clinicians that have scores above the performance threshold or additional performance threshold will be lower.

d. Estimated Number of Clinicians Eligible for MIPS Eligibility for the CY 2022 Performance Period/2024 MIPS Payment Year

(1) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the CY 2022 performance period/2024 MIPS payment year and the effect of the final

policies in this final rule, we ran two models as described in section VI.F.18., a baseline model and final policies model.

For the baseline and final policies models, we used the same eligibility files and approach described in the CY 2021 PFS final rule (85 FR 85013) which resulted in the inclusion of 1.6 million clinicians who had PFS claims from October 1, 2018 to September 30, 2019, as well as additional clinicians associated with a group who had at least one PFS claim from October 1, 2019, through December 31, 2019. We used the same exclusion criteria to exclude clinicians from our MIPS eligibility assessment as described in the CY 2021 PFS final rule RIA (85 FR 85013) with the following model updates:

(1) In both the baseline and final policies models, we excluded practitioners in Next Generation ACOs because the Next Generation ACO model ends in the CY 2021 MIPS performance period.

(2) In both the baseline and final policies models, to determine which clinicians in the initial population of 1.6 million should be excluded as QPs, we used Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2019 QP performance period. We elected to use this data source because the APM participant list for the 2019 final snapshot can reliably be used for RIA projections. From this data, we calculated the QP and Partial QP determinations as described in section of IV.A.4.c.(1)(b) of this final rule for the 2022 QP performance period for both models.

(3) In the final policies model, we included in our estimated MIPS eligible population for the CY 2022 performance period/2024 MIPS payment year clinical social workers and CNMs as finalized in section IV.A.3.a.(1) of this final rule.

(4) In the final policies model, we are integrating the provision that starting with the CY 2022 MIPS performance period/2024 MIPS payment year, small practices, excluding virtual groups, must submit data as a group in any performance category to indicate that they wish to be scored as a group for Medicare Part B claims. This affects eligibility because previously a single Medicare Part B claims submission, without any other submission, started a group score. Once a group score is created, a clinician who was individually excluded from MIPS for being under the low-volume threshold, may now be eligible if the group exceeds the low-volume threshold. This policy is described at section IV.A.3.a.(3) of this rule.

(b) Assumptions Related To Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (TIN/NPI) or group (TIN) levels based on how data are submitted including under the APM Entity level if the clinician is part of an APM Entity in a MIPS APM (hereafter, a MIPS APM Entity) that elects to submit to MIPS. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment.

For the final policies model, we describe below the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.6 million clinicians. We present in section VI.F.18.d.(1)(c) the incremental impact of the final policies from the baseline model for the CY 2022 performance period/2024 MIPS payment year on the MIPS eligible clinician population and their associated PFS allowed charges. We applied the same assumptions presented in the CY 2021 PFS final rule RIA to apply the low-volume threshold and to understand whether clinicians participate as a group, virtual group, APM entity, or as individuals (85 FR 85013 through 85016), except for three modifications. We assumed only individuals or APM TINs that exceeded the low-volume threshold will receive an APM Performance Pathway (APP) score consistent with the policy as finalized in the CY 2021 PFS final rule (85 FR 84897).[281] We assumed APM TINs that qualified for opt-in and submitted data as a TIN will also be eligible. Finally, we did not consider clinicians in groups as MIPS eligible clinicians nor start a group score for clinicians in small practices with only Medicare Part B claims submissions to reflect the policy finalized at section IV.A.3.a.(3) of this rule.

Table 144 summarizes our eligibility estimates for the final policies model. We identify approximately 212,000 clinicians[282] as having ''required eligibility'' in Table 144. These clinicians will be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. These clinicians may ultimately choose to participate in MIPS as an individual, group, virtual group or APM entity or to not participate. Regardless of how they participate they will be considered MIPS eligible. We estimate approximately 595,000 additional MIPS eligible clinicians will be eligible as ''group eligibility'' in Table 144. These clinicians belong to an APM entity, group or virtual group that meets the low-volume threshold and submits to MIPS. If they were not associated with the group submission, these clinicians would not be eligible for MIPS. Finally, we estimate about 3,000 clinicians will be eligible through ''opt-in eligibility'' through the ''opt-in'' policy for a total MIPS eligible clinician population of approximately 810,000. This leads to an associated $67 billion allowed PFS charges estimated to be included in the CY 2022 performance period/2024 MIPS payment year.

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[281] Under the policy, APM TINs must submit data, but as that was not a requirement for 2019 Shared Saving Program participants, we assumed all TINs that exceed the low-volume threshold would submit data.

[282] The count of 212,000 MIPS eligible clinicians for required eligibility is rounded and includes those who participated in MIPS (approximately 186,000 MIPS eligible clinicians), as well as those who did not participate (approximately 26,000 MIPS eligible clinicians).

TABLE 144: Description of MIPS Eligibility Status for CY 2022 Performance Period/2024 MIPS Payment Year Using the CY 2022 PFS Final Rule Assumptions**

		CY 2022 PFS Final Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	185,684	$45,201
	Do not participate in MIPS	26,087	$6,117
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	594,567	$15,194
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	3,255	$77
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**809,593***	**$66,589**
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	411,837	$10,529
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	100,501	$565
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	303,873	$14,951
Total Number of Clinicians Not MIPS Eligible		816,211	$26,045
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,625,804	$92,634

* Estimated MIPS Eligible Population

** This table does not include clinicians impacted by the automatic extreme and uncontrollable policy. (approximately 6,000 clinicians and $531 million in PFS allowed charges). It also excludes CPC+, NextGen and submitters with one or more categories identified as being suppressed as a result of bad data.

*** Allowed charges estimated using 2019 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

Furthermore, we estimate there will be approximately 412,000 clinicians as ''Potentially MIPS eligible'' in Table 144. These clinicians are not MIPS eligible but could be if their practice decides to participate or they elect to opt-in. These clinicians will be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group, or clinicians in a group that does not submit are eligible to opt-into MIPS individually and choose to do so. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate the MIPS eligible clinician population could be as high as 1.2 million clinicians. Finally, we estimate approximately 101,000 clinicians will not be MIPS eligible because they and their group are below the low-volume threshold on all three criteria and another approximately 304,000 will not be MIPS eligible because they are categorically excluded regardless of volume or submission activity.

Eligibility among many clinicians is contingent on submission to MIPS as a

group, virtual group or election to opt-in, therefore we will not know the number of MIPS eligible clinicians who submit until the submission period for the 2022 MIPS performance period is closed. For this final policies model analysis, we use the estimated population of 809,593 MIPS eligible clinicians described above.

(c) Estimated Impact of the Final Policies on MIPS Eligibility and PFS Allowed Charges

We illustrate in Table 145 how the final policies to add clinical social workers and CNMs as MIPS eligible clinician types and the policy to require small practices to submit data as a group for a group quality performance category score as finalized in sections IV.A.3.a.(1) and IV.A.3.a.(3) of this final rule affects the estimated number of MIPS eligible clinicians. The amended regulation text that we finalized in section IV.A.3.a.(2) of this final rule does not make modify how we assess eligibility in MIPS in our final policies model.

The first row in Table 145 presents the estimates from the RIA baseline model with the number of individuals that will be MIPS eligible clinicians for the 2022 performance period/2024 MIPS payment year if this rule does not take effect. The second row presents estimates from the RIA final policies model with the incremental impact of adding the two new MIPS eligible clinician types on the number of MIPS eligible clinicians for the CY 2022 performance period/2024 MIPS payment year. As shown in Table 145, the final policies lead to a small increase in the number of MIPS eligible clinicians (1.1 percent increase) and a minimal increase in the PFS allowed charges (0.1 percent increase) for the CY 2022 performance period/2024 MIPS payment year.

TABLE 145: Effect of Eligibility Changes on the Expected Number of Clinicians and the Allowed Paid Amount in the CY 2022 Performance Period/2024 MIPS Payment Year

Policy changes	Estimated cumulative effect of policy change on number of clinicians	Estimated number of clinicians impacted by policy change	% Change /from Baseline in number of MIPS eligible clinicians	Estimated Cumulative PFS Allowed Charges (mil)	% Change in PFS Allowed Charges from Baseline
Baseline policies model: If the CY 2022 PFS final rule did not exist.	801,013	N/A	N/A	66,503	N/A
Final policies model: After applying policies finalized in the CY 2022 PFS final rule.	809,593	8,580	1.1%	$66,589	0.1%

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e. Estimated Impacts on Payments to MIPS Eligible Clinicians for the CY 2022 Performance Period/2024 MIPS Payment Year

(1) Summary of Approach

In sections IV.A.3.d., IV.A.3.e. and IV.A.3.f. of this final rule, we present several provisions which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VI.F.18.e.(2). of this RIA as we describe our methodology to estimate MIPS payments for the CY 2022 performance period/2024 MIPS payment year. We then present the impact of the overall final policies on the CY 2022 performance period/2024 MIPS payment year and then compare select metrics to the baseline model, which only incorporates previously finalized policies for the CY 2022 performance period/2024 MIPS payment year. By comparing the baseline model to the final policies model, we can estimate the incremental impact of this rule's policies to the CY 2022 performance period/2024 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, and MIPS eligible clinicians can participate as an individual, group, virtual group, or APM Entity in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VI.F.18. of this final rule, we generally used data submitted for the 2019 performance period. For the cost performance category, we used the same data as the CY 2020 PFS final rule (84 FR 63169), which is primarily testing data for the cost measures.

The estimated payment impacts presented in this final rule are averages by practice size weighted by Medicare utilization. The payment impact for a MIPS eligible clinician will vary from the average and will depend on the measure submissions, scores and their performance.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2022 performance period/2024 MIPS payment year for this final rule, we generally used 2019 MIPS performance period data for both the baseline and final policies models. Our baseline and final policies scoring models included the 801,013 and 809,593 estimated MIPS eligible clinicians, respectively, as described in section VI.F.18.d.(1) of this RIA.

To estimate the impact of MIPS policies on MIPS eligible clinicians, we generally used the 2019 MIPS performance period submissions data, including data submitted for the quality, improvement activities, and Promoting Interoperability performance categories. We supplemented this information with 2019 data available for CAHPS for MIPS and CAHPS for ACOs, testing data for the revised total per capita cost measure and Medicare Spending Per Beneficiary (MSPB) clinician measures which were finalized in the CY 2020 PFS final rule (84 FR 62969 through 62977), testing data for the new episode cost measures, administrative claims data for the new quality performance category measures, and other data sets.[283] We calculated a hypothetical final score for the 2022 performance period/2024 MIPS

[283] Data submitted to MIPS for the 2018 MIPS performance period data was used for the improvement score for the quality performance category. We also incorporated some additional data sources when available to represent more current data.

payment year for the baseline and final policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, where each are described in detail in the following subsections.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a methodology like the one described in the CY 2021 PFS final rule (85 FR 85016 through 85017) for baseline and final policy RIA models for the CY 2022 performance period/2024 MIPS payment year.

For the baseline policies RIA model, which does not reflect the final policies for CY 2022 performance period/2024 MIPS payment year from this final rule, we made the following modifications to reflect the previously finalized policies for the CY 2022 performance period/2024 MIPS payment year for the quality performance category:

- As previously finalized in the CY 2021 PFS final rule (85 FR 84870 and 85 FR 84843), we removed the Web Interface as a collection type in MIPS and through the APP for the CY 2022 performance period/2024 MIPS payment year. Although the Web Interface is to be reinstated for groups for the CY 2022 performance period/2024 MIPS payment year and ACOs for CY 2022 performance period/2024 MIPS payment year through CY 2024 performance period/2026 MIPS payment year as discussed in sections IV.A.3.d.(1)(d) and IV.A.3.c.(2)(a), respectively, the baseline model is attempting to capture the CY 2022 performance period/2024 MIPS payment year as if this provision did not exist. Therefore, the baseline model does not incorporate the Web Interface as a collection type for groups and ACOs. To estimate a quality performance category score for clinicians in groups who previously used the Web Interface as a collection type in 2019, we assumed these groups will use the other two other collection types (MIPS CQMs and eCQMs) available in the 2022 performance period/2024 MIPS payment year. We then applied the same methodology described in the CY 2021 PFS proposed rule when the removal of Web Interface as a collection type was previously proposed (85 FR 50387 through 50388) using 2019 MIPS submissions data. To estimate a quality performance category score for ACOs, we used the same methodology described in the CY 2021 PFS proposed rule when the Web Interface was not included in the APP (85 FR 50388).
- We used the published 2021 MIPS historical quality benchmarks file to identify measures subject to the topped out scoring cap that was finalized (82 FR 53721 through 53727).[284]

For the final policies model, we made the following modifications to the baseline model to reflect the new final policies for the 2022 performance period/2024 MIPS payment year for the quality performance category:

- As discussed in section IV.A.3.d.(1)(e) of this final rule, we finalized one new administrative claims measure for those for whom it is applicable: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions. To implement this policy in our final policies RIA model for the CY 2022 performance period/2024 MIPS payment year, we used testing data for this new administrative claims measure.
- As discussed in section IV.A.3.d.(1)(c) of this final rule, we are finalizing our proposals with modification to maintain the data completeness criteria threshold of at least 70 percent for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years for QCDR measures, MIPS CQMs, or eCQMs. This is not a change from our baseline model assumptions.
- As discussed in section IV.A.3.d.(1)(e) of this final rule, we are finalizing our proposal to establish measure substantive change criteria. We did not make modifications to the final policies model for this policy. We scored measures using the benchmarks described below.
- In section IV.A.3.d.(1)(g) of this final rule, we are finalizing several changes to the CAHPS for MIPS survey. We did not incorporate these changes into our model due to the lack of data.
- In Appendix 1 of this final rule, we added 4 new quality measures, removed 13 measures, and finalized 87 substantially modified measures. Consistent with prior rules, (83 FR 50053), our RIA estimates assume that clinicians who reported Medicare Part B claims, eCQM, MIPS CQM and QCDR measures that are removed would find alternate measures; therefore, we assign points to the measures that and included them in our scoring model.
- As discussed in section IV.A.3.e.(1)(c)(ii) of this final rule, we did not finalize our proposal to use performance period benchmarks for the CY 2022 performance period in accordance with § 414.1380(b)(1)(ii) as opposed to a historical benchmark. For the final policies model, we utilized the most recent benchmark file: the 2021 MIPS performance period historic benchmarks.[285] However, the 2019 performance data we are using to estimate future performance includes data on measures that do not have a benchmark in the 2021 MIPS benchmark file (either because the measure was removed or because there were significant changes). If a benchmark was not available in the 2021 MIPS performance period historic benchmark file, then we supplemented the 2021 MIPS benchmark file with the benchmarks used for the CY 2019 performance period/2021 MIPS payment year.
- As discussed in section IV.A.3.e.(1)(c)(iii)(A) of this final rule, we are delaying our proposal to remove the 3-point floor for each measure that can be reliably scored against the benchmark and score the measure from 1 to 10 points until the CY 2023 performance period/2025 MIPS payment year. Similarly, we are delaying our proposal in section IV.A.3.e.(1)(c)(iii)(B) of this final rule to remove the special scoring policy of scoring 3 points for class 2 measures, except for clinicians in small practices until the CY 2023 performance period/2025 MIPS payment year. Therefore, our RIA for the CY 2022 performance period/2024 MIPS payment year re-established the 3-point floor for class 1 measures and 3 points for class 2 measures.
- As discussed in section IV.A.3.e.(1)(c)(iii)(B), we are finalizing our proposed policies for scoring new measures with modifications. For measures in their first two performance periods that meet data completeness and can be reliably scored against a benchmark (class 4a measures), we will assign a floor of 7 points for measures in their first year and a floor of 5 points for measures in their second year. For new measures in their first two performance periods that meet data completeness, but cannot be reliably scored against a benchmark because they lack a benchmark or do not meet case minimum in the program (class 4b measures), we will assign 7 points for measures in their first year and 5 points for measures in their second year. We incorporated these scoring changes into our final policies model. Because we are using 2019 MIPS performance period

[284] Data downloaded on April 9, 2021 from *https://qpp.cms.gov/resources/resource-library.*

[285] Data downloaded on September 1, 2021 from *https://qpp.cms.gov/resources/resource-library.*

data, we assume that measures new to MIPS in 2019 are in their first year and measures new to MIPS in 2018 are in their second year.

- As discussed in sections IV.A.3.e.(1)(c)(vii) and IV.A.3.e.(1)(c)(viii) of this final rule, we finalized our proposal to remove measure bonus points for reporting high priority measures and for submitting with end-to-end electronic reporting beginning in the 2022 MIPS performance period. We incorporated these scoring changes into our final rule model for all MIPS collection types.
- As discussed in section IV.A.3.d.(1)(d), we are extending the Web Interface measures for the CY 2022 performance period/2024 MIPS payment year for groups and virtual groups using the existing 10 CMS Web Interface measures. To estimate the impact of this policy, we used the same methodology described in the CY 2021 PFS final rule (85 FR 85016 through 85017) using 2019 MIPS submissions data.
- Finally, we will extend the CMS Web Interface as a means of reporting quality under the APM Performance Pathway for Shared Savings Program ACOs for the 2022 performance period/2024 MIPS payment year through the 2024 performance period/2026 MIPS payment years as described in section IV.A.3.c.(2)(a) of this final rule. Under the provision, Web Interface reporting will work in the same manner as for performance year 2021, where ACOs will have the option of reporting either the CMS Web Interface, the APP eCQM/MIPS CQM measure set, or both. To estimate the impact of this policy, we used the same methodology described in the CY 2021 PFS final rule RIA (85 FR 85016 through 85017) when Web Interface was retained for the APP.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a similar methodology described in the CY 2020 PFS final rule (84 FR 63169) with the modifications to the baseline and the final policies RIA model described in this section.

In the baseline model, we refined our methodology for developing benchmarks to better reflect the previously finalized policy in CY 2017 Quality Payment Program final rule (81 FR 77308 through 77309). We did not estimate cost improvement scoring that starts in the 2022 performance period/2024 MIPS payment year as previously finalized at § 414.1380(a)(1)(ii) and in the CY 2019 PFS final rule (83 FR 58956) since we did not have sufficient data to conduct improvement scoring, which requires 2 years of cost data to model.

In the final policies model, we modified the baseline model to incorporate the provision to add five new episode-based cost performance category measures in the CY 2022 performance period/2024 MIPS payment year as described in section IV.A.3.d.(2) of this final rule, by using claims data from January 1, 2019 to December 31, 2019. Cost measures were scored if the clinicians or groups met or exceeded the case volume: 10 episodes for Melanoma Resection to align with the reporting case minimum for procedural cost measures currently in use in MIPS, 20 episodes for Sepsis to align with the reporting case minimum for acute inpatient condition cost measures currently in use in MIPS, 20 episodes for Diabetes and Asthma/COPD as used in field testing for these chronic measures, and 20 episodes for Colon Resection. These new cost episode-based measures were calculated for both the TIN/NPI and the TIN.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

For the baseline model, we estimated the facility-based score using the scoring policies finalized in the CY 2018 Quality Payment Program final rule (82 FR 53763) and the methodology described in the CY 2020 PFS final rule (84 FR 63169). For the final policies model, we used the methodology for the CY 2022 performance period/2024 MIPS payment year as discussed in section IV.A.3.e.(2)(b)(v)(B) of this final rule. We proposed at § 414.1380(e)(vi) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission. Therefore, if a MIPS eligible clinician or a group is eligible for facility-based measurement, but they participate in MIPS as an individual or group, we used the higher final score between the facility-based scoring and MIPS submission-based scoring.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

For the baseline model, we used the CY 2019 MIPS Promoting Interoperability performance period data submissions data to estimate CY 2022 MIPS performance for the Promoting Interoperability performance category. We made the following two modifications to the 2019 performance period scoring to reflect the previously finalized policy changes between the CY 2019 and CY 2021 performance periods: (1) We doubled the bonus points for clinicians who submitted the PDMP measure as described in section IV.A.3.d.(4)(c)(i) of this final rule; and (2) we did not incorporate the Verify Opioid Treatment Agreement measure data, a measure that was finalized in the CY 2019 performance period (83 FR 59807) but removed in the CY 2020 performance period (84 FR 62994). We retained the PDMP bonus for the baseline model for continuity between the CY 2021 and 2022 performance periods and for consistency since bonuses for the quality performance category were retained for the baseline as well. Because we lacked data on who would adopt the finalized Health Information Exchange bi-directional exchange measure for the CY 2021 performance period we only used past reporting on the two existing Health Information Exchange Objective measures to estimate CY 2022 Promoting Interoperability performance.

For the final policies model, we considered the following policy provisions as potential modifications to the baseline model:

- In section IV.A.3.d.(4)(c)(i) of this final rule, we finalized our proposal for the PDMP measure to remain optional and at 10 points. Modifications were not made to reflect this policy in the final policies model since the baseline model already incorporated this policy.
- In section IV.A.3.d.(4)(c)(ii) of this final rule, we did not finalize our proposed modifications to the Provide Patients Electronic Access to Their Health Information measure. For this model, we did not make any modifications and continued to use the Provide Patients Electronic Access to Their Health Information measure that was submitted for the 2019 MIPS performance period.
- In section IV.A.3.d.(4)(c)(iii) of this final rule, we finalized to require two of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the CY 2022 performance period: Immunization Registry Reporting; and Electronic Case Reporting. We also finalized in section IV.A.3.d.(4)(c)(iii) of this final rule to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures, and to make them optional and available for bonus points beginning with the CY 2022 performance period/2024 MIPS payment year. We did not model these policy changes because the Promoting

Interoperability data we used for this analysis is based on the CY 2019 performance period when a clinician was only required to report two of the possible 5 measures for the Public Health and Clinical Data Exchange Objective. We believe incorporating this policy might artificially lower scores for the Public Health and Clinical Data Exchange Objective because there was no requirement to specifically report the Immunization Registry Reporting and Electronic Case Reporting measures in 2019.

- In section IV.A.3.d.(4)(d) of this final rule, we finalized the additional requirement that eligible clinicians must attest to conducting an annual assessment of the High Priority Guide of the SAFER Guides beginning with the 2022 performance period. This policy was not implemented in the final policies model as it does not affect eligibility or payment. We included this policy in our burden calculations in section V.B.8.g.(3) of this rule.
- In section IV.A.3.d.(4)(g) of this final rule, we finalized changes to the attestation statements for information blocking. We did not include this policy in our model due to lack of information.
- In section IV.A.3.d.(4)(h)(i) of this final rule, we finalized beginning with the CY 2022 performance period/2024 MIPS payment year, we will no longer require an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting. We will assign a weight of zero only in the event a small practice did not submit any data for any of the measures specified for the Promoting Interoperability performance category. This policy was implemented in the final policies model.
- In section IV.A.3.d.(4)(h)(ii) and IV.A.3.d.(4)(h)(iii) of this final rule, we finalized our proposal to continue the existing policy to reweight the Promoting Interoperability performance category for NPs, PAs, CRNAs, CNSs, physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the CY 2022 performance period/2024 MIPS payment year. The baseline model already incorporated this policy.
- In section IV.A.3.d.(4)(h)(iv), we finalized that we will apply the same Promoting Interoperability reweighting policy we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to clinical social workers. This policy was implemented in the final policies model.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline model, we modeled the improvement activities performance category score based on CY 2019 performance period data and APM participation identified in section VI.F.18.d.(1) of this final rule. For clinicians and groups not participating in a MIPS APM, we used the CY 2019 submissions improvement activities score. We did not model the policy finalized for the CY 2020 performance period (84 FR 62980) to require a minimum threshold of 50 percent of clinicians in a group to complete an improvement activity for the group to receive credit since we did not have data to determine the proportion of clinicians in a group that completed the improvement activity. We continued to apply the methodology described in the CY 2020 PFS final rule (84 FR 63170) to assign an improvement activities performance category score. For the APM participants identified in section VI.F.18.d.(1) of this final rule, we assigned an improvement activity performance category score of 100 percent.

For the final policies model, we did not make modifications to the baseline model for the improvement activities changes finalized in section IV.A.3.d.(3) of this final rule. The final policies are (1) revise group reporting requirements for the 50 percent threshold to address subgroups; (2) revise the timeframe for improvement activities nominated during a PHE; (3) revise the required criteria for improvement activity nominations received through the Annual Call for Activities; (4) suspend activities that raise possible safety concerns or become obsolete from the program when this occurrence happens outside of the rulemaking process; (5) add 7 new improvement activities, modify 15 existing improvement activities, and remove 6 previously adopted improvement activities; (6) revise the ''Drug Cost Transparency to include requirements for use of real-time benefit tools'' improvement activity; and (7) add the COVID–19 ''Clinical Data Reporting with or without Clinical Trial'' improvement activity. For policy 1, we lacked data to model the impact on improvement activities performance category. Policies 2 and 3 are related to the call for improvement activities which does not affect the improvement activities performance category scores. Policies 4 through 7 address changes to specific improvement activities or the improvement activity inventory. We anticipate most clinicians performing improvement activities will continue to identify and report similar improvement activities from the inventory in future years. Please see section VI.F.18.g.(2)(f) of this final rule for additional details on the impact of these policy changes.

(f) Methodology To Estimate the Complex Patient Bonus Points

In section IV.A.3.e.(2)(a)(iii)(B) of this final rule, we will continue to apply the complex patient bonus, with updates, for the CY 2022 performance period/2024 MIPS payment year. For the baseline model, we used the complex patient bonus information calculated for the 2019 performance period data for the CY 2022 performance period/2024 MIPS payment year, as was previously done in the CY 2021 PFS final rule (85 FR 85017).

For the final policies model, we calculated the complex patient bonus using the calculation in section IV.A.3.e.(2)(a)(iii)(B) of this final rule for the CY 2022 performance period/2024 payment year. We finalized updates to the complex patient bonus for the CY 2022 performance period/2024 MIPS payment year and future MIPS performance periods/payment years to account for social and medical complexity, while still using our current established indicators of dual proportion and HCC risk scores, respectively. Consistent with the policy for the 2022 performance period, our final policies RIA model calculated and applied the separate risk indicator complex patient bonus components methodology with a single overall cap.

(g) Methodology To Estimate the Final Score

We did not make changes for how we calculated the MIPS final score. Our baseline and final policies models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For the baseline model, we applied the performance category weights and redistribution weights finalized in the CY 2021 PFS final rule (85 FR 84913 through 84916).

For the final policies model, we modified the redistribution policy for small practices as described in section IV.A.3.e.(2)(b)(iii)(A) of this final rule.

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For

MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to section IV.A.3.e.(2)(b)(ii) of this final rule.

(h) Methodology To Estimate the MIPS Payment Adjustment

For the baseline model, we applied the hierarchy as finalized in the CY 2021 PFS final rule (85 FR 84917 through 84919) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. For the final policies model, we applied the scoring hierarchy finalized in section IV.A.3.f.(5) of this final rule. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages, and additional payment adjustment for exceptional performance (§ 414.1405).

For the baseline model, we applied the performance threshold and additional performance thresholds finalized for the CY 2021 performance period/2023 payment year (85 FR 84923), of 60 and 85, respectively. For the final policies model, we used the performance threshold of 75 points in section IV.A.3.f.(2) and the additional performance threshold of 89 points in section IV.A.3.f.(3). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the paid amount for covered professional services furnished by the MIPS eligible clinician. As discussed in the CY 2021 PFS final rule RIA (85 FR 85013), we adjusted the paid amount of non-engaged clinicians to equal their proportion of paid amount prior to the PHE for COVID–19 for the baseline and final policies models.

(3) Impact of Payments by Practice Size

As we shift from previous MIPS transition policies by removing bonuses from the quality performance category and increasing the performance threshold and the additional performance threshold, we observe large changes between the baseline model and final policies model.

First, we observe an increase in the funds available for redistribution due to the increase in clinicians with final scores below the performance threshold. The baseline model estimates $428 million will be redistributed through BN and that $500 million will be distributed to MIPS eligible clinicians for exceptional performance. The mean and median final scores for the baseline model are 78.13 and 82.59, respectively. Our final policies model estimates that $603 million will be redistributed through BN. For clinicians who meet or exceed the additional performance threshold, an additional $360 million was estimated to be distributed. The mean and median final scores for the final policies model are 75.21 and 79.59, respectively.

In the final policies model, the estimated bonus for exceptional performance is less than the $500 million of available funding because the maximum additional payment adjustment for clinicians with exceptional performance reached 10 percent. As finalized in the 2017 QPP final rule (81 FR 77339 through 77340), we stated the maximum additional payment adjustment would be 10 percent, which is established by the statute, and that it would be multiplied by a scaling factor that cannot exceed 1.0. We reached the maximum additional payment adjustment allowed of 10 percent because the additional performance threshold is higher, and fewer clinicians performed above this higher additional performance threshold while a greater percentage of clinicians performed below the additional performance threshold. As a result, fewer clinicians are estimated to share the funds available through the additional bonus for exceptional performance.

Second, we observe an increase in the maximum positive payment adjustment. The baseline model estimates the maximum positive MIPS payment adjustment based on the budget neutral pool at 1.5 percent and the maximum positive MIPS additional payment adjustment for exceptional performance at 5.1 percent, for a combined maximum payment adjustment of 6.6 percent. The final policies model estimates the maximum MIPS positive payment adjustment based on the budget neutral pool is 4.4 percent and the maximum positive additional MIPS payment adjustment for exceptional performance bonus at 10.0 percent for a combined maximum payment adjustment of 14.4 percent.

Finally, we see narrower differences in performance across practice sizes due to the shift from MIPS transition policies. Table 146 shows the overall impact of the payment adjustments by practice size and based on whether clinicians are expected to submit data to MIPS for the final policies model. In Table 147, we present the overall impact of the baseline and the final policies models among clinicians who submit data to assess the incremental impact of the final policies. The overall proportion of clinicians receiving a positive or neutral payment adjustment decreases from 91.7 percent to 66.8 percent with the implementation of the final policies that shift away from MIPS transition policies. In addition, we no longer observe a disproportionate number of clinicians in small practices receiving a negative payment adjustment when implementing the final policies.

For the CY 2022 performance period/2024 payment year, we have policies targeted towards small practices including special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs, which we describe in section VI.F.18.g.(2)(e) of this final rule. The intention of the final policies is to provide a more equitable participation process and reduce the disparity in performance between clinicians in large and small practices. These findings and final policies reflect movement away from the transition policies implemented during the early years of MIPS and how MIPS has shifted its focus to value rather than primarily on engagement. However, non-engagement by not submitting data to MIPS among clinicians in small practices is still a concern. Among those who we estimate will not submit data to MIPS, 86 percent are in small practices (22,475 out of 26,180 clinicians who do not submit data). We intend to continue working with stakeholders to improve engagement in MIPS among clinicians in small practices.

We want to highlight we are using 2019 MIPS performance period submissions data to simulate a 2022 MIPS performance period final score, and it is likely that there will be changes that we cannot account for at this time, including services and payments disrupted by the PHE for COVID–19 or clinicians changing behavior in response to the performance thresholds increased for the CY 2022 performance period/2024 MIPS payment year to avoid a negative payment adjustment. It should also be noted that the estimated number of clinicians who do not submit data to MIPS may be an overestimate of non-engagement in MIPS for the CY 2022 performance period/2024 MIPS payment year. This is because the PHE for COVID–19 may have resulted in fewer clinicians submitting data to MIPS or more clinicians electing to apply for the extreme and uncontrollable circumstances policies due to the PHE for COVID–19 for the 2019 MIPS performance period. Therefore, engagement levels in MIPS

for the CY 2022 performance period/2024 MIPS payment year may differ from these reported estimates. We also note this participation data is generally based off participation for the 2019 performance period, which is associated with the CY 2019 performance period/2021 MIPS payment year and had a performance threshold of 30 points, and that participation may change for the CY 2022 performance period/2024 MIPS payment year when the performance threshold is 75 points.

Finally, the combined impact of negative and positive adjustments and the additional positive adjustments for exceptional performance as a percent of paid amount among those that do not submit data to MIPS on average was negative 8.5 percent. It was not the maximum negative payment adjustment of 9 percent because some MIPS eligible clinicians that do not submit data to MIPS can still receive a MIPS final score that is greater than ¼ of the performance threshold (and avoid the maximum negative adjustment as stipulated by section 1848(q)(6)(A)(iv)(II) of the Act [286]) if they have sufficient claims volume to measure performance for cost measures or quality administrative claim measure, which utilizes administrative claims data and does not require separate data submission to MIPS.

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TABLE 146: MIPS Estimated CY 2022 Performance Period/MIPS 2024 Payment Year Impact on Total Estimated Paid Amount by Participation Status and Practice Size**

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount***
Among those who submit data**					
1) 1-15	108,274	63.6%	22.4%	36.4%	1.5%
2) 16-24	36,925	56.8%	15.7%	43.2%	0.5%
3) 25-99	174,982	60.7%	15.7%	39.3%	0.9%
4) 100+	463,232	70.6%	12.1%	29.4%	1.1%
Overall	**783,413**	**66.8%**	**14.5%**	**33.2%**	**1.2%**
Among those not submitting data					
1) 1-15	22,475	0.0%	0.0%	100.0%	-8.4%
2) 16-24	1,094	0.0%	0.0%	100.0%	-8.5%
3) 25-99	2,028	0.0%	0.0%	100.0%	-8.5%
4) 100+	583	0.0%	0.0%	100.0%	-8.6%
Overall	**26,180**	**0.0%**	**0.0%**	**100.0%**	**-8.5%**

NOTE: Results of this model may change significantly if more clinicians apply for the application-based extreme and uncontrollable circumstances policy exception in CY 2021 because of the PHE for COVID-19.
*Practice size is the total number of TIN/NPIs in a TIN.
** 2019 data used to estimate CY 2022 performance period/2024 MIPS payment year payment adjustments. Payments estimated using 2019 dollars trended to 2024.
***The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.
****Includes facility-based clinicians cost and quality data are submitted through hospital programs.

[286] Section 1848(q)(6)(A)(iv)(II) of the Act stipulates that MIPS eligible professionals with MIPS final scores that are equal to or greater than 0, but not greater than ¼ of the performance threshold, receive a negative payment adjustment factor that is equal to the negative of the applicable percent which is 9 percent for the CY 2022 performance period/2024 MIPS payment year.

TABLE 147: CY 2022 Performance Period/2024 MIPS Payment Year Impact on Total Estimated Paid Amount among Clinicians Who Submit Data by Practice Size for the Baseline and Finalized Policies Models**

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount***
Baseline model among clinicians who engaged with MIPS**					
1) 1-15	107,393	78.8%	38.9%	21.2%	1.2%
2) 16-24	36,447	86.3%	39.8%	13.7%	1.5%
3) 25-99	172,758	89.7%	42.5%	10.3%	1.6%
4) 100+	457,313	95.9%	43.4%	4.1%	1.5%
Overall	**773,911**	**91.7%**	**42.4%**	**8.3%**	**1.4%**
Finalized policies model among clinicians who engaged with MIPS**					
1) 1-15	108,274	63.6%	22.4%	36.4%	1.5%
2) 16-24	36,925	56.8%	15.7%	43.2%	0.5%
3) 25-99	174,982	60.7%	15.7%	39.3%	0.9%
4) 100+	463,232	70.6%	12.1%	29.4%	1.1%
Overall	**783,413**	**66.8%**	**14.5%**	**33.2%**	**1.2%**

*Practice size is the total number of TIN/NPIs in a TIN.
**2019 data used to estimate 2022 performance period payment adjustments. Payments estimated using 2019 dollars trended to 2024.
***The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.
****Includes facility-based clinicians whose cost and quality data are submitted through hospital programs.

f. Estimated Impacts on Payments to MIPS Eligible Clinicians for the CY 2023 Performance Period/2025 MIPS Payment Year

We proposed for the CY 2023 MIPS Performance Period to begin transitioning to MIPS Value Pathways (MVPs) and introduce subgroup reporting in the CY 2023 MIPS performance period/2025 payment year. As described in section IV.A.3.b.(2)(c) of this final rule, the first step in the transition plan for MVPs and subgroup reporting is to be voluntary, where eventually MVPs and subgroups will become required. Additionally, subgroups, if applicable, will have the option to report an APP. Since MVP and subgroup reporting will only begin in the CY 2023 performance period/2025 MIPS payment year, we do not have the data to report who will select MVPs and who will report through subgroups in the first year and how these clinicians will score. As discussed in section IV.A.3.b.(5) of this final rule, for MVP scoring policies, we evaluated all traditional MIPS scoring policies and maintained those that are required under section 1848(q)(2) of the Act such as requirements to measure achievement and improvement of the quality and cost of care. We noted MVPs offer incentives in terms of requiring fewer measures and activities tied to a specialty or medical condition which can offer clinicians a more cohesive experience and that we would continue to evaluating additional incentives that align with our scoring policies and the goals of MVPs in future rulemaking. For this RIAs, we assume clinicians who elect to use MVPs and subgroups for reporting to MIPS will perform similarly to how they performed through traditional MIPS because the scoring policies are similar. We will revisit this assumption in future rulemaking as needed. As discussed in section V.B.8.e.(7)(a) of this final rule, for the purposes of estimating burden associated with the provision to implement MVP and subgroup reporting, we assume that 10 percent of MIPS eligible clinicians in the CY 2022 performance period/2024 MIPS payment year will report as MVP participants in the CY 2023 performance period/2025 MIPS payment year. In addition, we assume that there will be 20 subgroup reporters in the CY 2023 performance period/2025 MIPS payment year. We anticipate a per respondent reduction of 3 hours and $412 dollars per CQM/QCDR quality submission, 3 hours and $336 per eCQM quality submission, and 5 hours and $717 per claims quality submission. Overall, we estimate a net reduction in burden of $7,463,145 in the quality performance category ICRs due to the introduction of MVP and subgroup reporting in the CY 2023 performance period/2025 MIPS payment year. We refer readers to section V.B.8.e.(7)(a)(iii) of this final rule for further discussion of our burden associated with MVPs and subgroups including the number of respondents.

g. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting the payment adjustments, we proposed several policies that have an impact on burden in the CY 2022 and CY 2023 performance periods/2024 and 2025 MIPS payment years. In section V.B.8 of

this final rule, we outline estimates of the costs of data collection that includes both the effect of policy updates and adjustments due to the use of updated data sources. For each provision included in this regulation which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 148. We also provide additional burden discussions that we are not able to quantify.

As discussed in the section V.B.8 of this final rule, we are setting forth our estimates for the CY 2023 performance period/2025 MIPS payment year as new burden with no currently approved estimate. To provide the reader a better sense of the differences in burden between our CY 2022 and CY 2023 performance period/2024 and 2025 MIPS payment year estimates due to changes in policy, we are presenting our CY 2023 performance period/2025 MIPS payment year estimates in Table 148 in comparison to the CY 2022 performance period/2024 MIPS payment year estimate found in the CY 2021 PFS final rule. In Table 148, we are only including our CY 2023 performance period/2025 MIPS payment year estimates for the ICRs where our estimate is different from our CY 2022 performance period/2024 MIPS payment year estimate.

TABLE 148: Incremental Burden from Associated Final Policies

Burden Description and associated finalized proposals	Burden Hours	Burden Dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2021 PFS final rule into the CY 2022 and 2023 MIPS performance periods (as discussed in section V.B.8.p.)	1,468,566	$148,078,846
Burden change due to policy to continue the CMS Web Interface measures as a collection type/submission type for CY 2022	+7,030	+$669,433
Burden change due to policy to sunset the CMS Web Interface measures as a collection type/submission type for CY 2023*	0	0
Burden change due to policy to continue CMS Web Interface group registration for CY 2022	+23	+2,190
Burden change due to policy to continue CMS Web Interface group registration for CY 2023	0	0
Burden change due to the policy to require QCDRs to submit participation plans for the CY 2022 self-nomination period, if necessary	+30	+$2,857
Burden change due to the policy to require qualified registries to submit participation plans for the CY 2022 self-nomination period., if necessary	+57	+$5,428
Burden change due to the revised criteria for nomination of improvement activities: increase of criteria from 1 to 8 including addition of 2 new criteria for nomination of improvement activities beginning with the CY 2022 Annual Call for MIPS Improvement Activities	+43	+$6,492
Burden change due to automatic reweighting of the Promoting Interoperability performance category for small practices	-3,474	-$330,747
Burden change due to SAFER guides attestation requirement for the Promoting Interoperability performance category for CY 2022	+1,033	+$98,362
Burden change due to the new ICR for capturing MVP registration requirement for clinicians participating in MVPs reporting beginning with the CY 2023 MIPS performance period*	+3,229	+$307,465
Burden change due to the new ICR for capturing subgroup registration requirement for clinicians choosing to participate as subgroups for reporting the MVP or the APP beginning with the CY 2023 MIPS performance period*	+10	+$952
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to MVP Quality Submissions beginning with the CY 2023 MIPS performance period*	-40,115	-$4,036,981
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to MVP Quality Submissions beginning with the CY 2023 MIPS performance period*	-46,742	-$4,748,523
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to MVP Quality Submissions beginning with the CY 2023 MIPS performance period*	-38,398	-$3,934,272
Burden change due to new ICR for capturing the reduced reporting requirements for the quality performance category of MVPs beginning with the CY 2023 MIPS performance period *	+83,673	+$8,564,736
Total change in burden due to policy for CY 2022	**+3,805**	**+$358,395**
Total change in burden due to policy for CY 2023, in comparison to CY 2022 estimate from CY 2021 PFS Final	**-41,591**	**-4,159,851**

Burden Description and associated finalized proposals	Burden Hours	Burden Dollars
Rule		
Total burden set forth in the CY 2022 PFS final rule for CY 2022	**1,428,391**	**$144,014,757**
Total burden set forth in the CY 2022 PFS final rule for CY 2023	**1,383,049**	**$139,501,770**

* The total change in burden due to this policy includes a decrease in burden due to elimination of the "Quality Data Submission: CMS Web Interface collection type" ICR beginning with the CY 2023 MIPS performance period and "Group Registration for CMS Web Interface" ICR beginning with the CY 2023 MIPS performance period as well as an increase in burden for the "Quality Data Submission: MIPS CQM and QCDR collection type" and "Quality Data Submission: eCQM collection type" ICRs beginning with the CY 2023 MIPS performance period for respondents who previously submitted via the CMS Web Interface submitting data via an alternate collection type. Burden will decrease in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRS beginning with the CY 2023 MIPS performance period due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as an MVP participant. Total change in burden also includes the increase in submission burden due to the introduction of the "MVP Quality Submission," "MVP registration," and "Subgroup registration" ICRs beginning with the CY 2023 MIPS performance period. See section V.B.8 of this final rule.

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(2) Additional Impacts to Clinicians

(a) Web Interface

As discussed in section IV.A.3.d.(1)(d) of this final rule, we finalized the proposal to continue the use of the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians for the CY 2022 performance period/2024 MIPS payment year. We are also sunsetting the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the CY 2023 performance period/2025 MIPS payment year. As discussed in section IV.A.3.c.(2)(a), we are also extending the CMS Web Interface as a means of reporting quality under the APP for Shared Savings Program ACOs for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2025 MIPS payment year.

We refer readers to sections V.B.8.e.(8) and V.B.8.e.(10) of this final rule for our discussion on the estimated burden associated with the extension of the CMS Web Interface collection type in CY 2022 performance period/2024 MIPS payment year and the sunset of the CMS Web Interface collection type in the CY 2023 performance period/2025 MIPS payment year (for those not using the APP). Additionally, we assume that the impacts associated with the sunset of CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians will remain the same as our discussion in the CY 2021 PFS final rule (85 FR 85020 through 85021).

(b) Administrative Claims Measure

As discussed in section IV.A.3.d.(1)(e), we are adding one new administrative claims measures beginning in the CY 2022 performance period/2024 MIPS payment year and for future performance periods: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions. We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure that clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience. In summary, we are acknowledging that while there are no data submission requirements per § 414.1325(a)(2)(i) for administrative claim measures, there may be associated costs for clinicians and group practices to monitor new administrative claim measures; however, we are unable to quantify that impact.

(c) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.3.d.(3)(c)(ii) of this final rule, we finalized the proposals to remove 7 previously adopted improvement activities, modify 15 existing improvement activities, and adopt 5 new improvement activities. We refer readers to Appendix 2 of this final rule for further details. We do not believe these changes to the inventory will impact time or financial burden on stakeholders because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect these changes to the inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate most clinicians performing improvement activities, to comply with existing MIPS policies, will continue to perform the same activities under the policies in this final rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the CY 2022 performance period/2024 MIPS payment year.

(d) Stakeholders Nominating Improvement Activities

In section IV.A.3.d.(3)(c)(i)(B) of this rule, we finalized these proposals: (1) To revise the required criteria for improvement activity nominations received through the Annual Call for Activities; (2) changes to the timeline for improvement activities nomination during a PHE; and (3) to suspend

activities that become obsolete or impacted by clinical practice guideline changes from the program when this occurrence happens outside of the rulemaking process.

Regarding the provision to clarify the timeline for an improvement activity nominated during the PHE, we believe this provision will not affect our currently approved burden estimates since we believe that the number of nominations will not change, but it would make an activity available for reporting to clinicians in the same performance year it was intended to be implemented. In section IV.A.3.d.(3)(c)(i)(B)(aa) of this rule, we finalized the proposal that in order to implement a new improvement activity for a PHE during the same year as the nomination, the nomination will need to be received no later than January 5th of the nomination year to be included in a rule for notice-and-comment rulemaking during that fiscal or calendar year, a necessary precursor to implementation if it were to be finalized. As described in section V.B.8.j of this rule, we expect additional nominations may be received as a result of this provision, but we do not have any data with which to estimate what the additional number may be. As a result, we did not make any revisions to our currently approved burden estimate.

Regarding the provision to suspend activities that become obsolete or impacted by clinical practice guideline changes from the program when this occurrence happens outside of the rulemaking process, we do not anticipate additional burden for stakeholders because of the provision described above as the policy does not change requirements for the nomination of improvement activities.

As described in section IV.A.3.d.(3)(c)(i)(B) of this rule, due to the provisions to add two new criteria and to increase the number of criteria stakeholders are required to meet when submitting an activity provision from a minimum of 1 to all 8 criteria, which includes the two new criteria, we proposed to revise our estimated annual information collection burden for nomination of improvement activities to 136 hours (31 nominations × 4.4 hr/nomination) at a cost of $20,355 (31 × [(2.8 hr × $114.24/hr) + (1.6 hr × $210.44/hr)]).

(e) Impact on Small Practices

As described in section VI.F.18.e.(3) of this final rule RIA, we found 85 percent of clinicians who did not submit data to MIPS were in small practices. However, the estimated number of MIPS eligible clinicians who do not submit data, including those in small practices, may be smaller in the CY 2022 performance period/2024 MIPS payment year since the submission window for the 2019 performance period was impacted by the start of the PHE for COVID–19. CMS is committed to identifying flexibilities and options to help clinicians in small practices participate meaningfully and successfully in MIPS. Specifically, CMS finalized several policies to support clinicians in small practices once they engage with MIPS in the quality, improvement activities and Promoting Interoperability performance categories for the CY 2022 performance period/2024 MIPS payment year. Based on our RIA model findings described in section VI.F.18.e.(3) of this final rule, the final policies for the CY 2022 performance period/2024 payment year led to clinicians in small practices no longer disproportionately receiving negative payment adjustments compared to clinicians in larger sized practices. Therefore, the combination of the special scoring policies for clinicians in small practices is expected to positively affect this group of clinicians and will hopefully encourage and improve future engagement in MIPS among clinicians in small practices.

(f) Impact on Third Party Intermediaries

In section IV.A.3.h. of this rule, we finalized multiple changes to the third-party intermediary regulations at § 414.1400. Specifically, we finalized: (1) Reorganization and consolidation of § 414.1400 generally; (2) an expansion of the general participation requirements of third-party intermediaries to third party intermediaries reporting to MIPS on behalf of APM Entities in order to align reporting requirements for all participants in MIPS; (3) a requirement that, beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. Health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data; (4) to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 performance period/2025 MIPS payment year; (5) to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 performance period/2019 MIPS payment year) through the 2020 performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023; (6) a requirement that, beginning with the 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval; (7) a requirement that, beginning with the CY 2023 performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the agency; and (8) to add a rejection criterion to state that a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. Additionally, to provide further clarification of our current policy (84 FR 63070 through 63073), we finalized the proposal to state that if a QCDR measure owner is not approved during a given self-nomination period, any associated QCDR measures with that QCDR would also not be approved.

With regard to the reorganization and consolidation of § 414.1400 generally, we do not anticipate this to require any additional effort for affected entities as the provision is to allow CMS to reorganize the existing information.

For the requirements related to expanding the general participation requirements of third-party intermediaries to third party intermediaries reporting to MIPS on behalf of APM Entities in order to align reporting requirements for all participants in MIPS, we did not propose to revise our burden estimates as this requirement is not different from how third-party intermediaries currently submit data for the quality, improvement activities and Promoting Interoperability performance categories in MIPS on behalf of individual eligible clinicians and groups.

As previously discussed in section IV.A.3.h.(2)(b)(ii) of this rule, we finalized the proposal to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 performance period/2025 MIPS payment year. During the MVP Town Hall held in January 2021 (85 FR 74729), we heard from third-party intermediaries that they are confident that they can make the necessary updates to allow for subgroup reporting, if they have enough time. A few vendors suggested that we add

subgroup reporting to the existing CEHRT requirements. Given our provision described in section IV.A.3.b.(2)(d) of this rule to delay the implementation of subgroup reporting option to the CY 2023 performance period/2025 MIPS payment year, we assume that the delay will give these entities adequate time to make the necessary updates. We assume that there will be no additional burden that third-party intermediaries will incur to implement the subgroup reporting option. We anticipate that there may be administrative burden associated with changes in workflows to their existing systems for submission of subgroup data for the CY 2023 performance period/ 2025 MIPS payment year. However, given that each of these entities and their information technology systems are unique, we are unable to quantify the burden for these entities to capture and submit data on behalf of clinicians who may choose to participate as subgroups.

We do not anticipate a significant impact to QCDRs and qualified registries resulting from the finalized provision to require QCDRs and qualified registries to conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits. First, we are not revising our burden estimates because the finalized data validation requirements are like existing expectations which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999). Second, we believe that the requirements for conduct of the data validation audits are aligned with methods and procedures which stakeholders currently utilize.

As discussed in section IV.A.3.h.(3)(a)(i) of this rule, due to the provision to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 performance period/ 2019 MIPS payment year) through the CY 2020 performance period/2022 MIPS payment year to submit a participation plan as part of their self-nomination for CY 2023 performance period/2025 MIPS payment year, we refer readers to section V.B.8.c.(2) of this rule for details on the adjusted burden.

As discussed in section V.B.8.c.(2) of this rule, we are not adjusting our burden estimates due to the provision related to two new rejection criteria for QCDR measures.

(g) Assumptions & Limitations

We note several limitations to our estimates of clinicians' MIPS eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the CY 2022 performance year/2024 MIPS payment year. Due to the PHE for COVID–19, we are aware that there may be changes in health care delivery and billing patterns that will impact results for the CY 2022 performance year/2024 MIPS payment year that we are not able to model with our historic data sources. The scoring model results presented in this final rule assume that CY 2019 Quality Payment Program data submissions and performance are representative of CY 2022 Quality Payment Program data submissions and performance. The estimated performance for the CY 2022 performance year/2024 MIPS payment year using CY 2019 Quality Payment Program data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2019 MIPS performance period/2021 MIPS payment year was significantly lower (30 out of 100 points) than the performance threshold for the 2022 performance year/2024 payment year (75 out of 100). We anticipate clinicians may participate more robustly by submitting more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in in the CY 2019 Quality Payment Program and submitted data would continue to elect to opt-in in the CY 2022 performance year/2024 MIPS payment year. It is difficult to predict, based on 2019 data, whether clinicians will elect to opt-in to participate in MIPS with the CY 2022 performance year/2024 payment year finalized policies.

In addition to the limitations described throughout the methodology sections, there are additional limitations to our estimates including: (1) To the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 144; and (2) due to updates in measure specifications and new measures, our cost performance is modeled using test data that does not always overlap with CY 2019 so we may not be capturing performance for clinicians or groups that change practices or TINs between when the testing data and the 2019 performance period. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify.

G. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented the estimated impact on total allowed charges by specialty.

1. Alternatives Considered for Utilization Data in PFS Ratesetting

As discussed earlier in this section II.C.1 (Changes in Relative Value Unit (RVU) Impacts), our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2021 with payment rates for CY 2022 using CY 2020 Medicare utilization. As an alternative to using CY 2020 data, we considered using CY 2019 utilization data for the purposes of determining the CY 2022 RVUs, as well as in determining the CY 2022 BN adjustment and conversion factor. We considered using CY 2019 data due to the PHE for COVID–19, which has impacted the delivery of health care services over the past 18 months. Increases in remote delivery of services to reduce risk of exposure to both practitioner and patients, as well as postponement of elective procedures have resulted in a change to service utilization patterns across Medicare FFS payment systems. Specific to the PFS, overall service utilization decreased by approximately 20 percent in CY 2020 compared to CY 2019, which caused us to question whether CY 2020 data is the best available data to use for CY 2022 ratesetting.

In order to determine if lower overall utilization in CY 2020 would result in differential impacts on specialties and practitioners, we modeled the PFS ratesetting process using CY 2019 utilization data. We found that the use of CY 2020 as opposed to CY 2019 data in establishing payment rates had relatively little differential impacts on payment, despite the approximately 20 percent decrease in overall service utilization. Table 149 illustrates specialty-specific impacts for the proposed rule using CY 2019 data.

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TABLE 149: CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty using CY 2019 Claims for the Proposed Rule

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$265	0%	-2%	0%	-2%
Anesthesiology	$1,971	0%	1%	0%	1%
Audiologist	$75	0%	-1%	0%	-1%
Cardiac Surgery	$255	0%	0%	0%	0%
Cardiology	$7,087	0%	-1%	0%	-1%
Chiropractic	$743	0%	1%	0%	0%
Clinical Psychologist	$884	0%	0%	0%	0%
Clinical Social Worker	$922	0%	0%	0%	0%
Colon and Rectal Surgery	$172	0%	0%	0%	0%
Critical Care	$375	0%	0%	0%	0%
Dermatology	$3,971	0%	0%	0%	0%
Diagnostic Testing Facility	$750	0%	-1%	0%	0%
Emergency Medicine	$3,116	0%	0%	0%	0%
Endocrinology	$575	0%	2%	0%	2%
Family Practice	$6,676	0%	2%	0%	2%
Gastroenterology	$1,799	0%	0%	0%	0%
General Practice	$443	0%	2%	0%	2%
General Surgery	$2,059	0%	0%	0%	0%
Geriatrics	$202	0%	1%	0%	2%
Hand Surgery	$256	0%	2%	0%	2%
Hematology/Oncology	$1,903	0%	-2%	0%	-2%
Independent Laboratory	$650	0%	-2%	0%	-2%
Infectious Disease	$657	0%	-1%	0%	-1%
Internal Medicine	$11,327	0%	1%	0%	1%
Interventional Pain Mgmt	$1,002	0%	1%	0%	0%
Interventional Radiology	$483	0%	-9%	0%	-8%
Multispecialty Clinic/Other Phys	$158	0%	0%	0%	0%
Nephrology	$2,457	0%	0%	0%	0%
Neurology	$1,582	0%	1%	0%	1%
Neurosurgery	$810	0%	0%	0%	0%
Nuclear Medicine	$53	0%	-1%	0%	-1%
Nurse Anes / Anes Asst	$1,251	0%	1%	0%	1%
Nurse Practitioner	$5,476	0%	1%	0%	1%
Obstetrics/Gynecology	$679	0%	1%	0%	1%
Ophthalmology	$5,365	0%	0%	0%	0%
Optometry	$1,388	0%	1%	0%	1%
Oral/Maxillofacial Surgery	$81	0%	-3%	0%	-3%
Orthopedic Surgery	$3,891	0%	1%	0%	1%
Other	$49	0%	0%	0%	0%
Otolarngology	$1,344	0%	-1%	0%	-1%
Pathology	$1,237	0%	-1%	0%	-1%
Pediatrics	$71	2%	2%	0%	5%
Physical Medicine	$1,204	0%	0%	0%	0%
Physical/Occupational Therapy	$4,861	0%	0%	0%	0%
Physician Assistant	$3,115	0%	1%	0%	1%
Plastic Surgery	$380	0%	1%	0%	1%
Podiatry	$2,256	0%	1%	0%	1%
Portable X-Ray Supplier	$95	0%	10%	0%	10%
Psychiatry	$1,200	0%	1%	0%	1%
Pulmonary Disease	$1,704	0%	1%	0%	1%
Radiation Oncology and Radiation Therapy Centers	$1,825	0%	-5%	0%	-5%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Radiology	$5,064	0%	-1%	0%	-1%
Rheumatology	$615	0%	0%	0%	0%
Thoracic Surgery	$341	0%	0%	0%	0%
Urology	$1,945	0%	0%	0%	0%
Vascular Surgery	$1,269	0%	-7%	0%	-7%
Total	$100,377	0%	0%	0%	0%

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The majority of specialties experienced shifts of less than a percent when we used CY 2019 data, as opposed to CY 2020 data, as displayed in Table 136, as the basis for setting rates. Several specialties shifted by approximately one percent. We did not detect a pattern of specialties that were notably affected by the choice of claims data, either positively or negatively. While Pediatrics shifted from a 1 percent impact when we used CY 2020 claims data to a 5-payment impact when we used CY 2019 claims data, this shift is likely due to the smaller amount of allowed charges associated with the Pediatrics specialty.

We analyzed the percentage change in total RVUs per practitioner. Using CY 2019 utilization data, Total RVUs change between −1 percent and 1 percent for 53 percent of practitioners, representing more than 48 percent of the changes in Total RUs for all practitioners, similar to the results we found when using CY 2020 claims that we discussed in section II.C.1. Variations by specialty were also similar to the results we found using CY 2020 claims and are contained in the public use file that describes the percentage change in total RVUs per practitioner.

Similar to the process described in section II.C.1. of this final rule, we used CY 2019 claims data to estimate the CY 2021 PFS CF to be 33.6184 which reflects a BN adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, which we estimated to be −0.04 using CY 2019 data, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the expiration of the 3.75 percent fee schedule payment increase for CY 2021 provided by the CAA. The anesthesia CF, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments, would shift by a similar magnitude as the PFS CF. Thus, the estimated PFS CF and anesthesia CF using CY 2019 data is slightly higher compared to using claims data for CY 2020 with an estimated difference of 0.0336 (a little less than three and half cents). We note that the BN adjustment will be recalculated for the CY 2022 PFS final rule and the use of CY 2019 claims may or may not be higher than the use of CY 2020 claims based on which policies are ultimately finalized.

Comment: We received few comments on our Alternatives Considered for Utilization Data in PFS Ratesetting. One commenter stated that they supported the use of the alternate CY 2019 claims data because it resulted in a slight improvement (approximately 1 percent) in the impact of changes in RVUs for their specialty. A different commenter stated that practice patterns in CY 2020 were atypical as a result of the COVID–19 pandemic and they believed that the use of 2019 claims data would be likely to more closely approximate overall PFS service utilization and costs in 2022.

Response: We continued to believe that the use of CY 2020 as opposed to CY 2019 data in establishing payment rates had relatively little differential impacts on payment, despite the approximately 20 percent decrease in overall service utilization. We found that the use of CY 2020 as opposed to CY 2019 data in establishing payment rates had little differential impact on payment at the specialty, service categories, and individual services levels. We also did not detect a pattern of specialties who were notably affected by the choice of claims data, either positively or negatively. We received few comments on this alternative considered which we believe indicates support for our use of CY 2020 claims data from the majority of commenters.

After consideration of the comments, we are finalizing our continued use of CY 2020 claims data instead of the potential alternative to use CY 2019 claims data for the purposes of determining the CY 2022 RVUs as well as in determining the CY 2022 BN adjustment and conversion factor.

2. Alternatives Considered for Split (or Shared) Visits

In section II.F of this final rule, we codify our current policy allowing billing of certain ''split'' or ''shared'' E/M visits by a physician, when the visit is performed in part by both a physician and an NPP, who are in the same group and the physician performs a substantive portion of the visit. We will codify in our regulations a definition of a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and NPP who are in the same group, in accordance with applicable laws and regulations, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting (rather than as a split (or shared) visit). The physician or NPP who performs the substantive portion of the split (or shared) visit will bill for the visit. We are also finalizing our proposed definition of substantive portion as more than half of the total time spent by the physician and NPP.

We considered several alternative approaches. First, we considered the option of disallowing split (or shared) visit billing beginning in CY 2022. Under this alternative, in settings where payment for ''incident to'' services is prohibited, physicians and NPPs would only be able to bill for visits they furnish in their entirety under their own NPI. Such a policy would be administratively simple, and reduce the likelihood of paying significantly more than the actual resource costs incurred. When physicians and practitioners furnish services in facility settings, they do not ordinarily incur the cost of clinical staff or other PE costs involved in furnishing the services. When the physician bills for an E/M visit, in accordance with section 1833(a)(1)(N) of the Act, the Medicare Part B payment is equal to 80 percent of the payment basis under the PFS which, under section 1848(a)(1) of the Act, is the lesser of the actual charge or the full fee schedule

amount for the service. In contrast, if the NPP bills for it, in accordance with section 1833(a)(1)(O) of the Act, the Medicare Part B payment is equal to 80 percent of the lesser of the actual charge or 85 percent of the fee schedule rate. Because of this payment differential and the lower resource costs associated with E/M visits performed partly by a physician and partly by an NPP, it could be argued that the physician should not be able to bill for such a visit and be paid at the higher fee schedule amount. Our proposal was informed by our belief that longstanding clinical practice relies substantially upon shared visits between physicians and NPPs in facility settings. To avoid the potential disruption in this common medical practice approach, we did not propose to disallow billing for split (or shared) visits.

Comment: We received public comments confirming that it would be disruptive of current practice patterns to disallow split (or shared) visit billing. We did not receive public data indicating specifically how often split (or shared) visits occur.

Response: After consideration of the public comments, we are finalizing a policy to continue allowing billing of split (or shared) visits under specified conditions. We will require a modifier on claims for these types of visits, as proposed, to help inform future policy in this area.

We also considered several alternatives for how to define the substantive portion of a split (or shared) visit. We considered defining ''substantive portion'' as any face-to-face portion of the split (or shared) visit, consistent with our current definition. We did not believe it would be appropriate to consider just any portion of the visit—with or without direct patient contact— as a substantive portion. For instance, we did not believe it would be appropriate to consider a brief or trivial interaction, with or without direct patient contact, such as where the physician merely ''pokes their head'' into the room, to be a substantive portion of the visit. We did not believe it would be appropriate to permit a physician to bill for a visit if they do not substantially participate in the visit, given that physicians are paid under the PFS at a higher rate than NPPs. Therefore, we proposed to define ''substantive portion'' as more than half of the total time spent by the physician or NPP.

Another alternative we considered, but did not propose, was to utilize the medical decision making (MDM) to define substantive portion. We did not propose this approach because MDM is not easily attributed to a single physician or NPP when the work is shared, because MDM is not necessarily quantifiable and can depend on patient characteristics. We believed that time is a more precise factor than MDM to use as a basis for deciding which practitioner performs the substantive portion of the visit. We believed that using the time spent by each practitioner furnishing the split (or shared) visit would provide a more precise metric than potentially finding a way to parse MDM between the physician and the NPP.

We also considered defining substantive portion as performance of the history and/or physical exam, which are key components of certain E/M visits. Given recent changes in the CPT E/M Guidelines, history and physical exam are no longer necessarily included in all E/M visits, because for office/outpatient E/M visits, the visit level can now be selected based on either MDM or time, and history and exam are performed only as medically appropriate. Also, the CPT Editorial Panel is considering removing history and physical exam as key visit components for institutional visits, similar to the changes already made for office/outpatient E/M visits. Accordingly, defining ''substantive portion'' as any key component including history or exam did not seem to be a viable approach.

Lastly, we considered not defining substantive portion and instead leaving determinations regarding the substantive portion to MAC and/or medical review discretion. However, this approach would impose a significant burden on MACs to assess individual cases and could lead to too much regional variation in payment. We solicited public comment to help inform what we consider to be the ''substantive portion'' of a split (or shared) visit in institutional settings and assist us in consideration of our definition of ''substantive portion''.

We received public comments to help inform what we consider to be the ''substantive portion'' of a split (or shared) visit in institutional settings and assist us in consideration of our definition of ''substantive portion.'' We refer readers to section II.F. of this final rule with comment period for a complete discussion of the public comments on this topic and our responses, summarized below.

Comment: The commenters agreed that the individual who performs the substantive portion should bill for the visit. Approximately half of the commenters supported our proposal, believing that it was appropriate and would provide a clear rule. However, approximately half of the public comments recommended alternative definitions of substantive portion, including:

- A lower percentage of time (25 to 30 percent of the total time) (several comments).
- MDM (several comments).
- Some portion of MDM (several comments).
- Choice of MDM or time, for example, based on whichever is used to select visit level (several comments).
- One of the three key components of history, exam, or MDM, at least until the AMA completes changes for E/M visit coding and the CPT E/M Guidelines that the commenters expect for 2023 (several comments).
- Some combination of the above, for example, more than half of the MDM or more than half of total time (several comments).
- Working with the CPT Editorial Panel to develop a policy (several comments).

These commenters were concerned about a perceived devaluation of the medical decision-making portion of visits, disruptions to current practice patterns, and administrative burdens associated with timing each of the practitioner's contribution to the visit.

Response: Regarding recommendations to consider the substantive portion to be a lower percentage of time, having reviewed our current policy, we do not believe that the higher physician payment rate under the PFS should be made when a physician performs less than half of the visit, such as a quarter or a third of the total time or less than half of the MDM. We do not think that MDM is necessarily the most critical or central component of E/M visits, and it is not the only service component being paid for. PFS payment rates incorporate and assume a certain amount of physician time per visit, reflected in the assigned RVUs and reflected annually in our physician time files. PFS payment rates reflect the typical amount of time spent on visits, and the Act requires us to reflect both time and intensity of work (physician and practitioner) in our payment rates. We do not believe this in any way devalues the unique education, training, experience, or expertise of physicians, but rather that both time and expertise are important and included in payment under the PFS. We continue to believe that MDM cannot be readily attributed to only the physician or the NPP, or definitively divided between them.

We believe the commenters overestimate the administrative burden

of tracking and attributing time, given the advent of EHRs and new E/M visit coding structures. However, we understand that an adjustment period may be needed to establish systems to track and attribute time for split (or shared) visits, especially since the coding for E/M visits in many facility settings will not use MDM or time to distinguish visit levels until 2023. Therefore, we are finalizing our definition of substantive portion for split (or shared) visits as proposed (more than half of the total time spent by the physician and NPP performing the split (or shared) visit) beginning January 1, 2023. However, we are modifying our proposed policy for one transitional year. For CY 2022, except for critical care visits, the substantive portion will be defined as one of the three key components (history, exam, or MDM), or more than half of the total time spent by the physician and NPP performing the split (or shared) visit). In other words, for CY 2022, the practitioner who spends more than half of the total time, or performs the history, exam, or MDM can be considered to have performed the substantive portion and can bill for the split (or shared) E/M visit. We wish to be clear that practitioners can still use MDM to select visit level for the E/M split (or shared) visit, as proposed. We also are clarifying that when one of the three key components is used as the substantive portion in CY 2022, the practitioner who bills the visit must perform that component in its entirety in order to bill (see section II.F.1.c.1. of this final rule for a more detailed discussion).

For visits that are already timed (that is, critical care services), the choice to use more than half of the total time, or performance of the history, exam, or MDM will not apply. For critical care visits, starting in CY 2022, the substantive portion will be more than half of the total time, as proposed. We will continue to review and consider any future changes by the AMA/CPT Editorial Panel to the CPT E/M Guidelines for split (or shared) visits. We also intend to monitor the claims data for split (or shared) visits, to better understand how frequently practitioners use or rely upon this billing construct.

We considered disallowing split (or shared) billing in critical care, SNF and nursing facility (NF) visits, as well as new patient and initial patient visits. We require certain SNF/NF visits to be provided entirely by a physician, but we believed we should allow split (or shared) visit billing for other visits that can be split (or shared) in these settings. (We refer readers to our Conditions of Participation in 42 CFR 483.30 for information regarding the SNF/NF visits that are required to be performed in their entirety by a physician. That regulation requires that certain SNF/NF visits must be furnished directly and solely by a physician). However, we believed current clinical practice generally allows sharing of critical care visits by appropriately trained and qualified practitioners, and we solicited comment on this belief and this alternative considered. We proposed to allow split (or shared) visit billing in critical care because we believe the practice of medicine has evolved towards a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by clinicians in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued current policy may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care.

Comment: We received many comments on our proposals for allowed settings of care, all in support of those proposals.

Response: We thank the commenters for their support. After consideration of the public comments, we are finalizing as proposed.

We proposed to allow split (or shared) visits for both new and established patients as well as initial and subsequent visits. After conducting an internal review, including consulting our medical officers, we believed that the practice of medicine has evolved toward a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by practitioners in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued the manual instructions may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care. In considering and reevaluating our policy, we saw no reason to preclude the physician or NPP from billing for split (or shared) visits for a new patient, in addition to an established patient, or for initial and subsequent split (or shared) visits. Therefore, we proposed to permit the physician or NPP to bill for split (or shared) visits for both new and established patients, as well as for initial and subsequent visits. We believed this approach is also consistent with the CPT E/M Guidelines for split (or shared) visits, which does not exclude these types of visits from being billed when furnished as split (or shared) services.

Comment: We received many comments on this proposal, all in support of it.

Response: We thank the commenters for their support. After consideration of public comments, we are finalizing as proposed.

3. Alternatives Considered for Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802, 414.806)

This provision implements new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of the CAA (for the purposes of this section of this final rule, hereinafter is referred to as ''section 401''). These new requirements will improve the accuracy of reported prices and limit the use of WAC-based pricing.

As discussed in section III.D.1. of this final rule, section 1847A(c)(6)(A) of the Act incorporates the definition of manufacturer at section 1927(k)(5) of the Act, but permits the Secretary to exempt repackagers from the definition of manufacturer, as determined appropriate, for purposes of section 1847A(f)(2) of the Act.

We considered whether to implement the flexibility afforded by the statute. However, implementing the flexibility afforded by the statute could potentially lead to a gap in the ASP reporting requirements, meaning that ASPs could be distorted to the extent that certain sales are carved out of the reporting requirement through the use of repackagers.

As discussed previously in this RIA, we are unable to quantitatively estimate the impacts of this provision. We welcomed comments on our approach, and on the alternative relative to: (1) The likely costs or savings (to manufacturers, beneficiaries, the government, and other stakeholders); and (2) any other related impacts of this provision.

4. Alternatives Considered for the MDPP Expanded Model Emergency Policy

For the MDPP Expanded Model Emergency Policy, no alternatives were considered. The 2-year MDPP service period has depressed interest in MDPP among would-be MDPP suppliers. These actions address stakeholder comments on the barriers to MDPP expanded model success. If we do not take action, we will not be able to scale MDPP as intended, impacting Medicare beneficiary access to this program. Reducing the MDPP from a 24- to a 12-month services period, increasing the year 1 performance payments, and waiving the Medicare provider enrollment application fee not only better aligns the model with the evidence that helped certify the DPP model test initially, but it will encourage eligible organizations to enroll as MDPP suppliers.

5. Alternatives Considered for the Quality Payment Program

We view the performance threshold as a critical factor affecting the distribution of payment adjustments in the Quality Payment Program. We ran a separate final policies RIA model based on the actual mean for the CY 2019 performance period/2021 MIPS payment year with a performance threshold of 86 and an additional performance threshold of 92 points, which are potential values that may be used for the CY 2022 performance period/2024 MIPS payment year. The model with a performance threshold of 86 and additional performance threshold of 92 has the same mean and median final score as our policies RIA model since the performance threshold does not change the final score. We estimate that $ 907 million will be redistributed through BN. For clinicians who meet or exceed the additional performance threshold, an additional $241 million was distributed. The maximum positive payment adjustment will be 18.2 percent prior to the maximum additional payment adjustment and 28.2 percent after considering the MIPS maximum positive payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 74.0 percent of MIPS eligible clinicians will receive a negative payment adjustment among those that submit data.

We report the findings for the baseline model which describes the impact for the CY 2022 performance period/2024 MIPS payment year if this regulation did not exist. The baseline model has a final score mean of 78.13 and median of 82.59. We estimate that $428 million will be redistributed through BN. There will be a maximum payment adjustment of 6.6 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 8.3 percent of MIPS eligible clinicians will receive a negative payment adjustment among those that submit data.

H. Impact on Beneficiaries

We do not believe these provisions will have a negative impact on beneficiaries given overall PFS BN.

1. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802, 414.806)

Section 1927(b)(3)(A)(iii) of the Act requires manufacturers with a Medicaid drug rebate agreement to report ASP data consistent with the information required for such reporting at section 1847A of the Act. Some manufacturers without Medicaid drug rebate agreements voluntarily submit ASP data for their single source drugs or biologicals that are payable under Part B, however other manufacturers without Medicaid drug rebate agreements do not voluntarily submit such data. Without manufacturer reported ASP data, CMS cannot calculate the ASP payment limit, and consequently, payment is typically based on Wholesale Acquisition Cost (WAC).

Consistent with section 1847A(c)(3) of the Act and our regulations at § 414.804(a)(2), the ASP is net of price concessions. However, consistent with the definition of WAC at section 1847A(c)(6)(B) of the Act, the WAC is not net of price concessions and is thus nearly always, and sometimes significantly, higher than ASP. Drugs with payment allowances based on WAC may have greater ''spreads'' between acquisition costs and payment than drugs for which there is an ASP-based payment allowance, which, in turn, may: (1) Incent the use of the drug based on its spread rather than on purely clinical considerations; (2) result in increased payments under Medicare Part B; and (3) result in increased beneficiary cost sharing. This provision implements new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of Division CC, Title IV of the CAA, 2021. These new requirements will improve the accuracy of reported payment limits and limit the use of WAC-based pricing.

For single source drugs, these changes may result in lower payment limits because, typically, the WAC plus 3 percent is higher than ASP plus 6 percent. This then translates to cost savings for both the government and beneficiaries, who will pay coinsurance on a lesser amount. However, for the reason stated earlier in this RIA (see section VI.G.4. of this final rule), we are unable to predict the magnitude of this effect.

Similarly, payment limits for multiple source drugs could increase or decrease, and we are unable to predict the direction or magnitude of specific or aggregate effects at this time.

2. Determination of ASP for Certain Self-Administered Drug Products

Although we are unable to quantify the total magnitude of the potential savings, these changes have the potential to substantially reduce program expenditures and beneficiary coinsurance. The OIG's July 2020 report (discussed in section III.D.2. of this final rule) determined that the inclusion of self-administered versions of certolizumab and abatacept in their respective volume-weighted, average ASPs, alone, has resulted in $173 million in additional Medicare beneficiary coinsurance between 2014 and 2018.

The regulatory changes have the potential to result in decreased payment limits for identified billing and payment codes and could, in turn, substantially reduce beneficiary coinsurance. Since section 405 of Division CC, Title IV of the CAA, 2021 directs CMS to implement the statutory changes at section 1847A(g)(3) of the Act beginning on July 1, 2021, these potential savings may be observed within the year.

3. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

This change will have a positive impact on eligible MDPP beneficiaries, as it better aligns with the CDC's National DPP, giving both the participants and the coaches similar messaging around this program, regardless of payer. MDPP suppliers often offer the MDPP set of services to mixed cohorts, or classes with participants who are not eligible for MDPP, but who are enrolled in a National DPP cohort. Since MDPP generally follows the CDC's National DPP and aligns its program with the CDC's DPRP Standards, it is confusing to participants, coaches, and staff when talking about a 2-year program to its eligible Medicare participants when the non-Medicare participants have a 1-year program. Finally, reducing the MDPP service period from 2 years to one (1) year allows more cohorts to start and finish MDPP during the expanded

model initial period of performance, which ends in March 2023.

4. Quality Payment Program

There are several changes in this rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, will lead to more meaningful and relevant data being available to beneficiaries on the type and scope of care provided by clinicians on the compare tool. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate this will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

K. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's rule will be the number of reviewers of last year's rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's rule in detail, and it is also possible that some reviewers will choose not to comment on the rule. For these reasons we thought that the number of commenters will be a fair estimate of the number of reviewers of last year's rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it will take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $913.92 (8.0 hours × $114.24). Therefore, we estimated that the total cost of reviewing this regulation is $32,380,186 ($885.92 × 35,430 reviewers on this year's proposed rule).

J. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 150 and 151 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2021 to CY 2022 based on the FY 2022 President's Budget baseline.

TABLE 150: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2022 Annualized Monetized Transfers	Estimated increase in expenditures of $2.7 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 151: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2022 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.7 billion
From Whom to Whom?	Beneficiaries to Federal Government.

K. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2021.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health insurance, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

■ 2. In § 403.902—

■ a. Amend the definition of ''Ownership or investment interest'' by adding paragraphs (3)(vi) and (vii);

■ b. Add a definition for ''Physician-owned distributorship'' in alphabetical order; and

■ c. Revise the definition of ''Short term medical supply or device loan''.

The additions and revision read as follows:

§ 403.902 Definitions.

* * * * *

Ownership or investment interest

* * *

(3) * * *

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under section 401(a) of the Internal Revenue Code of 1986.

* * * * *

Physician-owned distributorship, for the purposes of determining the existence of a reportable ownership or investment interest under this subpart, means an entity that:

(1) Meets the definition of an applicable manufacturer or applicable group purchasing organization as defined in this section, and

(2) Meets at least one of the following two conditions:

(i) Has a minimum of 5 percent direct or indirect ownership or investment interest in the applicable manufacturer or applicable group purchasing organization held by a physician or a physician's immediate family member, or

(ii) A physician or a physician's immediate family member receives compensation from the applicable manufacturer or group purchasing organization in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from the sale or distribution of devices by the applicable manufacturer or group purchasing organization in which the physician or physician's immediate family member has ownership.

(3) This physician owned distributor definition does not apply for purposes of any other laws or regulations, including, but not limited to, section 1877 of the Act, the regulations at 42 CFR part 411, subpart J, section 1128B of the Act, or the regulations at 42 CFR 1001.952.

* * * * *

Short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 cumulative days per calendar year or a quantity of 90 cumulative days of average daily use per calendar year, to permit evaluation of the device or medical supply by the covered recipient.

* * * * *

■ 3. Amend § 403.904 by adding paragraph (a)(3) to read as follows:

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) * * *

(3) An applicable manufacturer or applicable group purchasing organization that has reported payments or transfers of value under the scope of this section may not remove, delete, or alter any record/(s) unless an error is discovered in the information that had been furnished, or the record is otherwise believed to meet exceptions for reporting.

* * * * *

■ 4. Amend § 403.908 by revising paragraph (c)(3) and adding paragraph (c)(4) to read as follows:

§ 403.908 Procedures for electronic submission of reports.

* * * * *

(c) * * *

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information. These points of contact must be updated for 2 years following record submission.

(4) An applicable manufacturer or applicable group purchasing organization that meets the definition of physician-owned distributorship as defined in § 403.902 must identify its status as a physician-owned distributorship when registering or recertifying.

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 5. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 6. Amend § 405.902 by adding definitions for ''Additional documentation'', ''Additional documentation request (ADR)'', ''Post-payment medical review'', and ''Prepayment medical review'' in alphabetical order to read as follows:

§ 405.902 Definitions.

* * * * *

Additional documentation means any information requested by a contractor when conducting a prepayment review or post-payment review.

Additional documentation request (ADR) means a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review.

* * * * *

Post-payment medical review (or post-payment review) means a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate.

Prepayment medical review (or prepayment review) means a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made.

* * * * *

■ 7. Add § 405.903 to read as follows:

§ 405.903 Prepayment review.

(a) A contractor may select a claim(s) for prepayment review.

(b) In conducting a prepayment review, a contractor may issue additional documentation requests to a provider or supplier.

(1) A provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request, except as stated in paragraph (b)(2) and (c) of this section.

(2) A contractor may accept documentation received after 45-calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

(c) A provider or supplier will be provided 30 calendar days to submit additional documentation in response to a UPIC's request for additional documentation. A UPIC may accept documentation received after the 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

(d) A contractor's prepayment review will result in an initial determination under § 405.920.

■ 8. Add §§ 405.929 and 405.930 under the undesignated ceneter heading ''Initial Determinations'' in subpart I to read as follows:

§ 405.929 Post-payment review.

(a) A contractor may select a claim(s) for post-payment review, which is conducted under the reopening authority in § 405.980.

(b) In conducting a post-payment review, a contractor may issue an additional documentation request to a provider or supplier.

(1) A provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request, except as stated in paragraph (b)(2) and (c) of this section.

(2) A contractor may accept documentation received after 45 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

(c) A provider or supplier will be provided 30 calendar days to submit additional documentation in response to a UPIC's request for additional documentation. A UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

(d) The outcome of a contractor's review will result in either no change to the initial determination or a revised determination under § 405.984.

§ 405.930 Failure to respond to additional documentation request.

If a contractor gives a provider or supplier notice and time to respond to an additional documentation request and the provider or supplier does not provide the additional documentation in a timely manner, the contractor has authority to deny the claim.

■ 9. Amend § 405.986 by revising the paragraph (a) subject heading to read as follows:

§ 405.986 Good cause for reopening.

(a) *Establishing good cause for reopening.* * * *

* * * * *

■ 10. Amend § 405.2411 by—

■ a. Revising paragraph (b)(2);

■ b. Redesignating paragraph (b)(3) as (b)(4); and

■ c. Adding a new paragraph (b)(3).

The revision and addition read as follows:

§ 405.2411 Scope of benefits.

* * * * *

(b) * * *

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife or clinical psychologist employed or under contract with the RHC or FQHC at the time the services are furnished;

(3) Inclusive of hospice attending physician services, and are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant designated by the patient as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished; and

* * * * *

■ 11. Amend § 405.2446 by revising paragraph (c) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(c) FQHC services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility, other institution used as a patient's home, or are hospice attending physician services furnished during a hospice election.

* * * * *

■ 12. Amend § 405.2462—

■ a. By revising paragraphs (a) and (b);

■ b. By redesignating paragraphs (c) through (g) as paragraphs (e) through (i), respectively;

■ c. By adding new paragraphs (c) and (d); and

■ d. In newly redesignated paragraph (e) introductory text, by removing the reference ''paragraph (d)'' and adding in its place ''paragraph (f)''.

The revisions and additions read as follows:

§ 405.2462 Payment for RHC and FQHC services.

(a) *Payment to independent RHCs that are authorized to bill under the reasonable cost system.* (1) RHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate, subject to a payment limit per visit determined in paragraph (b) of this section, for each beneficiary visit for covered services. This rate is determined by the Medicare Administration Contractor (MAC), in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(b) *RHC payment limit per visit.* (1) In establishing limits on payment for rural health clinic services provided by rural health clinics the limit for services provided prior to April 1, 2021:

(i) In 1988, after March 31, at $46 per visit; and

(ii) In a subsequent year (before April 1, 2021), at the limit established for the previous year increased by the percentage increase in the Medicare Economic Index (MEI) (as defined in section 1842(i)(3) of the Act) applicable to primary care services (as defined in section 1842(i)(4) of the Act) furnished as of the first day of that year.

(2) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by rural health clinics or any rural health clinic that is enrolled on or after January 1, 2021 under section 1866(j) of the Act), the limit for services provided:

(i) In 2021, after March 31, at $100 per visit;

(ii) In 2022, at $113 per visit;

(iii) In 2023, at $126 per visit;

(iv) In 2024, at $139 per visit;

(v) In 2025, at $152 per visit;

(vi) In 2026, at $165 per visit;

(vii) In 2027, at $178 per visit; and

(viii) In 2028, at $190 per visit.

(ix) In a subsequent year, at the limit established for the previous year increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such year.

(3) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by provider-based rural health clinics as described in section (c)(4) of this part, the limit for services provided:

(i) In 2021, after March 31, at an amount equal to the greater of:

(A) For rural health clinics that had an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021, or

(*2*) The payment limit per visit applicable in paragraph (b)(2) of this section.

(B) For rural health clinics that did not have an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2021, or

(*2*) The payment limit per visit applicable in paragraph (b)(2) of this section.

(ii) In a subsequent year, at an amount equal to the greater of:

(A) The amount established under paragraph (b)(3)(i)(A) or (B) of this section, as applicable for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year, or

(B) The payment limit per visit applicable under paragraph (b)(2) of this section for such subsequent year.

(c) *Payment to provider-based RHCs that are authorized to bill under the reasonable cost system.* (1) An RHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC is—

(i) An integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(ii) Operated with other departments of the provider under common licensure, governance and professional supervision.

(2) An RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraphs (b)(1) and (2) of this section, for each beneficiary visit for covered services when in a hospital with greater than 50 beds as determined in § 412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(3) Prior to April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate and is not subject to a payment limit per visit described in paragraphs (b)(1) and (2) of this section for each beneficiary visit for covered services when in a hospital with less than 50 beds as determined in § 412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(4) On or after April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraph (b)(3) of this section, for each beneficiary visit for covered services when it meets the specified qualifications in paragraph(d) of this section. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(d) *Specified qualifications.* A provider-based rural health clinic must meet the following qualifications to have a payment limit per visit established in accordance with paragraph (b)(3) of this section.

(1) As of December 31, 2020, was in a hospital with less than 50 beds (as determined in § 412.105(b) of this subchapter) and after December 31, 2020, in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the COVID–19 Public Health Emergency (PHE)); and one of the following circumstances:

(i) As of December 31, 2020, was enrolled under section 1866(j) of the Act (including temporary enrollment during the COVID–19 PHE); or

(ii) Submitted an application for enrollment under section 1866(j) of the Act (or a request for temporary enrollment during the COVID–19 PHE) that was received not later than December 31, 2020.

(2) [Reserved]

* * * * *

■ 13. Amend § 405.2463 by revising paragraphs (a)(1)(i) introductory text and (b)(3) introductory text to read as follows:

§ 405.2463 What constitutes a visit.

(a) * * *

(1) * * *

(i) Face-to-face encounter (or, for mental health disorders only, an encounter that meets the requirements under paragraph (b)(3) of this section) between an RHC patient and one of the following:

* * * * *

(b) * * *

(3) *Visit—Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary

is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

■ 14. Amend § 405.2466 by revising paragraph (b)(1)(iv) to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iv) For RHCs and FQHCs, payment for pneumococcal, influenza, and COVID–19 vaccine and their administration is 100 percent of Medicare reasonable cost.

* * * * *

■ 15. Amend § 405.2469 by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 16. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 17. Amend § 410.33 by—

■ a. Revising paragraphs (c) and (g)(6)(i) and (ii);

■ b. Redesignating paragraphs (g)(8)(i) through (iii) as paragraphs (g)(8)(i)(A) through (C), respectively; and

■ c. Adding paragraphs (g)(8)(i) introductory text and (g)(8)(ii); and

■ d. Revising paragraph (g)(9).

The revisions and additions read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(c) *Nonphysician personnel.* (1) Except as otherwise stated in paragraph (c)(2) of this section, any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(2) For services that do not require direct or in-person beneficiary interaction, treatment, or testing, any nonphysician personnel used by the IDTF to perform the tests must meet all applicable State licensure requirements for doing so. If there are any applicable State licensure requirements, the IDTF must maintain documentation available for review that these requirements are met.

* * * * *

(g) * * *

(6) * * *

(i) Except as otherwise stated in paragraph (g)(6)(ii) of this section, have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must—

(A) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and

(B) Notify the CMS designated contractor in writing of any policy changes or cancellations.

(ii) Paragraph (g)(6)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

* * * * *

(8) * * *

(i) Except as otherwise stated in paragraph (g)(8)(ii) of this section, answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

* * * * *

(ii) Paragraph (g)(8)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

(9) Openly post these standards for review by patients and the public. (This requirement does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.)

* * * * *

■ 18. Amend § 410.37 by adding paragraph (j) to read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(j) *Expansion of coverage of colorectal cancer screening tests.* Effective January 1, 2022, colorectal cancer screening tests include a planned screening flexible sigmoidoscopy or screening colonoscopy that involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

■ 19. Amend § 410.47—

■ a. In paragraph (a), by revising the definitions of ''Individualized treatment plan'', ''Medical director'', Outcomes assessment'', ''Physician prescribed exercise'', ''Psychosocial assessment'', and ''Supervising physician'';

■ b. By revising paragraphs (b) through (e);

■ c. By removing paragraph (f); and

■ d. By redesignating paragraph (g) as paragraph (f).

The revisions read as follows:

§ 410.47 Pulmonary rehabilitation program: Conditions of coverage.

(a) * * *

Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following:

(i) A description of the individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services furnished under the plan.

(iii) The goals set for the individual under the plan.

Medical director means the physician who oversees the pulmonary rehabilitation program at a particular site.

Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes the following:

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

(ii) Objective clinical measures of exercise performance and self-reported measures of shortness of breath and behavior.

* * * * *

Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as conditioning, breathing retraining, step, and strengthening) as determined to be appropriate for individual patients by a physician.

Psychosocial assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition which includes an assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment, and psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

* * * * *

Supervising physician means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under pulmonary rehabilitation programs.

(b) *General rule*—(1) *Covered conditions.* Medicare Part B covers pulmonary rehabilitation for beneficiaries:

(i) With moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease;

(ii) Who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks;

(iii) Additional medical indications for coverage for pulmonary rehabilitation may be established through a national coverage determination (NCD).

(2) *Components.* Pulmonary rehabilitation must include all of the following:

(i) Physician-prescribed exercise during each pulmonary rehabilitation session.

(ii) Education or training that is closely and clearly related to the individual's care and treatment which is tailored to the individual's needs and assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling.

(iii) Psychosocial assessment.

(iv) Outcomes assessment.

(v) An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

(3) *Settings.* (i) Medicare Part B pays for pulmonary rehabilitation in the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have the following:

(A) A physician immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

(B) The necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and defibrillator) to treat chronic respiratory disease.

(c) *Medical director standards.* The physician responsible for a pulmonary rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(d) *Supervising physician standards.* Physicians acting as the supervising physician must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(e) *Limitations on coverage:* The number of pulmonary rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor.

* * * * *

■ 20. Amend § 410.49—

■ a. In paragraph (a), by revising the definition of ''Medical director'', revising paragraph (i) in the definition of ''Outcomes assessment'', and revising the definition of ''Physician-prescribed exercise''; and

■ b. By revising paragraphs (b)(1) introductory text, (b)(2) introductory text, (b)(2)(ii), (b)(3)(i) introductory text, (d) introductory text, (e) introductory text, and (f).

The revisions read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

(a) * * *

Medical director means the physician who oversees the cardiac rehabilitation or intensive cardiac rehabilitation program at a particular site.

Outcomes assessment * * *

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

* * * * *

Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as strengthening and stretching) as determined to be appropriate for individual patients by a physician.

* * * * *

(b) * * *

(1) *Covered conditions.* Medicare Part B covers cardiac rehabilitation and intensive cardiac rehabilitation for beneficiaries who have experienced one or more of the following:

* * * * *

(2) *Components.* Cardiac rehabilitation and intensive cardiac rehabilitation must include all of the following:

* * * * *

(ii) Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the individual's needs.

* * * * *

(3) * * *

(i) Medicare Part B pays for cardiac rehabilitation and intensive cardiac rehabilitation in the following settings:

* * * * *

(d) *Medical director standards.* The physician responsible for a cardiac rehabilitation program or intensive cardiac rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

* * * * *

(e) *Supervising physician standards.* Physicians acting as the supervising physician must possess all of the following:

* * * * *

(f) *Limitations on coverage*—(1) *Cardiac rehabilitation.* The number of cardiac rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor.

(2) *Intensive cardiac rehabilitation.* Intensive cardiac rehabilitation sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

■ 21. Amend § 410.59 by revising paragraph (a)(4)(iii)(B) and adding paragraphs (a)(4)(iv) and (v) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(4) * * *

(iii) * * *

(B) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a 15-minute (or other time interval) timed code, a portion of a unit of service separately from the part furnished by the occupational therapist such that the minutes for that portion of a service (or unit of a service) furnished by the occupational therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day when the occupational therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the occupational therapy assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the occupational therapist and occupational therapy assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes and no more than 28 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the occupational therapy assistant and one unit is billed without the prescribed modifier for the service provided by the occupational therapist.

* * * * *

■ 22. Amend § 410.60 by revising paragraph (a)(4)(iii)(B) and adding paragraphs (a)(4)(iv) and (v) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(4) * * *

(iii) * * *

(B) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a 15-minute (or other time interval) timed code, a portion of a unit of service separately from the part furnished by the physical therapist such that the minutes for that portion of a service (or unit of a service) furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day, when the physical therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the physical therapist assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the physical therapist and physical therapist assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the physical therapist assistant and one unit is billed without the prescribed modifier for the service provided by the physical therapist.

* * * * *

■ 23. Amend § 410.67—

■ a. In paragraph (b), by revising paragraphs (3) and (4) in the definition of ''Opioid use disorder treatment service'';

■ b. By revising paragraphs (d)(4)(ii) and (iii) and (d)(5); and

■ c. By adding paragraph (d)(6).

The revisions and addition read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service

* * *

(3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the therapy

services may be furnished using audio-only telephone calls if all other applicable requirements are met.

* * * * *

(d) * * *

(4) * * *

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this subchapter.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504(d) of this subchapter.

(5) Payment for medications delivered, administered or dispensed to a beneficiary as part of the bundled payment or an adjustment to the bundled payment under paragraph (d)(4)(i) of this section is considered a duplicative payment if a claim for delivery, administration or dispensing of the same medications for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. CMS will recoup the duplicative payment made to the opioid treatment program.

(6) For purposes of the adjustment to the bundled payment under paragraph (d)(4)(i)(A) of this section, after the end of the Public Health Emergency as defined in § 400.200 of this chapter, when services are furnished using audio-only technology the practitioner must certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because audio/video communication technology was not available to the beneficiary.

* * * * *

■ 24. Add § 410.72 to read as follows:

§ 410.72 Registered dietitians' and nutrition professionals' services.

(a) *Definition: Registered dietitians and nutrition professionals.* Meet the qualifications at § 410.134.

(b) *Covered registered dietitian and nutrition professional services.* Medicare Part B covers:

(1) *Coverage condition.* Medical nutrition therapy (MNT) services as defined at § 410.130 under the conditions of coverage at § 410.132.

(2) *Other services.* Registered dietitians and nutrition professionals may also provide diabetes self-management (DSMT) services if they are or represent an accredited DSMT entity and have an order from a physician or qualified nonphysician practitioner who is treating the patient's diabetic condition.

(3) *Limits on MNT and DSMT.* (i) DSMT and MNT cannot be furnished to a patient on the same date of service, and

(ii) MNT and DSMT services cannot be furnished incident to the professional services of a physician or nonphysician practitioner service.

(c) *Limitations.* The following services are not registered dietitian or nutrition professional services for purposes of billing Medicare Part B:

(1) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating hospital.

(2) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating SNF.

(3) Services furnished by a registered dietitian or nutrition professional to a patient in a Medicare-participating ESRD facility in accordance with the limitation on coverage of MNT service listed at § 410.132(b)(1).

(d) *Professional services.* Registered dietitians and nutrition professionals can be paid for professional services only when the services have been directly performed by them.

(e) *Telehealth services.* MNT and DSMT services may be provided as telehealth services (meeting the requirements in § 410.78) when registered dietitians or nutrition professionals act as distant site practitioners.

(f) *Restrictions.* The services of a registered dietitian or nutrition professional are provided on an assignment-related basis, and a registered dietitian or nutrition professional may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the registered dietitian or nutrition professional must refund the full amount of the impermissible charge to the beneficiary.

■ 25. Amend § 410.74 by revising paragraphs (a)(2)(v) and (d)(2) to read as follows:

§ 410.74 Physician assistants' services.

(a) * * *

(2) * * *

(v) Prior to January 1, 2022, furnishes services that are billed by the employer of a physician assistant; and

* * * * *

(d) * * *

(2) The services of a physician assistant are provided on an assignment-related basis, and the physician assistant may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the physician assistant must refund the full amount of the impermissible charge to the beneficiary.

* * * * *

■ 26. Amend § 410.75 by revising paragraph (e)(2) to read as follows:

§ 410.75 Nurse practitioners' services.

* * * * *

(e) * * *

(2) The services of a nurse practitioner are provided on an assignment-related basis, and the nurse practitioner may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the nurse practitioner must refund the full amount of the impermissible charge to the beneficiary.

* * * * *

■ 27. Amend § 410.76 by revising paragraph (e)(2) to read as follows:

§ 410.76 Clinical nurse specialists' services.

* * * * *

(e) * * *

(2) The services of a clinical nurse specialist are provided on an assignment-related basis, and the clinical nurse specialist may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the clinical nurse specialist must refund the full amount of the impermissible charge to the beneficiary.

* * * * *

■ 28. Amend § 410.77 by revising paragraph (d)(2) to read as follows:

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

* * * * *

(d) * * *

(2) The services of a certified nurse-midwife are provided on an assignment-related basis, and the certified nurse-midwife may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made

payment for a service in excess of these limits, the certified nurse-midwife must refund the full amount of the impermissible charge to the beneficiary.

* * * * *

■ 29. Amend 410.78 by revising paragraph (a)(3) and adding paragraphs (b)(3)(xiii) and (xiv) and (b)(4)(iv)(D) to read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means, except as otherwise provided in this paragraph, multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. For services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology. A modifier designated by CMS must be appended to the claim for services described in this paragraph to verify that these conditions have been met.

* * * * *

(b) * * *

(3) * * *

(xiii) A rural emergency hospital (as defined in section 1861(kkk)(2) of the Act), for services furnished on or after January 1, 2023.

(xiv) The home of a beneficiary for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder for services furnished on or after the first day after the end of the PHE as defined in our regulation at § 400.200 except as otherwise provided in this paragraph. Payment will not be made for a telehealth service furnished under this paragraph unless the following conditions are met:

(A) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service;

(B) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, at least once within 12 months of each subsequent telehealth service described in this paragraph, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens associated with an in-person service outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reason(s) for this decision in the patient's medical record.

(C) The requirements of paragraphs (b)(3)(xiv)(A) and (B) may be met by another physician or practitioner of the same specialty and subspecialty in the same group as the physician or practitioner who furnishes the telehealth service, if the physician or practitioner who furnishes the telehealth service described under this paragraph is not available.

(4) * * *

(iv) * * *

(D) Services furnished on or after the first day after the end of the PHE as defined in our regulation at § 400.200 for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder. Payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

* * * * *

■ 30. Amend § 410.79 by revising paragraphs (c)(1)(ii) and (e)(3)(v)(C) to read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(c) * * *

(1) * * *

(ii) An MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary:

(A) Starts his or her first core session on or before December 31, 2021;

(B) Attends at least one in-person core maintenance session during the final core maintenance session interval; and

(C) Achieves or maintains the required minimum weight loss at a minimum of one in-person core maintenance session during the final core maintenance session interval.

* * * * *

(e) * * *

(3) * * *

(v) * * *

(C) Beneficiaries who began the set of MDPP services between January 1, 2021 and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually can elect to attend ongoing maintenance sessions; and may restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record.

* * * * *

■ 31. Amend § 410.105 by revising paragraph (d)(3)(ii) and adding paragraphs (d)(3)(iii) and (iv) to read as follows:

§ 410.105 Requirements for coverage of CORF services.

* * * * *

(d) * * *

(3) * * *

(ii) Except as provided in paragraph (d)(3)(iii) of this section, furnishes a portion of a service, or in the case of a 15-minute (or other time interval) timed code, a portion of a unit of service, separately from the part furnished by the physical or occupational therapist such that the minutes for that portion of a service (or unit of a service) exceed 10 percent of the total time for that service (or unit of a service).

(iii) Paragraph (d)(3)(ii) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day when the physical or occupational therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the physical therapist assistant or occupational therapy assistant.

(iv) Where there are two remaining 15-minute units to bill of the same service and the physical therapist and the physical therapist assistant or the occupational therapist and the occupational therapy assistant, as applicable, each provided between 9 and 14 minutes, with a total time of at least 23 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the physical therapist assistant or occupational therapy assistant and one unit is billed without the prescribed modifier for the service provided by the

physical therapist or occupational therapist.

■ 32. Amend § 410.130 by revising the definition of ''Chronic renal insufficiency'' and removing the definition of ''Treating physician''.

The revision reads as follows:

§ 410.130 Definitions.

* * * * *

Chronic renal insufficiency means the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate [GFR] 15–59 ml/min/1.73m ^{2}).

* * * * *

■ 33. Amend § 410.132 by revising paragraphs (a), (b)(5), and (c) to read as follows:

§ 410.132 Medical nutrition therapy.

(a) *Conditions for coverage of MNT services.* Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by a physician.

(b) * * *

(5) An exception to the maximum number of hours in paragraphs (b)(2), (3), and (4) of this section may be made when a physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

(c) *Referrals.* Referral may only be made by a physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in this subpart with documentation noted by a referring physician in the beneficiary's medical record.

■ 34. Amend § 410.150 by revising paragraph (b)(15) to read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(15)(i) Prior to January 1, 2022, to the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies provided incident to his or her services. Payment is made to the employer of a physician assistant regardless of whether the physician assistant furnishes services under a W–2, employer-employee employment relationship, or whether the physician assistant is an independent contractor who receives a 1099 reflecting the relationship. Both types of relationships must conform to the appropriate guidelines provided by the Internal Revenue Service. A qualified employer is not a group of physician assistants that incorporate to bill for their services. Payment is made only if no facility or other provider charges or is paid any amount for services furnished by a physician assistant.

(ii) Effective on or after January 1, 2022, payment is made to a physician assistant for professional services furnished by a physician assistant in all settings in both rural and nonrural areas and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges, or is paid, any amount for the furnishing of professional services of the physician assistant.

* * * * *

■ 35. Amend § 410.152 by revising paragraphs (l) introductory text and (l)(5) to read as follows:

§ 410.152 Amounts of payment.

* * * * *

(l) *Amount of payment*: Preventive services. Except as provided otherwise in this paragraph, Medicare Part B pays 100 percent of the Medicare payment amount established under the applicable payment methodology for the service furnished by a provider or supplier for the following preventive services:

* * * * *

(5) Colorectal cancer screening tests (excluding barium enemas).

(i) For the colorectal cancer screening tests described in § 410.37(j), Medicare Part B pays at the specified percentage as follows:

(A) 80 percent for CY 2022.

(B) 85 percent for CY 2023 through 2026.

(C) 90 percent for 2027 through 2029.

(D) 100 percent beginning January 1, 2030.

(ii) [Reserved]

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 36. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 37. Amend § 411.351 by revising the definition of ''List of CPT/HCPCS Codes'' to read as follows:

§ 411.351 Definitions.

* * * * *

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually and posted on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.*

* * * * *

■ 38. Amend § 411.354 by revising paragraphs (c)(2)(ii)(A) through (C) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(c) * * *

(2)* * *

(ii) * * *

(A)(*1*) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and

(*2*) The amount of compensation that the physician (or immediate family member) receives per individual unit—

(*i*) Is not fair market value for items or services actually provided;

(*ii*) Could increase as the number or value of the physician's referrals to the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals to the entity decreases;

(*iii*) Could increase as the amount or value of the other business generated by the physician for the entity furnishing DHS increases, or could decrease as the amount or value of the other business generated by the physician for the entity furnishing DHS decreases; or

(*iv*) Is payment for the lease of office space or equipment or for the use of premises or equipment.

(B) For purposes of applying paragraph (c)(2)(ii)(A)(*2*) of this section, the individual unit is:

(*1*) Item, if the physician (or immediately family member) is compensated solely per item provided.

(*2*) Service, if the physician (or immediate family member) is compensated solely per service provided, which includes arrangements where the ''service'' provided includes both items and services.

(*3*) Time, if the conditions of paragraph (c)(2)(ii)(B)(1) or (*2*) of this section are not met.

(C) If the financial relationship between the physician (or immediate family member) and the person or entity

in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the nonownership or noninvestment interest closest to the referring physician (or immediate family member) is used to determine whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and whether the amount of compensation that the physician (or immediate family member) receives per individual unit meets the conditions in paragraph (c)(2)(ii)(A)(*2*) of this section. (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii).

* * * * *

■ 39. Amend § 411.355 by revising paragraph (h) to read as follows:

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

* * * * *

(h) *Preventive screening tests and vaccines.* (1) Preventive screening tests and vaccines that meet the following conditions:

(i) The preventive screening test or vaccine is listed on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph is applicable.

(ii) The preventive screening test or vaccine is covered by Medicare.

(iii) The preventive screening test or vaccine is subject to a CMS-mandated frequency limit.

(2) During such period as the vaccine is not subject to a CMS-mandated frequency limit, paragraph (h)(1)(iii) of this section does not apply to a COVID–19 vaccine identified on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph is applicable.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 40. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 41. Amend § 414.64 by revising paragraph (a) to read as follows:

§ 414.64 Payment for medical nutrition therapy.

(a) *Payment under the physician fee schedule.* Medicare payment for medical nutrition therapy is made under the physician fee schedule in accordance with subpart B of this part. Payment to nonphysician professionals, as specified in paragraph (b) of this section, is 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charges or 85 percent of the physician fee schedule amount.

* * * * *

■ 42. Amend § 414.84—
■ a. By revising paragraphs (b)(1)(i);
■ b. In paragraph (b)(1)(ii), by removing the reference ''CY 2018'' and adding in its place the reference ''CY 2022'';
■ c. By revising paragraph (b)(2)(i);
■ d. In paragraph (b)(2)(ii), by removing the reference CY 2018'' and adding in its place the reference ''CY 2022'';
■ e. By revising paragraph (b)(3)(i);
■ f. In paragraph (b)(3)(ii), by removing the reference ''CY 2018'' and adding in its place the reference ''CY 2022'';
■ g. By revising paragraph (b)(4)(i)(A);
■ h. In paragraph (b)(4)(i)(B), by removing the reference ''CY 2018'' and adding in its place the reference ''CY 2022'';
■ i. By revising paragraph (b)(4)(ii)(A);
■ h. In paragraph (b)(4)(ii)(B), by removing the reference ''CY 2018'' and adding in its place the reference ''CY 2022''; and
■ j. By revising paragraphs (b)(5), (b)(6)(i), (b)(7)(i) and (ii), and (c).

The revisions read as follows:

§ 414.84 Payment for MDPP Services.

* * * * *

(b) * * *

(1) * * *

(i) For a first core session furnished January 1, 2022, through December 31, 2022 the amount is $35.

* * * * *

(2) * * *

(i) For the fourth core session furnished January 1, 2022, through December 31, 2022 the amount is $105.

* * * * *

(3) * * *

(i) For the ninth core session furnished January 1, 2022, through December 31, 2022 the amount is $175.

* * * * *

(4) * * *

(i) * * *

(A) For a second core maintenance session January 1, 2022, through December 31, 2022 the amount is $93.

* * * * *

(ii) * * *

(A) For a second core maintenance session January 1, 2022, through December 31, 2022 the amount is $75.

* * * * *

(5) *Performance Goal 5: Attends two ongoing maintenance sessions and maintains the required minimum weight loss during an ongoing maintenance session interval.* For an MDPP beneficiary who attends his or her first core session on or before December 31, 2021, CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends two ongoing maintenance sessions during an ongoing maintenance session interval, achieves attendance at that second ongoing maintenance session upon attendance at an ongoing maintenance session furnished by that supplier, and achieves or maintains the required minimum weight loss as measured in-person during an ongoing maintenance session furnished during the applicable ongoing maintenance session interval. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per ongoing maintenance session interval. The amount of this performance payment is determined as follows:

(i) For a second ongoing maintenance session furnished in interval 1 (months 13–15 of the MDPP services period), January 1, 2022, through December 31, 2022, the amount is $52.

(ii) For a second ongoing maintenance session furnished in interval 2 (months 16–18 of the MDPP services period), January 1, 2022, through December 31, 2022, the amount is $52.

(iii) For a second ongoing maintenance session furnished in interval 3 (months 19–21 of the MDPP services period), January 1, 2022, through December 31, 2022, the amount is $53.

(iv) For a second ongoing maintenance session furnished in interval 4 (months 22–24 of the MDPP services period), January 1, 2022, through December 31, 2022 the amount is $53.

(v) For a second ongoing maintenance session furnished during a subsequent year. The performance payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(6) * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2022, through December 31, 2022, the amount is $169.

* * * * *

(7) * * *

(i) For a core session or core maintenance session, as applicable,

furnished January 1, 2022, through December 31, 2022, the amount is $35.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(c) *Bridge payment.* CMS makes a bridge payment to an MDPP supplier only for a core session or core maintenance session furnished to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier. An MDPP supplier that has previously been paid either a bridge payment or a performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment for that beneficiary. A bridge payment is made only on an assignment-related basis in accordance with § 424.55 of this subchapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a bridge payment only to an MDPP supplier that complies with all applicable enrollment and program requirements, and only for MDPP services furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The amount of the bridge payment is determined as follows:

(1) For core session or core maintenance session, as applicable, furnished January 1, 2022, through December 31, 2022, the amount is $35.

(2) For core session and core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2022. The bridge payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

* * * * *

■ 43. Amend § 414.626 by revising paragraphs (b)(1) and (f) to read as follows:

§ 414.626 Data reporting by ground ambulance organizations.

* * * * *

(b) * * *

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance organization must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to CMS or its contractor.

* * * * *

(f) *Public availability of data.* Beginning in 2024, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

* * * * *

■ 44. Amend § 414.802 by revising the definition of ''Drug'' to read as follows:

§ 414.802 Definitions.

* * * * *

Drug means a drug or a biological, and for purposes of applying section 1847A(f) of the Act, includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

* * * * *

■ 45. Section 414.806 is revised to read as follows:

§ 414.806 Penalties associated with misrepresentation and the failure to submit timely and accurate ASP data.

(a) *Misrepresentation.* Section 1847A(d)(4)(A) of the Act specifies the penalties associated with misrepresentations in the reporting of the manufacturer's average sales price for a drug as defined at § 414.802.

(b) *Failure to provide timely information or the submission of false information.* (1) For a manufacturer that has entered into and has in effect a rebate agreement under section 1927 of the Act, section 1927(b)(3)(C) of the Act specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

(2) For a manufacturer that has not entered into and does not have in effect a rebate agreement under section 1927 of the Act, sections 1847A(d)(4)(B) and (C) of the Act specify the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

■ 46. Amend § 414.904 by adding paragraph (d)(4) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(d) * * *

(4) *Payment adjustment for certain drugs for which there is a self-administered version*—(i) *In general.* Except as provided in paragraphs (d)(4)(ii) and (iii) of this section, if the Inspector General identifies a drug or biological product in a study described in section 1847A(g)(1) of the Act, the Secretary must apply the payment limit for the applicable billing and payment code as specified in paragraph (d)(4)(iv) of this section, beginning with the first day of the second quarter after such study is publicly available. The methodology described in this paragraph will be recalculated each quarter thereafter, except when conditions described in paragraph (d)(4)(ii) are met.

(ii) *Exception.* The adjustment described in paragraph (d)(4)(i) of this section does not apply to the payment limit for a billing and payment code for a quarter if, at the time that ASP calculations are finalized for such quarter, the drug in the dosage form described by the billing and payment code is included by the FDA on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

(iii) *Special rule for certain billing and payment codes.* Effective July 1, 2021, for a billing and payment code described under section 1847A(g)(3) of the Act, the payment limit for the applicable billing and payment code must be determined as described in paragraph (d)(4)(iv) of this section, and the exception specified at paragraph (d)(4)(ii) of this section does not apply.

(iv) *Lesser-of methodology.* For purposes of this section, the payment limit is the lesser of:

(A) The payment limit determined under section 1847A of the Act for such billing and payment code if each National Drug Code for such product so identified under section 1847A(g)(1) of the Act were excluded from such determination; and

(B) The payment limit otherwise determined under section 1847A of the Act for such billing and payment code without application of section 1847A(g) of the Act.

(v) *NDC changes.* For an Inspector General-identified National Drug Code, as described under section 1847A(g)(1) or (3) of the Act, for which the manufacturer has redesignated the National Drug Code (without changes to the dosage form), the application of the lesser-of methodology described in this paragraph must use manufacturer-reported ASP data associated with the redesignated National Drug Code in the same manner as the one originally identified by the Inspector General.

* * * * *

■ 47. Amend § 414.1300 by revising paragraphs (a)(2) and (3) to read as follows:

§ 414.1300 Basis and scope.

(a) * * *

(2) Section 1848(k)—Quality Reporting System.

(3) Section 1848(m)—Incentive Payments for Quality Reporting.

* * * * *

■ 48. Amend § 414.1305—

■ a. By revising the definitions of ''Collection type'' and ''Meaningful EHR user for MIPS'';

■ b. In the definition of ''MIPS determination period'', by revising paragraph (2);

■ c. In the definition of ''MIPS eligible clinician'', by revising the introductory text, paragraph (2) introductory text, and adding paragraph (3);

■ d. By adding the definitions of ''Multispecialty group'', ''MVP participant'', ''Population health measure'', ''QCDR measure'', ''Single specialty group'', ''Special status'' and ''Subgroup'' in alphabetical order; and

■ e. By revising the definition of ''Submission type''.

The revisions and additions read as follows:

§ 414.1305 Definitions.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey; and administrative claims measures.

(1) For the CY 2021 through CY 2024 performance periods/2023 through 2026 MIPS payment years, collection types include CMS Web Interface measures for APM Entities reporting through the APM Performance Pathway in accordance with § 414.1367.

(2) [Reserved]

* * * * *

Meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT.

* * * * *

MIPS determination period means:

* * *

(2) Subject to § 414.1310(b)(1)(iii), an individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold or as having special status, as applicable, during the first segment of the MIPS determination period will be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician, group, or APM Entity group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of such segment.

MIPS eligible clinician as identified by a unique billing TIN and NPI combination used to assess performance, means any of the following (except as excluded under § 414.1310(b)):

* * * * *

(2) For the 2021 through 2023 MIPS payment years:

* * * * *

(3) For the 2024 MIPS payment year and future years:

(i) A clinician described in paragraph (2) of this definition;

(ii) A clinical social worker (as defined in section 1861(hh)(1) of the Act);

(ii) A certified nurse midwife (as defined in section 1861(gg)(2) of the Act); and

(vii) A group that includes such clinicians.

* * * * *

Multispecialty group means a group that consists of two or more specialty types.

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

* * * * *

Population health measure means a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services.

* * * * *

QCDR measure means a quality measure that is submitted by a QCDR and approved by CMS under § 414.1400. QCDR measures consist of:

(1) Measures that are not included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year; and

(2) Measures that are included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year, but have undergone substantive changes, as determined by CMS.

* * * * *

Single specialty group means a group that consists of one specialty type.

* * * * *

Special status means that a MIPS eligible clinician:

(1) Meets the definition of an ASC-based MIPS eligible clinician, facility-based MIPS eligible clinician, hospital-based MIPS eligible clinician, non-patient facing MIPS eligible clinician, or is in a small practice; or

(2) Is located in an HPSA or rural area.

Subgroup means a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI.

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to:

(1) Direct;

(2) Log in and upload;

(3) Log in and attest;

(4) Medicare Part B claims; and

(5) CMS Web Interface (except as provided in paragraph (5)(i) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years).

(i) For the CY 2021 through CY 2024 performance periods/2023 through 2026 MIPS payment years, submission types include the CMS Web Interface for APM Entities reporting through the APM Performance Pathway in accordance with § 414.1367.

(ii) [Reserved]

* * * * *

■ 49. Amend § 414.1310 by revising paragraph (e)(1) to read as follows:

§ 414.1310 Applicability.

* * * * *

(e) * * *

(1) Except as provided under §§ 414.1315(a)(2), 414.1317(b), 414.1318(b), and 414.1370(f)(2) each MIPS eligible clinician in the group receives a final score based on the group's combined performance assessment.

* * * * *

■ 50. Amend § 414.1317 by revising paragraph (b)(2) to read as follows:

§ 414.1317 APM Entity groups.

* * * * *

(b) * * *

(2) *Performance category weights.* The cost performance category weight is zero percent of the final score for an APM Entity. The performance category reweighting scenarios under § 414.1380(c)(2) apply to an APM Entity.

* * * * *

■ 51. Section 414.1318 is added to subpart O to read as follows:

§ 414.1318 Subgroups.

(a) *Eligibility and special status*—(1) *General.* Except as provided under paragraph (a)(2) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for subgroups are determined at the group level in accordance with §§ 414.1305 and 414.1310.

(2) *Exclusions.* An individual eligible clinician or group that elects to participate in MIPS as a MIPS eligible clinician in accordance with § 414.1310(b)(1)(iii)(A) or (b)(2) is not eligible to participate in a subgroup.

(b) *Final score.* Except as provided under § 414.1317(b), each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance assessment.

(c) *Subgroup reporting requirements.* For individual eligible clinicians to participate in MIPS as a subgroup, all of the following requirements must be met:

(1) Individual eligible clinicians that elect to participate in MIPS as a subgroup must aggregate their quality and improvement activities performance data across the subgroup's identifier.

(2) Individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all the MIPS performance categories based on an MVP in accordance with § 414.1365 and on the APM Performance Pathway in accordance with § 414.1367, as applicable. Subgroups that are MVP Participants must adhere to an election process described in § 414.1365(b).

■ 52. Amend § 414.1320 by—

■ a. Redesignating paragraphs (d) through (g) as paragraphs (e) through (h), respectively; and

■ b. Adding a new paragraph (d).

The addition reads as follows:

§ 414.1320 MIPS performance period.

* * * * *

(d) For purposes of the CY 2020 performance period/2022 MIPS payment year, the performance period for:

(1) The quality and cost performance categories are the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) The improvement activities performance categories are a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

* * * * *

■ 53. Amend § 414.1325 by revising paragraph (c)(1) to read follows:

§ 414.1325 Data submission requirements.

* * * * *

(c) * * *

(1) For the quality performance category, the direct; login and upload; Medicare Part B claims (beginning with the CY 2019 MIPS performance period/2021 MIPS payment year, for small practices only); and CMS Web Interface (for groups consisting of 25 or more eligible clinicians, a third party intermediary submitting on behalf of a group) submission type.

* * * * *

■ 54. Amend § 414.1340 revising paragraphs (a)(3) and (b)(3) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(3) At least 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2022, 2023, 2024, and 2025.

* * * * *

(b) * * *

(3) At least 70 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2022, 2023, 2024, and 2025.

* * * * *

■ 55. Amend § 414.1350 by revising paragraph (c)(4) and adding paragraph (c)(6) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(c) * * *

(4) For the procedural episode-based measures specified beginning with the CY 2019 performance period/2021 MIPS payment year, the case minimum is 10, unless otherwise specified for individual measures. Beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum for Colon and Rectal Resection procedural episode-based measure is 20 episodes.

* * * * *

(6) For the chronic condition episode-based measures specified beginning with the CY 2022 performance period/2024 MIPS payment year, the case minimum is 20.

* * * * *

■ 56. Amend § 414.1360 by revising paragraph (a)(2) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(2) *Groups and virtual groups.* Beginning with the 2022 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

* * * * *

■ 57. Section 414.1365 is added to subpart O to read as follows:

§ 414.1365 MIPS Value Pathways.

(a) *General.* (1) Beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, CMS uses MVPs included in the MIPS final inventory of MVPs established by CMS through rulemaking to assess performance for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

(2) [Reserved]

(b) *MVP/Subgroup registration.* (1) To report an MVP, an MVP Participant must register for the MVP, and if applicable, as a subgroup during a period that begins on April 1 and ends on November 30 of the applicable CY performance period or a later date specified by CMS. To report the CAHPS for MIPS survey associated with an MVP, a group, subgroup or APM Entity must complete their registration by June 30 of such performance period or a later date specified by CMS.

(2) At the time of registration, the MVP Participant must submit the following information, as applicable:

(i) Each MVP Participant must select an MVP, 1 population health measure included in the MVP, and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored.

(ii) Each subgroup must submit a list of each TIN/NPI associated with the subgroup and a plain language name for the subgroup.

(c) *MVP reporting requirements*—(1) Quality. Except as provided in paragraph (c)(1)(i) of this section, an MVP Participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

(i) Paragraph (c)(1) introductory text of this section does not apply to a small practice that reports on an MVP that includes fewer than 4 Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

(ii) [Reserved]

(2) *Cost.* An MVP Participant is scored on the cost measures included in the MVP that they select and report.

(3) *Improvement activities.* An MVP Participant who reports an MVP, must report one of the following:

(i) Two medium-weighted improvement activities;

(ii) One high-weighted improvement activity;

(iii) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(4) *Foundational layer*—(i) Promoting interoperability. An MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described at § 414.1375(b).

(A) For the CY 2023 and 2024 performance periods/2025 and 2026 MIPS payment years, an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category.

(B) [Reserved]

(ii) *Population health measures.* Each MVP Participant is scored on 1 population health measure in accordance with paragraph (d)(1) of this section.

(d) *MVP scoring*—(1) General. An MVP Participant that is not an APM Entity is scored on measures and activities included in the MVP in accordance with paragraphs (d)(1) through (3) of this section. An MVP Participant that is an APM Entity is scored on measures and activities included in the MVP in accordance with § 414.1317(b).

(2) *Performance standards.* Unless otherwise indicated in this paragraph (d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP.

(3) *Performance categories.* An MVP Participant is scored under MIPS in four performance categories.

(i) *Quality performance category.* Except as provided in paragraphs (d)(3)(i)(A)(1) and (d)(3)(i)(B) of this section, the quality performance category score for MVP Participants is calculated in accordance with § 414.1380(b)(1) based on measures included in the MVP.

(A) *Population health measures.* Except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points.

(*1*) Subgroups are scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

(*2*) [Reserved]

(B) *Outcomes-based administrative claims measures.* MVP Participants receive zero measure achievement points for each selected outcomes-based administrative claims measure that does not have a benchmark or meet the case minimum requirement.

(ii) *Cost performance category.* The cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report.

(iii) *Improvement activities performance category.* The improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(iv) *Promoting interoperability performance category.* The Promoting Interoperability performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(4), except as provided in paragraph (d)(3)(iv)(A) of this section.

(A) If a subgroup does not submit its affiliated group's data for the Promoting Interoperability performance category, the subgroup will receive a score of zero for the Promoting Interoperability performance category.

(B) [Reserved]

(e) *Final score calculation.* The final score is calculated for an MVP Participant using the methodology at § 414.1380(c), unless otherwise indicated in this paragraph (e).

(1) *MVP performance category weights.* For an MVP Participant that is not an APM Entity, the final score is calculated using the performance category weights described at § 414.1380(c)(1). For an MVP Participant that is an APM Entity, the final score is calculated using the performance category weights described at § 414.1317(b).

(2) *Reweighting MVP performance categories*—(i) General reweighting. For an MVP Participant that is not an APM Entity, in accordance with paragraph (e)(2)(iii) of this section, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in the circumstances described at § 414.1380(c)(2)(i)(A)(2) through (9) and § 414.1380(c)(2)(i)(C). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b).

(ii) *Subgroups.* For an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the following circumstances independent of the affiliated group:

(A) A subgroup may submit an application to CMS demonstrating that it was subject to extreme and uncontrollable circumstances and receive reweighting in accordance with § 414.1380(c)(2)(i)(A)(6) and (c)(2)(i)(C)(2). In the event that a

subgroup submits data for a performance category, the scoring weight described at § 414.1380(c)(1) would be applied and its weight would not be redistributed.

(B) A subgroup will receive reweighting if CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for the subgroup are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the subgroup and its agents, in accordance with § 414.1380(c)(2)(i)(A)(9) and (c)(2)(i)(C)(10).

(iii) *Reweighting scenarios.* For an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in accordance with § 414.1380(c)(2)(ii). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b).

(3) *Facility-based scoring.* If an MVP Participant, that is not an APM Entity, is eligible for facility-based scoring, a facility-based score also will be calculated in accordance with § 414.1380(e).

(4) *Complex patient bonus.* A complex patient bonus will be added to the final score for an MVP Participant in accordance with § 414.1380(c)(3).

■ 58. Amend § 414.1375—
■ a. By revising paragraph (b)(2)(ii);
■ b. By revising the paragraph (b)(3) subject heading;
■ c. By revising paragraph (b)(3)(ii) introductory text; and
■ c. Adding paragraph (b)(3)(iii).

The revisions and addition read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(b) * * *

(2) * * *

(ii) Beginning with the 2021 MIPS payment year:

(A) Report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs;

(B) For each required measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion; and

(C) Beginning with the 2024 MIPS payment year, report that the MIPS eligible clinician completed the actions included in the SAFER Guides measure during the year in which the performance period occurs.

(3) *Engaging in activities related to supporting providers with the performance of CEHRT; support for health information exchange and the prevention of information blocking; actions to limit or restrict the compatibility or interoperability of CEHRT.* * * *

* * * * *

(ii) *Support for health information exchange and the prevention of information blocking.* For the 2019, 2020, 2021, 2022, and 2023 MIPS payment years, the MIPS eligible clinician must attest to CMS that he or she—

* * * * *

(iii) *Actions to limit or restrict the compatibility or interoperability of CEHRT.* Beginning with the 2024 MIPS payment year, the MIPS eligible clinician must attest to CMS that he or she—

(A) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(B) [Reserved]

■ 59. Amend § 414.1380 by—
■ a. Revising paragraphs (b)(1)(i) introductory text and(b)(1)(i)(A)(*1*);
■ b. Adding paragraphs (b)(1)(i)(A)(*3*) and (b)(1)(i)(C);
■ c. Revising paragraphs (b)(1)(iii), (b)(1)(v)(A) introductory text, and (b)(1)(v)(B) introductory text;
■ d. Adding paragraph (b)(1)(v)(B)(*1*)(*iii*);
■ e. Revising paragraphs (b)(1)(vi)(C) introductory text, (b)(1)(vi)(C)(*4*), (b)(1)(vi)(E), (b)(1)(vii) introductory text, (b)(1)(vii)(A), (b)(2)(iii) introductory text, and (b)(2)(v) introductory text;
■ f. Adding paragraphs (b)(2)(v)(A) and (B);
■ g. Revising paragraph (b)(4)(ii) introductory text and (b)(4)(ii)(C);
■ h. Revising the table in paragraph (c) introductory text;
■ i. Revising paragraph (c)(2)(i)(A)(*4*);
■ j. Removing and reserving paragraph (c)(2)(i)(A)(*5*);
■ k. Revising paragraphs (c)(2)(i)(C)(*9*), (c)(2)(ii)(A), and (c)(2)(ii)(F);
■ l. Adding paragraph (c)(2)(ii)(G); and
■ m. Revising paragraphs (c)(3) and (e)(6)(iv) through (vi).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(i) *Measure achievement points.* For the CY 2017 through 2021 performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. Except as provided under paragraph (b)(1)(i)(C) of this section, beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) for each such measure. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(A) * * *

(*1*) Except as provided in paragraphs (b)(1)(i)(A)(*2*) and (*3*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement. Beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians other than small practices receive 0 measure achievement points

for each such measure, and small practices receive 3 measure achievement points for each such measure.

* * * * *

(*3*) Beginning with the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians receive 7 measure achievement points for each submitted measure in its first year in MIPS and 5 measure achievement points for each submitted measure in its second year in MIPS that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

* * * * *

(C) *New measures.* Beginning with the CY 2023 performance period/2025 MIPS payment year, for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340, a MIPS eligible clinician receives between 7 and 10 measure achievement points (including partial points) for each such measure in its first year in MIPS and between 5 and 10 measure achievement points for each such measure in its second year in MIPS.

* * * * *

(iii) *Minimum case requirements.* Except as otherwise specified in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

(v) * * *

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures.

* * * * *

(B) *End-to-end electronic reporting.* Subject to paragraph (b)(1)(v)(B)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary.

(*1*) * * *

(*iii*) Beginning in the 2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus for submitting using end-to-end electronic reporting.

* * * * *

(vi) * * *

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category score as described in paragraph (b)(1)(vii) of this section.

* * * * *

(*4*) Beginning with the CY 2018 performance period/2020 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

* * * * *

(E) For the purpose of improvement scoring methodology, the term ''improvement percent score'' means the score that represents improvement for the purposes of calculating the quality performance category score as described in paragraph (b)(1)(vii) of this section.

* * * * *

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category score cannot exceed 100 percentage points.

(A) For each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes or errors'' means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the data submission deadline at § 414.1325(e)(1).

* * * * *

(2) * * *

(iii) The cost performance category score is the sum of the following, not to exceed 100 percent:

* * * * *

(v) A cost performance category score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(A) Beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(A), ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. Significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

(B) [Reserved]

* * * * *

(4) * * *

(ii) Beginning with the 2019 performance period/2021 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required measures and any applicable bonus scores, not to exceed 100 points.

* * * * *

(C) Each optional measure is worth five or ten bonus points, as specified by CMS.

* * * * *

(c) * * *

TABLE 1 TO PARAGRAPH (c) INTRODUCTORY TEXT

For the 2019 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)], not to exceed 100 points.
For the 2020 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.
Beginning with the 2021 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

* * * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) *For the Promoting Interoperability performance category:* (*i*) For the 2021 through 2024 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*ii*) For the 2019 through 2024 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*iii*) For the 2024 MIPS payment year, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(C) * * *

(*9*) For the 2020 MIPS payment year through the 2023 MIPS payment year the MIPS eligible clinician demonstrates through an application submitted to CMS that they are in a small practice as defined in § 414.1305, and overwhelming barriers prevent them from complying with the requirements for the Promoting Interoperability performance category. Beginning with the 2024 MIPS payment year the MIPS eligible clinician is in a small practice as defined in § 414.1305.

* * * * *

(ii) * * *

(A) For the 2019 MIPS payment year:

TABLE 2 TO PARAGRAPH (c)(2)(ii)(A)

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category score (%)	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0
Promoting Interoperability	25	0	50	25

* * * * *

(F) Except as provided in paragraph (c)(2)(ii)(G) of this section, beginning with the 2024 MIPS payment year:

TABLE 7 TO PARAGRAPH (c)(2)(ii)(F)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30

TABLE 7 TO PARAGRAPH (c)(2)(ii)(F)—Continued

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Promoting Interoperability	55	30	15	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

(G) For small practices beginning with the 2024 MIPS payment year:

TABLE 8 TO PARAGRAPH (c)(2)(ii)(G)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	40	30	30	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	50	0	50	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

* * * * *

(3) *Complex patient bonus.* For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, provided that a MIPS eligible clinician, group, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as stated in paragraphs (c)(3)(i) through (iv) of this section. Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii) of this section.

(i) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for MIPS eligible clinicians and groups, the complex patient bonus is calculated as follows: [The average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5].

(ii) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for APM Entities and virtual groups, the complex patient bonus is calculated as follows: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively, × 5].

(iii) For the 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, the complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv) of this section.

(iv) For the 2022 and 2023 MIPS payment years and associated performance periods, the complex patient bonus is calculated pursuant to paragraphs (c)(3)(i) and (ii) of this section, and the resulting numerical value is then multiplied by 2.0. The complex patient bonus cannot exceed 10.0.

(v) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM Entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. To determine the median for the respective risk indicator (HCC and dual proportion), risk indicators associated with the final score assigned to a clinician from the most recent prior performance period, for all those who have submitted data for at least one MIPS performance category or are facility-based, are used.

(vi) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific

risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(vii) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for APM Entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(viii) Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

* * * * *

(e) * * *

(6) * * *

(iv) *Quality.* The quality performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category

(v) *Cost.* The cost performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost performance category.

(A) *Other cost measures.* MIPS eligible clinicians who are scored under facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

(vi) *Use of score from facility-based measurement.* The MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology described in paragraph (e)(6) of this section unless:

(A) For the CY 2019 MIPS performance period/2021 MIPS payment year, through the CY 2021 MIPS performance period/2023 MIPS payment year, a clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

(B) Beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, a clinician or group receives a higher MIPS final score through another MIPS submission.

■ 60. Amend § 414.1395 by revising paragraph (c) to read as follows:

§ 414.1395 Public reporting.

* * * * *

(c) *New measures and activities.* (1) CMS does not publicly report any data on new quality or cost measure for the first 2 years in which it is in the program, after which CMS evaluates the measure to determine whether it is suitable for public reporting under paragraph (b) of this section.

(2) CMS does not publicly report any MVP data on new improvement activity or Promoting Interoperability measure, objective, or activity included in an MVP for the first year in which it is included in the MVP.

* * * * *

■ 61. Revise § 414.1400 to read as follows:

§ 414.1400 Third party intermediaries.

(a) *General.* (1) MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by any of the following third party intermediaries:

(i) QCDR;

(ii) Qualified registry;

(iii) Health IT vendor; or

(iv) CMS-approved survey vendor.

(2) Third party intermediary approval criteria—

(i) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(A) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(B) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(C) All data must be submitted in the form and manner specified by CMS.

(D) If the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(E) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(F) Prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan.

(ii) The determination of whether to approve an entity as a third party intermediary for a MIPS payment year may take into account:

(A) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and

(B) Whether the entity provided inaccurate information regarding the

requirements of this subpart to any eligible clinician.

(iii) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

(3) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(b) *Additional requirements for QCDRs and qualified registries*—(1) General. (i) Beginning with the CY 2021 performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories:

(A) Quality, except:

(1) The CAHPS for MIPS survey; and

(2) For qualified registries, QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless the third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4)(i) through (iii) or (c)(2)(i)(C)(1) through (7) or (c)(2)(i)(C)(9).

(ii) Beginning with the CY 2023 performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP.

(2) *Self-nomination.* For the CY 2018 and 2019 performance periods/2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR or qualified registry must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the CY 2020 performance period/2022 MIPS payment year and future years, entities seeking to qualify as a QCDR or qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR or qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the CY 2019 performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(3) *Conditions for approval.* (i) Beginning with the CY 2020 performance period/2022 MIPS payment year, the QCDR or qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) If an entity seeking to qualify as a QCDR or qualified registry uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

(iii) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the performance period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).

(iv) Beginning with the CY 2023 performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination for CMS' approval and may not change the plan once approved without the prior approval of the agency.

(v) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct annual data validation audits in accordance with this paragraph (b)(3)(v).

(A) The QCDR or qualified registry must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program.

(B) The QCDR or qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The QCDR or qualified registry must conduct data validation on data for each submitter type for which it will submit data, including MIPS eligible clinicians, groups, virtual groups, subgroups, APM entities, voluntary participants, and opt-in participants, if applicable.

(D) The QCDR or qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements:

(1) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR or qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR or qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR or qualified registry may use a sample size of 50 TIN/NPIs.

(2) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each QCDR or qualified registry data validation audit must include the following:

(1) Verification of the eligibility status of each eligible clinician, group, virtual group, subgroup, opt-in participant, and voluntary participant.

(2) Verification of the accuracy of TINs and NPIs.

(3) Calculation of reporting and performance rates.

(4) Verification that only the MIPS quality measures and QCDR measures, as applicable, that are relevant to the performance period will be used for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each data validation audit, including the overall data deficiencies or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or

error, and, how and when each deficiency or data error type was corrected.

(1) QCDRs and qualified registries must conduct validation on the data they intend to submit for the MIPS performance period and provide the results of the executed data validation plan by May 31st of the year following the performance period.

(2) [Reserved]

(vi) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with this paragraph (b)(3)(vi).

(A) If a data validation audit under paragraph (b)(3)(v) of this section identifies one or more deficiency or data error, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The QCDR or qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The QCDR or qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(3)(iv)(E) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

(vii) For the CY 2023 performance period/2025 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for any of the 2019 through 2023 MIPS payment years must submit a participation plan for CMS' approval. The participation plan must include the QCDR and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(viii) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(4) *QCDR measures for the quality performance category—(i) QCDR measure self-nomination requirements.* For the CY 2018 performance period/2020 MIPS payment year and future years, at the time of self-nomination an entity seeking to become a QCDR must submit the following information for any measure it intends to submit for the payment year.

(A) For MIPS quality measures, the entity must submit specifications including the MIPS measure IDs and specialty-specific measure sets, as applicable.

(B) For QCDR measures, the entity must submit for CMS-approval measure specifications including: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS approval of any QCDR measure specifications, the entity must publicly post the measure specifications for that QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

(ii) *QCDR measure submission requirements.* A QCDR must include the CMS-assigned QCDR measure ID when submitting data on any QCDR measure to CMS.

(iii) *QCDR measure approval criteria.* (A) QCDR measure requirements for approval are:

(*1*) QCDR measures that are beyond the measure concept phase of development.

(*2*) QCDR measures that address significant variation in performance.

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, all QCDR measures must meet face validity. To be approved for the CY 2023 performance period/2025 MIPS payment year, all QCDR measures must meet face validity for the initial MIPS payment year for which it is approved. For subsequent years after being initially approved, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

(*i*) To be included in an MVP for the CY 2022 performance period/2024 MIPS payment year and future years, a QCDR measure must be fully tested.

(*ii*) [Reserved]

(**4**) Beginning with the CY 2022 performance period/2023 MIPS payment year, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(*5*) Beginning with the CY 2020 performance period/2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

(B) QCDR measure considerations for approval include, but are not limited to:

(*1*) Measures that are outcome-based rather than clinical process measures.

(*2*) Measures that address patient safety and adverse events.

(*3*) Measures that identify appropriate use of diagnosis and therapeutics.

(**4**) Measures that address the domain of care coordination.

( ) Measures that address the domain for patient and caregiver experience.

(*6*) Measures that address efficiency, cost, and resource use.

(*7*) Beginning with the CY 2021 performance period/2023 MIPS payment year -

(*i*) That QCDRs link their QCDR measures as feasible to at least one cost measure, improvement activity, or an MVP at the time of self-nomination.

(*ii*) In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, CMS would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.

(*8*) Beginning with the CY 2020 performance period/2022 MIPS payment year CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(*9*) Greater consideration is given to measures for which QCDRs:

(i) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and

(*ii*) Utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint in the CMS Measures Management System to identify measurement gaps prior to measure development.

(*10*) Beginning with the CY 2020 performance period/2022 MIPS payment year, CMS places greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.

(*i*) Beginning with the CY 2020 performance period/2022 MIPS payment year, in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(*ii*) [Reserved]

(C) Beginning with the CY 2021 performance period/2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

(iv) *QCDR measure rejection criteria.* Beginning with the CY 2020 performance period/2022 MIPS payment year, QCDR measure rejection considerations include, but are not limited to:

(A) QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.

(B) QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.

(C) QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.

(D) QCDR measures that meet the topped out definition as described at § 414.1305.

(E) QCDR measures that are process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.

(F) Whether the QCDR measure has potential unintended consequences to a patient's care.

(G) Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

(H) QCDR measures that split a single clinical practice or action into several QCDR measures.

(I) QCDR measures that are ''check-box'' with no actionable quality action.

(J) QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.

(K) QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.

(L) QCDR measures that focus on rare events or ''never events'' in the measurement period.

(M) QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period.

(N) If a QCDR measure owner is not approved or is not in good standing, any associated QCDR measures will not be approved.

(c) *Additional requirements for Health IT vendors.* (1) Beginning with the CY 2021 performance period/2023 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:

(i) Health IT vendors that support MVPs must be able to submit data for all of the MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

(*1*) The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

(*2*) [Reserved]

(ii) Health IT vendors that do not support MVPs must be able to submit data for at least one of the MIPS performance categories described in paragraphs (c)(1)(i) of this section.

(iii) Beginning with the CY 2023 performance period/2025 MIPS payment year, Health IT vendors must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. Health IT vendors may also support the APP.

(2) [Reserved]

(d) *Additional requirements for CMS-approved survey vendors.* (1) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category.

(2) Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. For an entity to be a CMS-approved survey vendor, it must meet the following criteria:

(3) The entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

(i) At least 3 years of experience administering mixed-mode surveys (that is, surveys that employ multiple modes to collect date), including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);

(ii) At least 3 years of experience administering surveys to a Medicare population;

(iii) At least 3 years of experience administering CAHPS surveys within the past 5 years;

(iv) Experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available;

(v) Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

(vi) Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

(4) The entity has certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.

(5) The entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.

(6) The entity has submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.

(7) The entity has agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.

(8) The entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(e) *Remedial action and termination of third party intermediaries.* (1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) Require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the non-compliance.

(B) The impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program.

(C) The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.

(D) The detailed timeline for achieving compliance with the applicable requirements.

(ii) Publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(2) CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons:

(i) CMS has grounds to impose remedial action;

(ii) CMS has not received a CAP within the specified time-period or the CAP is not accepted by CMS; or

(iii) The third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

(3) Contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

(4) For purposes of this paragraph (e), CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, including but not limited to, if the submitted data:

(i) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies.

(ii) [Reserved]

(f) *Auditing of entities submitting MIPS data.* Any third party intermediary must comply with the following procedures as a condition of its qualification and approval to participate in MIPS as a third party intermediary.

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and, if available, email.

(2) The entity must retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(3) For the purposes of auditing, CMS may request any records or data retained for the purposes of MIPS for up to 6 years from the end of the MIPS performance period.

■ 62. Amend § 414.1405 by adding paragraphs (b)(9), (d)(7), and (g) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(9) Pursuant to the methodology established at paragraph (g) of this section, the performance threshold for the 2024 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

* * * * *

(d) * * *

(7) The additional performance threshold for the 2024 MIPS payment year is 89 points.

* * * * *

(g) *Performance threshold methodology.* For each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section.

■ 63. Amend § 414.1430 by—

■ a. Revising paragraph (a)(1)(iii);

■ b. Adding paragraphs (a)(1)(iv);

■ c. Removing the second occurrence of paragraph (a)(2)(ii);

■ d. Adding paragraphs (a)(2)(iii) and (iv); and

■ e. Revising paragraphs (b)(1)(i)(A) and (B) and (b)(2)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(1) * * *

(iii) 2023 and 2024: 50 percent.

(iv) 2025 and later: 75 percent.

(2) * * *

(iii) 2023 and 2024: 50 percent.

(iv) 2025 and later: 75 percent.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) 2021 through 2024: 50 percent.

(B) 2025 and later: 75 percent.

* * * * *

(2) * * *

(i) * * *

(A) 2021 through 2024: 35 percent.

(B) 2025 and later: 50 percent.

* * * * *

■ 64. Amend § 414.1450 by revising paragraph (c) introductory text to read as follows:

§ 414.1450 APM incentive payment.

* * * * *

(c) *APM Incentive Payment recipient.* CMS will pay the APM Incentive Payment amount for a payment year to a solvent TIN or TINs associated with the QP, identified based on Medicare Part B claims submitted for covered professional services during the base period or payment year, according to this section. If no TIN or TINs with which the QP has an association can be identified at a step, CMS will move to the next and successive steps listed in paragraphs (c)(1) through (8) of this section until CMS identifies a TIN or TINs with which the QP is associated, and to which CMS will make the APM

Incentive Payment. If more than one TIN is identified at a step, the payment will be proportionately divided among the TINs according to the relative total paid amounts for Part B covered professional services paid to each TIN for services provided during the base year.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 65. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 66. Section 415.140 is added to subpart D to read as follows:

§ 415.140 Conditions for payment: Split (or shared) visits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Facility setting for purposes of this section means institutional settings in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under § 410.26(b)(1) of this subchapter.

Split (or shared) visit means an evaluation and management (E/M) visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner who are in the same group, in accordance with applicable law and regulations such that the service could be could be billed by either the physician or nonphysician practitioner if furnished independently by only one of them.

Substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit, except as otherwise provided in this paragraph. For visits other than critical care visits furnished in calendar year 2022, *substantive portion* means one of the three key components (history, exam or medical decision-making) or more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit.

(b) *Conditions of payment.* For purposes of this section, the following conditions of payment apply:

(1) *Substantive portion of split (or shared) visit.* In general, payment is made to the physician or nonphysician practitioner who performs the substantive portion of the split (or shared) visit.

(2) *Medical record documentation.* Documentation in the medical record must identify the physician and nonphysician practitioner who performed the visit. The individual who performed the substantive portion of the visit (and therefore bills for the visit) must sign and date the medical record.

(3) *Claim modifier.* The designated modifier must be included on the claim to identify that the service was a split (or shared) visit.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 67. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 68. Amend § 423.160 by revising paragraph (a)(5) to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iv) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2025. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

(i) Prescriber and dispensing pharmacy are the same entity.

(ii) Prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data as of December 31st of the preceding year.

(iii) Prescriber has an NCPDP database address in the geographic area of an emergency or disaster declared by a Federal, State, or local government entity.

(iv) Prescriber has received a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances (EPCS) due to circumstances beyond the prescriber's control.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 69. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 70. Amend § 424.205 by redesignating paragraphs (b)(5) and (6) as paragraphs (b)(6) and (7), respectively, and adding new paragraph (b)(5).

The addition reads as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(b) * * *

(5) The Medicare provider enrollment application fee does not apply to all Medicare Diabetes Prevention Program (MDPP) suppliers that submit an enrollment application on or after January 1, 2022.

* * * * *

■ 71. Amend § 424.502 by revising the definition of ''Institutional provider'' to read as follows:

§ 424.502 Definitions.

* * * * *

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S, or an associated internet-based PECOS enrollment application.

* * * * *

■ 72. Amend § 424.530 by revising paragraphs (a)(2) introductory text and (a)(11)(i) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(2) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is—

* * * * *

(11) * * *

(i) A physician or other eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

* * * * *

■ 73. Amend § 424.535 by revising paragraphs (a)(2) introductory text,

(a)(8)(ii), (a)(13)(i), and (e) to read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(2) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is—

* * * * *

(8) * * *

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:

(A) The percentage of submitted claims that were denied during the period under consideration.

(B) Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

(C) The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

(D) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

* * * * *

(13) * * *

(i) A physician or other eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

* * * * *

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.

* * * * *

§ 424.545 [Amended]

■ 74. Amend § 424.545 in paragraph (b) by removing the reference ''§ 405.374'' and adding in its place the reference ''§ 424.546''.

■ 75. Add § 424.546 to read as follows:

§ 424.546 Deactivation rebuttals.

(a) *Rebuttal submittal period.* (1) If a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated under § 424.540, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS as permitted under § 424.545(b).

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (a)(1) of this section.

(b) *Rebuttal requirements.* A rebuttal submitted pursuant to this section and § 424.545(b) must:

(1) Be in writing.

(2) Specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or the effective date, and the reasons for disagreement.

(3) Submit all documentation the provider or supplier wants CMS to consider in its review of the deactivation.

(4) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(c) *Waiver of rebuttal rights.* The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (a) of this section and fully compliant with all of the requirements of paragraph (b) of this section constitutes a waiver of all rebuttal rights under this section and § 424.545(b).

(d) *CMS review.* Upon receipt of a timely and compliant deactivation rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation and/or the designated effective date are correct.

(e) *Imposition.* Nothing in this section or in § 424.545(b) requires CMS to delay the imposition of a deactivation pending the completion of the review described in paragraph (d) of this section.

(f) *Initial determination.* A determination made under this section is not an initial determination under § 498.3(b) of this chapter and therefore not appealable.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 76. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 77. Amend § 425.116 by revising paragraph (c) to read as follows:

§ 425.116 Agreements with ACO participants and ACO providers/suppliers.

* * * * *

(c) *Submission of agreements.* The ACO must submit an executed ACO participant agreement for each ACO participant that it requests to add to its list of ACO participants in accordance with § 425.118. The agreements may be submitted in the form and manner set forth in § 425.204(c)(6) or as otherwise specified by CMS.

■ 78. Amend § 425.204 by revising paragraphs (b), (c)(6), (f)(4)(ii)(A) and (B), (f)(4)(iii) introductory text, and (f)(4)(iii)(A) and adding paragraph (f)(4)(v) to read as follows:

§ 425.204 Content of the application.

* * * * *

(b) *Prior participation.* Upon request by CMS during the application cycle, the ACO must submit information regarding prior participation in the Medicare Shared Savings Program by the ACO, its ACO participants, or its ACO providers/suppliers, including such information as may be necessary for CMS to determine whether to approve an ACO's application in accordance with § 425.224(b).

(c) * * *

(6) Upon request by CMS during the application cycle or at any point during an agreement period, the ACO must submit documents demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. Upon such a request, the evidence to be submitted must include, without limitation, sample or form agreements and, in the case of ACO participant agreements, the first and signature page(s) of each executed ACO participant agreement.

CMS may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. The ACO must certify that all of its ACO participant agreements comply with the requirements of this part.

* * * * *

(f) * * *

(4) * * *

(ii) * * *

(A) One-half percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures and the number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(B) One percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(iii) CMS recalculates the ACO's repayment mechanism amount for the second and each subsequent performance year in the agreement period in accordance with paragraph (f)(4)(ii) of this section based on the certified ACO participant list for the relevant performance year, except that the number of assigned beneficiaries used in the calculations is the number of beneficiaries assigned to the ACO at the beginning of the relevant performance year under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3)(i) (for ACOs under prospective assignment).

(A) If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least $1,000,000, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount.

* * * * *

(v)(A) An ACO that established a repayment mechanism to support its participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, may elect to decrease the amount of its repayment mechanism if the repayment mechanism amount for performance year 2022, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(B) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(v). The ACO must submit such election, and revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

* * * * *

■ 79. Amend § 425.312 by revising paragraph (a)(2)(ii) and adding paragraph (a)(2)(iii) to read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) * * *

(ii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each fee-for-service beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

(iii) In the case of an ACO that has selected prospective assignment, by the ACO or ACO participant providing each prospectively assigned beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

* * * * *

■ 80. Amend § 425.400 by—

■ a. Revising paragraph (c)(1)(v) introductory text;

■ b. Adding paragraph (c)(1)(vi); and

■ c. Revising paragraphs (c)(2)(i) introductory text, (c)(2)(i)(A)(2), and (c)(2)(ii).

The revisions and addition read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(v) For the performance year starting on January 1, 2021:

* * * * *

(vi) For the performance year starting on January 1, 2022, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*9*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*10*) 99439 (code for non-complex chronic care management).

(*11*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*12*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*13*) 99495 and 99496 (codes for transitional care management services).

(*14*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 and G2252 (codes for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*13*) G2214 (code for psychiatric collaborative care model).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vi)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2)(i) Except as otherwise specified in paragraph (c)(2)(i)(A)(2) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

(A) * * *

(2) 99441, 99442, and 99443 (codes for telephone evaluation and management services). These codes are used in determining beneficiary assignment as specified in paragraphs (c)(2)(i) and (ii) of this section and until they are no longer payable under Medicare fee-for-service payment policies as specified under section 1834(m) of the Act and §§ 410.78 and 414.65 of this subchapter.

* * * * *

(ii) Except as otherwise specified in paragraph (c)(2)(i)(A)(2) of this section, the additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

■ 81. Amend § 425.512 by—

■ a. Revising paragraphs (a)(2) and (3);

■ b. Redesignating paragraph (a)(4) as paragraph (a)(5);

■ c. Adding a new paragraph (a)(4);

■ d. Revising newly redesignated paragraph (a)(5); and

■ e. Revising paragraphs (b)(2)(i) and (ii) and (b)(3)(i) and (ii).

The revisions and addition read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(2) For the first performance year of an ACO's first agreement period under the Shared Savings Program. If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter on the measures specified in this paragraph (a)(2) for the applicable performance year, the ACO will meet the quality performance standard.

(i) For performance years 2022, 2023, and 2024. The ten CMS Web Interface measures or the three eCQMs/MIPS CQMs, and the CAHPS for MIPS survey.

(ii) For performance year 2025 and subsequent performance years. The three eCQMs/MIPS CQMs and the CAHPS for MIPS survey.

(3) For performance year 2021. (i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this subchapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

(4) For performance years 2022 and 2023. (i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this subchapter according to the method of submission established by CMS and either:

(A) Achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

(B) If the ACO reports the three eCQMs/MIPS CQMs in the APP measure set, meeting the data completeness requirement at § 414.1340 of this subchapter and the case minimum requirement at § 414.1380 of this subchapter for all three eCQMs/MIPS CQMs, achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set.

(ii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

(5) For performance year 2024 and subsequent performance years. (i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this subchapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) If an ACO does not report any of the three eCQMs/MIPS CQMs and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

(b) * * *

(2) * * *

(i) For performance years 2021, 2022, and 2023, the ACO's minimum quality performance score is set to the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2024 and subsequent performance years, the ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(3) * * *

(i) For performance years 2021, 2022, and 2023, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2024 and subsequent performance years, CMS will use the higher of the ACO's quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category

scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following appendices will not appear in the Code of Federal Regulations.

BILLING CODE 4120–01–P

APPENDIX 1: MIPS QUALITY MEASURES

NOTE: Except as otherwise noted in this final rule, previously finalized measures and specialty measure sets will continue to apply for the CY 2022 performance period/2024 MIPS payment year and future years. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF # / eCQM NQF #.

TABLE Group A: New Quality Measures Finalized and Not Finalized for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

A.1. Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	481
Description:	Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.
Measure Steward:	Oregon Urology
Numerator:	Intravesical Bacillus-Calmette Guerin (BCG) instillation for initial dose or series. BCG is initiated within 6 months of the bladder cancer staging and during the measurement period.
Denominator:	All patients initially diagnosed with T1, Tis or high grade Ta non-muscle invasive bladder cancer and a qualified encounter in the measurement period.
Exclusions:	Denominator Exceptions: Unavailability of BCG Denominator Exclusions: Immunosuppressed patients, includes HIV and immunocompromised state. Immunosuppressive drug therapy. Active Tuberculosis. Mixed histology urothelial cell carcinoma including micropapillary, plasmacytoid, sarcomatoid, adenocarcinoma and squamous disease. Patients who undergo cystectomy, chemotherapy or radiation within 6 months of Bladder Cancer Staging.
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	eCQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it addresses a gap in care for patients diagnosed with bladder cancer. Treatment at this stage (non-muscle invasive) can help prevent invasion into the muscle layer which leads to potential bladder removal and additional chemotherapy and/or radiation treatment. It was reviewed by the 2016 National Quality Forum (NQF) Measure Application Partnership (MAP) with a recommendation to refine to address concerns what populations would be included or excluded from the measure. The measure was updated according to MAP feedback by redefining the eligible patient population and exclusions. The measure steward indicated that bladder cancer is ranked 10th for new cancer cases in 2020 and is the 9th leading cause of cancer death in the United States. There were an estimated 81,400 new cases in 2020 and 17,980 estimated deaths in 2020. Early detection (discovery of cancer in situ or localized to the primary site) is found in 85 percent of the patients, and with these there is a 5-year survival rate of 95.8 percent for in situ and 69.2 percent for localized. National Comprehensive Cancer Network (NCCN) Guidelines for Bladder Cancer (version 6.2020) defines intravesical Bacillus-Calmette-Guerin (BCG) as Category 1 Treatment for Ta - high grade, T1 and Tis non-muscle invasive bladder cancer. Most public data reflect prophylactic or adjuvant use of intravesical therapy with the goal of preventing recurrence or delaying progression to a higher grade or stage. Intravesical BCG has been shown to be an effective prophylaxis to prevent bladder cancer recurrences following transurethral resection of a bladder tumor (TURBT). The NCCN Bladder Cancer Panel Members recommend BCG as the preferred option over Mitomycin C for adjuvant treatment of high-grade lesions (Ta). BCG is also standard therapy for Primary Tis. Most T1 lesions are high risk and are similarly treated with adjuvant intravesical therapy with BCG being a Category 1 recommendation. (NCCN guidelines 6.2020). Based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical practice. Note: Refer to https://ecqi.healthit.gov/ecqm/ep/2022/cms646v2 for information on this measure.
We received no public comments on this new measure; therefore, we are finalizing the *Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer* measure as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

A.2. Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	482
Description:	Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.
Denominator:	All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month under the care of the same practitioner or group partner.
Exclusions:	Exclusions that are implicit in the denominator definition include: • Pediatric patients (<18 years old). • Patients on Peritoneal Dialysis for any portion of the reporting month. • Patient-months where there are more than one MCP provider listed for the month. In addition, patients with a catheter that have limited life expectancy, as defined by the following criteria are excluded: • Patients under hospice care in the current reporting month. • Patients with metastatic cancer in the past 12 months. • Patients with end stage liver disease in the past 12 months. • Patients with coma or anoxic brain injury in the past 12 months
Measure Type:	Intermediate Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We proposed this measure because it represents an intermediate outcome for maintenance hemodialysis patients and may incentivize clinicians to evaluate their vascular access with potential to reduce infection, mortality, and hospitalization rates. Long-term catheter use is associated with higher mortality rate than use of an arteriovenous fistula. The measure was evaluated by the MAP and it was conditionally supported pending NQF endorsement. While we agreed with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. The measure steward indicated, per their analysis of Consolidated Renal Operations in a Web enabled Network (CROWNWeb) data from January 2016 - December 2016, that the physician-level mean percentage of patient-months with a long-term catheter was 9.7 percent (SD=9.0 percent). Distribution: Min=0 percent, 1st quartile=4.5 percent, median=8.3 percent, 3rd quartile=12.7 percent, Max=100 percent. Reliability testing included 7,921 – 8,508 clinicians per month with moderate inter-unit reliability of 0.602 indicating that 60.2 percent of the variation in the annual long-term catheter rate can be attributed to between-practitioner differences in performance (signal) and about 39.8 percent to the within-practitioner variation (noise). Based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical practice. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

Comment: One commenter did not support this new measure and said that it had provided previous comments on this measure that the measure exclusions should be expanded to include patients for whom dialysis is part of palliative care, not only those who are receiving hospice care. The exclusions should also include patients who have had multiple previous unsuccessful attempts to establish permanent vascular access (either through placement of an arteriovenous fistula or arteriovenous graft), among other concerns.

Response: We believe this measure is important in addressing patient safety given the increased risk of blood stream infection with use of a central venous catheter, posing significant risks to patient morbidity and mortality. The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) still considers it reasonable to preferentially utilize AV access over CVC in prevalent HD patients, if possible. Additionally, KDOQI does acknowledge the patients receiving palliative care may be better served by a CVC for shorter-term dialysis, though this measure assesses numerator compliance at three months of continuous use[1] (DOI: https://doi.org/10.1053/j.ajkd.2019.12.001). Additionally, this is a respecified measure that aligns with the measure that is currently being utilized in the End Stage Renal Disease (ESRD) Quality Improvement Program (QIP), which is currently NQF endorsed. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the *Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate* measure as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

[1] KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update Charmaine E. Lok, et al. PRACTICE GUIDELINES| VOLUME 75, ISSUE 4, SUPPLEMENT 2, S1-S164, APRIL 01, 2020.

A.3. Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	483
Description:	The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive stakeholder engagement and comprehensive reviews of the literature.
Measure Steward:	The American Board of Family Medicine
Numerator:	The target population is all active patients in a practice during the performance reporting period. A patient is defined as active if the patient has had a documented interaction with the practice within 12 months of their birth month within the measurement period. The PCPCM PROM is the same for all patients, regardless of age. Because the PCPCM PROM applies to all patients and is not particular to a clinical encounter, it is administered once a year to each patient during their birth month. The target population is defined the same, regardless of unit of analysis (clinician, practice, or system). The numerator is the sum of all PCPCM PROM scores for active patients. 1. My practice makes it easy for me to get care. 2. My practice is able to provide most of my care. 3. In caring for me, my doctor considers all the factors that affect my health. 4. My practice coordinates the care I get from multiple places. 5. My doctor or practice knows me as a person. 6. My doctor and I have been through a lot together. 7. My doctor or practice stands up for me. 8. The care I get takes into account knowledge of my family. 9. The care I get in this practice is informed by knowledge of my community. 10. Over time, my practice helps me to stay healthy. 11. Over time, my practice helps me to meet my goals.
Denominator:	The denominator is the total number of complete PCPCM PROM instruments received in the reporting period. A completed PROM instrument is defined as a PROM instrument for which the patient has responded to at least 8 of 11 items. The target population is all active patients in a practice during the performance reporting period. A patient is defined as active if the patient has had a documented interaction with the practice within 12 months of their birth month during the measurement period. The PCPCM PROM is the same for all patients, regardless of age. Because the PCPCM PROM applies to all patients and is not particular to a clinical encounter, it is administered once a year to each patient during their birth month. The target population is defined the same, regardless of unit of analysis (clinician, practice, or system).
Exclusions:	None
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	For each MIPS eligible clinician, group, subgroup*, virtual group, and APM Entity, a minimum of 30 PCPCM PROM instruments per clinician are needed for submission of this measure. All valid survey results (as defined in the specification) should be included in the aggregate score. For MIPS eligible groups, subgroups*, virtual groups, and APM Entities with 5 or more clinicians, a minimum of 150 PCPCM PROM instruments per TIN for each site/location associated with the clinicians part of the group, subgroups, virtual groups, and APM Entities are needed for submission of this measure. For TINs with a composition of multiple specialty practices at one site/location, a minimum of 150 PCPCM PROM instruments per specialty practice within a TIN are needed for submission of this measure. If the MIPS eligible group, subgroup*, virtual group, and APM Entity with 5 or more clinicians encompasses multiple sites/locations, each site/location would need to meet the PCPCM PROM instruments requirements as stated. *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We proposed this measure because assessment of patient experience of care is a critical element of quality care and captures the voice of the patient which is an important component of delivering high-value primary care. There are currently a limited number of patient experience measures within the MIPS quality measure set. The original measure was evaluated by the NQF MAP and received conditional support pending NQF endorsement. While we agreed with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. Based on research of the available information presented to the MAP, evidence demonstrates a strong connection between patient experience of care and traditional health care outcomes, such as improved intermediate outcomes, greater adherence to recommended treatment, and reduced use of health care services. This measure addresses the Meaningful Measurement Area of Patient's Experience of Care and the MIPS high-priority category of Outcomes. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.
Comment: Commenters supported the addition of the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) to the MIPS program. The measure brings the patient voice front and center and is a strong, positive move in the measurement of primary care. It is a long-needed advance in the measurement of primary care that is wholistic and personal, not assessing a lab test, a fragment of care. The measure assesses patient experience and should be used across the entire health care industry. The measure provides an easy way to capture the patient experience and relationship. Several commenters preferred this new measure over measure Q321: CAHPS for MIPS Clinician/Group Survey, as it captures patient experience in care more effectively and has a lower burden and cost compared to CAHPS.	

Category	Description
This measure assesses whether the patient's needs, goals, and social systems are being considered when providing care. This measure also aligns with the Vision and Principles of a Quality Measurement Strategy for Primary Care and with the Meaningful Measures Initiative. Commenters believe this new measure addresses an area of care for which there is evidence that improvement results in improved patient outcomes. **Response:** We thank the commenters for supporting the new Patient Reported Outcome Performance Measure (PCPCM PRO-PM) in the MIPS program. **Comment:** One commenter indicated a State agency plans on using this well validated survey tool and encouraged CMS to expand the minimum case requirement as proposed. **Response:** We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. **Comment:** One commenter was supportive of PRO-PMs that are methodologically sound, and evidence based to assess, promote, and reward patient-centered care, but believes this new measure does not meet those criteria and there is a need to see additional data before it is ready for implementation. The commenter was concerned that this measure was poorly specified and did not have data to show that it would lead to improvements in care or clinical outcomes. The measure includes all patients who have completed the survey without any exclusions or risk adjustment, and this would result in a non-representative sample. Also, while the measure intends to establish a benchmark for good, comprehensive primary care, they noted the evidence that this measure will lead to improved outcomes and is actionable at the level of the individual clinician or group, has not been presented. There are no articles cited to support the actions that can be done to improve the scores on individual items. The vast majority of these interventions are at the system level. While the developer presents quite a bit of information regarding the validity and reliability of the PCPCM instrument, the commenter had a number of concerns regarding the face validity of the instrument. The commenter also expressed concerns on how the measure would work in a clinical practice when there are multiple issues to focus on during a patient visit, and therefore, is not certain the measure would apply to internal medicine. **Response:** During National Quality Forum (NQF) Measure Application Partnership (MAP) review, the measure steward indicated that case mix adjustment is being pursued to determine if it would be useful. There is a rank order difference with age, but it did not disadvantage any group. The measure steward also indicates that the measure has been tested in all types of settings among different age groups and it continues to maintain reliability and validity. The measure is validated in multiple languages and addresses the broad community. We believe assessment of patient experience of care is a critical element of quality care and captures the voice of the patient which is an important component of delivering high-value primary care. There are currently a limited number of patient experience measures within the MIPS quality measure set or for inclusion in MIPS Value Pathways (MVP). The PCPCM PRO is received once a year by active patients during the month of their birth. The measure steward indicates that this process allows the instrument to apply to the primary care experience as a whole and feedback affords the opportunity for continuous quality improvement. They also indicate that the 11 constructs assessed by the PCPCM PRO are widely hypothesized to be associated with better personal and population health, equity, quality, and sustainable health care expenditure. Therefore, we believe this measure is valid for reporting within MIPS. Fielding of the PCPCM PROM for reliability and validation was conducted both digitally and at point of care. The measure steward utilized three methods for reliability testing, and a multistep process for validity testing, which resulted in a fully tested measure. Based on the information submitted by the measure steward for this measure, the reliability and validity of the instrument are sufficient (refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650). In a recently submitted manuscript regarding the score validity and reliability of the PCPCM PROM, among 6 practices, there were significant differences (p=0.004) in PCPCM PROM scores with a moderate effect size (at least .5 standard deviation). **Comment:** One commenter opposed inclusion of this measure because the comprehensive set of patient-clinician interaction assessments within the composite measures are too burdensome for physicians and not as meaningful as intended, as stated during ongoing discussions with CMS and a medical society. Another similar commenter supported the development and implementation of PRO-PMs but believes that additional questions and work remain before their widespread use. While the reporting of this measure will be voluntary in MIPS, the commenter believes that additional research and guidance are needed on how PRO-PMs should be integrated into existing programs while minimizing any unintended consequences. **Response:** While we understand the need to reduce clinician reporting burden, we are committed to prioritizing outcome measures that are patient centered and incorporate the patient voice. We are focused on quality measurement to align with what is meaningful to patients and clinicians. **Comment:** One commenter supported the development and implementation of PRO-PMs but believes that additional questions and work remain before their widespread use, such as: the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact additional PRO-PMs may have on the reporting of well-established measures such as CG-CAHPs, and what level of data collection burden for an individual PRO-PM is acceptable for a hospital or other healthcare providers. While the reporting of this measure will be voluntary in MIPS, the commenter believes that additional research and guidance are needed on how PRO-PMs should be integrated into existing programs while minimizing any unintended consequences. **Response:** While we appreciate the commenter's concerns, as part of the Meaningful Measures Initiative we are committed to prioritizing outcome and patient reported outcome measures and measures that incorporate the patient voice. We believe this empowers patients to make the best-informed decisions about their healthcare. We also believe that by including this patient experience of care measure within the MIPS quality measure set, it provides clinicians with the opportunity to choose patient reported outcome measures that they find meaningful. **Comment:** One commenter recommended that CMS align with the CQMC's input on this measure. **Response:** We continue to make alignment across all programs a priority. While this measure may appear to be similar to the CAHPS Clinician & Group Surveys (CG-CAHPS) included in the CQMC ACO and PCMH / Primary Care Measures set, the measure steward has indicated only one question overlaps. Additionally, the measure steward indicated that CAHPS addresses patient experience, while this measure addresses the relationship with the primary care clinician or practice offering a broader scope and more meaning to both the clinician and the patient. It addresses all areas of primary care, comprehensiveness, community, access, coordination, and behavioral health. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. **Comment:** One commenter believes this measure was incomplete because it lacks fielding materials that all high-stakes surveys should have, including definitions of key terms for patients (for example, the PCPCM does not define what "my practice" or "my doctor" mean—which are the entities that the PCPCM asks patients to rate). Also, the only type of clinician referenced in the PCPCM is "my doctor," which is likely to confuse patients whose primary care clinician is a nurse practitioner. Additionally, the PCPCM has not undergone case-mix adjustment, which is critical to making valid comparisons between clinicians and practices, and this causes results to be invalid. The commenter learned that the PCPCM responses are statistically significantly associated with patient health status, age, and length of relationship with primary care provider. These findings suggest that these variables (at a minimum) be included developing case-mix adjustment for the PCPCM, before the PCPCM can be included in payment programs.	

Category	Description
	Response: There are currently a limited number of patient experience measures within the MIPS quality measure set or for inclusion in MIPS Value Pathways (MVP). This patient-reported outcome-based performance measure addresses the relationship with the primary care clinician or practices offering a broader scope and more meaning to both the clinician and the patient. The measure steward indicated that the 11 constructs assessed by the PCPCM PRO are widely hypothesized to be associated with better personal and population health, equity, quality, and sustainable health care expenditure. It addresses all areas of primary care, comprehensiveness, community, access, coordination, and behavioral health. During the NQF MAP review of the measure, the measure steward indicated that over 10,000 patient comments were utilized in development of the measure. This determined that patients use the term 'Dr.' regardless of the type of clinician seen. In addition, the measure steward indicated that case mix adjustment is being pursued to determine if it would be useful. There is a rank order difference with age, but it did not disadvantage any group. The measure steward also indicated that the measure has been tested in all types of settings among different age groups and it continues to maintain reliability and validity. The measure is validated in multiple languages and addresses the broad community. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, we are finalizing the *Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)* measure as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

A.4. Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with heart failure (HF) or cardiomyopathy.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is the number of acute cardiovascular-related admissions per 100 person-years at risk for admission during the measurement year. Time at risk is calculated as the number of days a patient is alive, from the start of the measurement period or first visit, until heart transplantation, LVAD implantation, or home inotropic therapy; enrollment in hospice; death; or the end of the measurement period. Time not considered at risk and excluded: Days spent in a hospital, SNF, or acute rehabilitation facility; 10 days following discharge from a hospital, SNF, or acute rehabilitation facility; and Time during and after LVAD implantation, home inotropic therapy, or heart transplantation. Acute cardiovascular-related admissions are defined using individual ICD-10-CM codes and the Agency for Healthcare Research and Quality's (AHRQ) Clinical Classification Software (CCS) diagnosis categories, which group clinically similar codes together. AHRQ CCS diagnosis categories used to define outcome: 55: Fluid and electrolyte disorders; 96: Heart valve disorders; 97: Peri-; endo-; and myocarditis; cardiomyopathy (except that caused by tuberculosis or sexually transmitted disease); 98: Essential hypertension; 100: Acute myocardial infarction; 102: Nonspecific chest pain; 104: Other and ill-defined heart disease; 105: Conduction disorders; 106: Cardiac dysrhythmias; 107: Cardiac arrest and ventricular fibrillation; 108: Congestive heart failure; non-hypertensive; 110: Occlusion or stenosis of precerebral arteries; 112: Transient cerebral ischemia; 115: Aortic; peripheral; and visceral artery aneurysms; 116: Aortic and peripheral arterial embolism or thrombosis; 157: Acute and unspecified renal failure; 245: Syncope. Subsets of the following AHRQ CCS diagnosis categories used to define outcome: 99: Hypertension with complications and secondary hypertension; 101: Coronary atherosclerosis and other heart disease; 103: Pulmonary heart disease; 109: Acute cerebrovascular disease; 114: Peripheral and visceral atherosclerosis; 117: Other circulatory disease; 130: Pleurisy; pneumothorax; pulmonary collapse; 131: Respiratory failure; insufficiency; arrest (adult); 133: Other lower respiratory disease; 237: Complication of device; implant or graft. The measure has several outcome exclusions: Planned admissions; Admissions from a skilled nursing facility (SNF) or acute rehab facility; Admissions within 10 days of discharge from a hospital, SNF, or acute rehab; Admissions after patient has entered hospice; Admissions before first visit to provider if no prior year visit; Admissions at time of or following: LVAD implantation, home inotropic therapy, or heart transplant.
Denominator:	The measure includes Medicare FFS beneficiaries ≥65 years of age with at least one inpatient principal diagnosis for heart failure/cardiomyopathy, or at least two outpatient or inpatient heart failure/cardiomyopathy diagnoses in any coding position (e.g., primary or secondary position) within the two years prior to the measurement year. • Beneficiaries must be enrolled full-time in Medicare Part A and B during the year prior to measurement and during the measurement period. Additionally, the cohort excludes: Patients with internalized left ventricular assist devices (LVADs); Patients with heart transplants; Patients on home inotropic therapy; Patients on hospice for any reason; Patients with end-stage renal disease (ESRD) – defined as chronic kidney disease stage 5 or on dialysis. Provider types included for measurement (vetted by TEP and Clinician Committee): Primary care providers (PCPs): CMS designates PCPs as physicians who practice internal medicine, family medicine, general medicine, or geriatric medicine, and non-physician providers, including nurse practitioners, certified clinical nurse specialists, and physician assistants; Cardiologists: Cardiologists are covered by the measure because they provide overall coordination of care for patients with HF and manage the conditions that put HF patients at risk for admission due to acute cardiovascular-related conditions. Outcome attribution: We begin by assigning each patient to the clinician most responsible for the patient's care, based on the pattern of outpatient visits with PCPs and relevant specialists. The patient can be assigned to a PCP, a cardiologist, or can be left unassigned. A patient who is eligible for attribution is assigned to a cardiologist if they have 2 or more visits with a single cardiologist, regardless of how many visits that patient has with a PCP. There are two scenarios where a patient can be assigned to a PCP. • First, if the patient has seen the PCP at least once but has no visits with a cardiologist, the patient is assigned to the PCP. • Second, if the patient has seen the PCP more than 2 or more times and has only one visit with a cardiologist, the patient is assigned to the PCP. If the patient has 1 visit each with a cardiologist and a PCP, the patient is assigned to the cardiologist. If the patient has 1 visit with a cardiologist and no visit with a PCP, the patient is assigned to the cardiologist. • Finally, the patient will be unassigned if they had no visits with a PCP or cardiologist. Patients are then assigned at the Taxpayer Identification Number (TIN) level, which includes solo clinicians and groups of clinicians who have chosen to report their quality under a common TIN. Patients "follow" their clinician to the TIN designated by the clinician (i.e. they are assigned to their clinician's TIN). Patients unassigned at the individual clinician-level, therefore, continue to be unassigned at the TIN level.
Exclusions:	Numerator Exclusions: The measure does not include the following types of admissions in the outcome because they do not reflect the quality of care provided by ambulatory care clinicians who are managing the care of HF patients: Planned admissions (utilizes the adapted planned admission algorithm (PAA) to identify and exclude admissions that are planned); Admissions that likely do not reflect the quality of heart failure management provided by ambulatory clinicians including: Admissions that occur within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility ("10-day buffer period"); Admissions that occur while patients are enrolled in Medicare's hospice benefit; Admissions that occur prior to the first visit with the assigned clinician. Admissions on the date or after any of the following: LVAD implantation, home inotropic therapy, or heart transplant (censored at the time of transition to advanced care).

Category	Description
	Denominator Exclusions: The measure excludes: 1. Patients without continuous enrollment in Medicare Parts A and B for the duration of the measurement period. 2. Patients who (or until death), were ever in hospice during the year prior to the measurement year or in hospice at the start of the measurement period. 3. Patients who have had no Evaluation & Management (E&M) visits to a MIPS eligible clinician. 4. Patients who have had a heart transplant, been on home inotropic therapy, or who have had a left ventricular assist device (LVAD) placed.
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	Administrative Claims
Measure-Specific Case Minimum/Performance Period:	MIPS eligible clinicians, groups, subgroups*, virtual groups, and APM Entities / 21 case minimum / 1 year performance period (January 1st – December 31st) *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We proposed this administrative claims outcome measure as HF is a leading cause of hospitalization in the United States and a major source of disease burden among the elderly population. Approximately 5.7 million adults in the United States have HF, costing the United States $30.7 billion each year, which includes the cost of health care services, medications for treatment, and missed days of work.[1] The toll on patients is also great, with high rates of hospitalization and mortality; nearly half of people with HF die within 5 years of their diagnosis.[2] Patients with chronic HF are vulnerable to a range of complications that may put them at risk for hospitalization, including worsening of HF symptoms and destabilization due to other conditions, such as respiratory disease or infection. To expand the list of available reporting options for clinicians, we proposed this HF measure for use in the MIPS program, as it is an administrative claims measure, which has no reporting burden. Another version of this measure specified for Accountable Care Organizations (ACOs), "Risk-standardized Acute Admission Rates for Patients with Heart Failure" (ACO-37, NQF ID 2886) was previously used in the CMS Medicare Shared Savings Program, initially for accountability and currently as an informational measure. We used the ACO-37 measure in the Shared Savings Program ACO quality measure set until 2019 and since 2019 has provided ACOs with their performance on the measure in quarterly claims-based reports for ACOs to use in quality improvement activities. The HF measure was evaluated by the NQF MAP who did not recommend for rulemaking with potential for mitigation citing NQF endorsement and an analysis of the appropriateness of the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. While we agreed with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. While the measure raises concerns that the risk adjustment may not adequately account for advanced heart failure stages, based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical practice and has provided valuable information for other programs. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.

Comment: One commenter supported this new measure in the MIPS program and its inclusion in proposed MVPs.

Response: We thank the commenter for supporting this new measure.

Comment: One commenter expressed concern that the denominator for this new measure (as well as new measure A.5) identifies provider types included for measurement. Among these provider types, physician assistants (PAs) are listed as examples of primary care providers. The commenter cautioned CMS to not assign PAs one label of provider type as PAs are generalists who work in both primary care and in specialty care. The commenter expressed concern that if PAs are categorized as one of these or another it would not be an accurate or fair depiction of the PA profession. The commenter requested that CMS be vigilant in its descriptions as to not set a precedent of identifying PAs as only primary care providers or only specialists as to result in future interpretations that may limit a PA's ability to practice or report on care they are trained and qualified to provide.

Response: We appreciate the comment that not all PAs practice as primary care providers. According to the 2020 NCCPA annual report (https://www.nccpa.net/wp-content/uploads/2021/07/Statistical-Profile-of-Certified-PAs-2020.pdf), 24.4 percent of certified PA's practice in primary care. The measure includes PAs since they are categorized by CMS as MIPS eligible providers and since they may play key roles in the management of patients with heart failure or cardiomyopathy. Non-physician practitioners may practice in primary care or in internal medicine subspecialties, including cardiology. The inclusion of PAs was vetted with the Clinician Committee during measure development, and the Committee favored including PAs for this measure. The Clinician Committee was a contractor-convened committee comprised of clinicians caring for patients in underserved and rural areas and was used to provide feedback during the measure development process on key methodological and clinical decisions.

Comment: Commenters opposed finalization of measure A.4: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System.

Key concerns cited by commenters included:

- Attribution of this measures to individual physicians or small group practices is not appropriate. Given that heart failure management benefits from close management by both the cardiologist and the primary care clinician, multiple attribution to all clinicians meeting the attribution criteria would more effectively promote team-based care and care coordination.
- Attribution of the individual provider for complex conditions and complex systems of care, including heart failure patients, is difficult to achieve and does not accurately reflect patient outcomes.
- MIPS participants would not know which patients were assigned to them until well after the reporting period ends (i.e., retrospectively), making it impossible for clinicians and practices to implement near real-time interventions.
- Attribution issues could potentially produce scores that are invalid and unreliable.
- Potential avoidance of patients that more likely to be non-adherent and the possibility of exacerbating disparities in care.
- Whether individual providers or even smaller multi-specialty practices could achieve adequate case minimums to fairly apply a population-level measure.

Category	Description
	• Low reliability minimum sample size and reliability thresholds, and the need for additional risk factors to be evaluated. • More data is needed on socioeconomic stratification and validity issues. • Conceptual language around planned admissions that may involve certain procedures such as revascularization, device implantation and ablation should potentially be carved out and categorized as episodes. • Clarity is needed around the definition of inpatient vs. outpatient providers (e.g., cardiologists). • CMS only submitted face validity testing during the recent NQF review and that should not be considered sufficient. • CMS should consider testing that demonstrates whether this measure attributed to physicians and practices is correlated to other outcome measures such as the hospital wide readmission measure (HWR) or total per capita cost (TPCC) measure. • Dual eligibility should be included in the adjustment since the results demonstrate that it is strongly predictive of an admission. • CMS continues to test social risk factors after assessment of clinical and demographic risk factors, and it is unclear why this multi-step approach is preferable. • All variables that are determined to be predictors that are outside of the control of a group should be included. **Response:** We agree that attribution is challenging, and no attribution algorithm can anticipate every pattern of care; however, CMS, the measure steward, carefully constructed this algorithm with input from a wide array of stakeholders to address as many scenarios as possible. The measure steward's contractor convened and obtained input from a Technical Expert Panel (TEP) and Clinician Committee. Feedback and guidance from the TEP including clinicians, patient advocate, and quality measure experts, as well as from a Clinician Committee comprised of professional society members and clinicians caring for patients from underserved and rural areas was sought and incorporated throughout the measure development to design an attribution algorithm that is both fair and transparent. We took into consideration that there are instances where patients with heart failure are seeing multiple providers who impact the risk of admission. An underlying premise of the approach to attribution, which was supported by the TEP and the Clinician Committee and aligned with the approach used for the multiple chronic conditions measure, is that ideally there is an individual clinician who is taking responsibility for managing and coordinating the care of a heart failure patient. This is an administrative claims measure and attribution for the measure is determined based upon the pattern of office visits with eligible clinicians, which reflect opportunities to deliver high-quality care, rather than based upon the costs of care. The patient is attributed to the individual clinician first. Then, the patient "follows" the individual clinician to the TIN level assignment. The TIN may be comprised of primary care providers, cardiologists, or it may be a multi-specialty TIN. However, the information about the composition of the TIN is not used for attribution. Non-physician practitioners may practice in primary care or in internal medicine subspecialties, including cardiology. Since the measure uses the pattern of outpatient (ambulatory) office visits to determine attribution, it automatically includes providers who see heart failure patients in these outpatient (ambulatory) settings. The measure uses these practice settings to determine which providers are eligible for the measure. In setting a minimum reliability threshold, CMS needed to balance measure reliability with the statutory requirement to make performance measures applicable to the broadest number of providers. We typically set a minimum reliability threshold of 0.4 in the MIPS program for these reasons. At the minimum reliability threshold of 0.4, the measure includes only 23.9 percent of TINs, but it does include 69.8 percent of clinicians (defined by unique NPI/TINs), 88.9 percent of patients, and 91.3 percent of the outcome. Thus, with this threshold many small-volume TINs are excluded since for them the measure would not be reliable. The NQF Admissions/Readmissions Standing Committee evaluated the measure's reliability and validity and the measure passed on both of these criteria. We test the impact of social risk factors after adjustment for demographic and clinical variables because some of the observed relationships between social risk factors and performance on quality measures may be the result of underlying differences in medical complexity, frailty, disability, and/or functional status. The use of the multi-step process allows us to determine whether the association of social risk factors with measure score is independent, or whether it is driven by these underlying and measurable differences in patient risk. This measure is adjusted for the AHRQ SES Index which captures multiple aspects of social deprivation that can impact patients' health and health outcomes, including poverty and median household income; unemployment; education; and housing value and quality. These factors are deeply rooted in societal disparities, and MIPS providers have little influence on their effect. While dual-eligible beneficiaries are likely to have fewer available health/healthcare supports, and may also have other unmeasured social risk factors (for example, low health literacy), we are not adjusting the model for dual eligibility because: adjusting for dual eligibility can mask disparities in care for dual-eligible beneficiaries, the marginal impact of including dual eligibility is attenuated after accounting for demographic, clinical, and frailty risk factors, as well as the AHRQ SES Index, clinicians may have more ability to mitigate social risk associated with dual eligibility, especially if a dual-eligible beneficiary is living in a non-socially deprived community, and TEP members supported including only the AHRQ SES Index in the model. The measure uses a risk standardized rate of cardiovascular-related unplanned hospital admissions. Planned admissions, even if costly, are not included in the measure outcome. Planned admissions are excluded from the outcome because they are unlikely to reflect the quality of ambulatory care and, as noted, may be beneficial in the long term. The measure has been recommended for endorsement by the NQF's Admissions/Readmissions Standing Committee. Although validity could be further demonstrated by testing correlation with a "gold standard" or with a quality measure focused on a similar quality domain, such a gold standard or closely related measure is not yet available. Although the Hospital Wide Readmission measure is an admission-based measure, it does not assess the quality of care for heart failure patients and is not focused on ambulatory providers. Similarly, the cost measure does not assess the quality of ambulatory care provided to heart failure patients. Therefore, this measure will not be finalized for inclusion as work will continue to address commenters' concerns with potential to propose inclusion of this measure in MIPS in future rulemaking. After consideration of the comments received, we are not finalizing the *Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System* measure at this time. We plan to continue to consider how to implement condition-specific measures such as this measure under MIPS. As with all its measures, we will conduct routine maintenance and will carefully consider all comments.

[1] Heidenreich Paul A, Trogdon Justin G, Khavjou Olga A, et al. Forecasting the Future of Cardiovascular Disease in the United States. Circulation. 2011;123(8):933-944.

[2] Mozaffarian D, Benjamin Emelia J, Go Alan S, et al. Heart Disease and Stroke Statistics—2016 Update. Circulation. 2016;133(4):e38-e360.

A.5. Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions [1]

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	484
Description:	Annual risk-standardized rate of acute, unplanned hospital admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with multiple chronic conditions (MCCs).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	"The outcome for this measure is the number of acute, unplanned hospital admissions per 100 person-years at risk for admission during the measurement period. Time Period The outcome includes inpatient admissions to an acute care hospital during the measurement year. Excluded Admissions This measure does not include the following types of admissions in the outcome because they do not reflect the quality of care provided by ambulatory care clinicians who are managing the care of MCC patients: 1. Planned hospital admissions. 2. Admissions that occur directly from a skilled nursing facility (SNF) or acute rehabilitation facility. 3. Admissions that occur within a 10-day "buffer period" of time after discharge from a hospital, SNF, or acute rehabilitation facility. 4. Admissions that occur after the patient has entered hospice. 5. Admissions related to complications from procedures or surgeries. 6. Admissions related to accidents or injuries. 7. Admissions that occur prior to the first visit with the assigned clinician or clinician group. To identify planned admissions, the measure adopted an algorithm CORE previously developed for CMS' hospital readmission measures, CMS' Planned Readmission Algorithm Version 4.0. [1,2] In brief, the algorithm uses the procedure codes and principal discharge diagnosis code on each hospital claim to identify planned admissions. A few specific, limited types of care are always considered planned (for example, major organ transplant, rehabilitation, and maintenance chemotherapy). Otherwise, a planned admission is defined as a non-acute admission for a scheduled procedure (for example, total hip replacement or cholecystectomy). Admissions for an acute illness are never considered planned. To identify complications of procedures or surgeries, we use the Agency for Healthcare Research and Quality's (AHRQ's) Clinical Classifications Software (CCS), which clusters diagnoses into clinically meaningful categories using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) or International Classification of Diseases, Tenth Revision, and Clinical Modification (ICD-10-CM) codes. We exclude the following 23 CCS categories. 1. 145: Intestinal obstruction without hernia 2. 237: Complication of device; implant or graft 3. 238: Complications of surgical procedures or medical care 4. 257: Other aftercare b) Accidents or injuries 5. 2601 E Codes: Cut/pierce 6. 2602 E Codes: Drowning/submersion 7. 2604 E Codes: Fire/burn 8. 2605 E Codes: Firearm 9. 2606 E Codes: Machinery 10. 2607 E Codes: Motor vehicle traffic (MVT) 11. 2608 E Codes: Pedal cyclist; not MVT 12. 2609 E Codes: Pedestrian; not MVT 13. 2610 E Codes: Transport; not MVT 14. 2611 E Codes: Natural/environment 15. 2612 E Codes: Overexertion 16. 2613 E Codes: Poisoning 17. 2614 E Codes: Struck by; against 18. 2615 E Codes: Suffocation 19. 2616 E Codes: Adverse effects of medical care 20. 2618 E Codes: Other specified and classifiable 21. 2619 E Codes: Other specified; NEC 22. 2620 E Codes: Unspecified 23. 2621 E Codes: Place of occurrence Person-time at risk Persons are considered at risk for hospital admission if they are alive, enrolled in Medicare FFS, and not in the hospital during the measurement period. In addition to time spent in the hospital, we also exclude from at-risk time: (1) time spent in a SNF or acute rehabilitation facility; (2) the time within 10 days following discharge from a hospital, SNF, or acute rehabilitation facility; and (3) time after entering hospice care. Citations 1. Yale New Haven Health Services Corporation – Center for Outcomes Research & Evaluation (YNHHSC/CORE). 2018 All-Cause Hospital Wide Measure Updates and Specifications Report - Hospital-Level 30-Day Risk-Standardized Readmission Measure – Version 7.0. Centers for Medicare & Medicaid Services; March 2018. 2. Horwitz L, Grady J, Cohen D, et al. Development and validation of an algorithm to identify planned readmissions from claims data. Journal of Hospital Medicine. October 2015;10(10):670-677."

Category	Description
Denominator:	"Patients included in the measure (target patient population) The cohort is comprised of patients whose combinations of chronic conditions put them at high risk of admission and whose admission rates could be lowered through better care. This definition reflects NQF's "Multiple Chronic Conditions Measurement Framework," which defines patients with MCCs as people "having two or more concurrent chronic conditions that…act together to significantly increase the complexity of management, and affect functional roles and health outcomes, compromise life expectancy, or hinder self-management." [1] The specific inclusion criteria are as follows. • Patient is alive at the start of the measurement period and has two or more of nine chronic disease groups in the year prior to the measurement period. Chronic conditions, except for diabetes, are defined using CMS' Chronic Conditions Data Warehouse (CCW). For diabetes, we used the diabetes cohort definition from the Accountable Care Organization (ACO) diabetes admission measure developed by CORE (v2018a ACO-36) as opposed to the definition used in CCW; CCW includes diagnoses for secondary and drug-induced diabetic conditions that are not the focus of the MIPS MCC admission measure. 1. Acute myocardial infarction (AMI), 2. Alzheimer's disease and related disorders or senile dementia, 3. Atrial fibrillation, 4. Chronic kidney disease (CKD), 5. Chronic obstructive pulmonary disease (COPD) or asthma, 6. Depression, 7. Diabetes, 8. Heart failure, and 9. Stroke or transient ischemic attack (TIA). • Patient is aged ≥65 years at the start of the year prior to the measurement period. • Patient is a Medicare FFS beneficiary with continuous enrollment in Medicare Parts A and B during the year prior to the measurement period. Provider types included for measurement • Primary care providers (PCPs): CMS designates PCPs as physicians who practice internal medicine, family medicine, general medicine, or geriatric medicine, and non-physician providers, including nurse practitioners, certified clinical nurse specialists, and physician assistants. • Relevant specialists: Specialists covered by the measure are limited to those who provide overall coordination of care for patients with MCCs and who manage the chronic diseases that put the MCC patients in the measure at risk of admission. These specialists were chosen with input from our Technical Expert Panel (TEP) and include cardiologists, pulmonologists, nephrologists, neurologists, endocrinologists, and hematologists/oncologists. Outcome attribution We begin by assigning each patient to the clinician most responsible for the patient's care, based on the pattern of outpatient visits with PCPs and relevant specialists. The patient can be assigned to a PCP, a relevant specialist, or can be left unassigned. • A patient who is eligible for attribution can be assigned to a relevant specialist only if the specialist has been identified as "dominant". A specialist is considered "dominant" if they have two or more visits with the patient, as well as at least two more visits than any primary care provider or other relevant specialist. • There are two scenarios where a patient can be assigned to a PCP. First, the patient must have seen at least one PCP. The patient will then be assigned to the PCP with the highest number of visits if there are no relevant specialists who are considered "dominant". Second, if the patient has had more than one visit with a relevant specialist, no "dominant" specialist has been identified, and has two or more visits with a PCP, they will be assigned to that PCP. • Finally, the patient will be unassigned if they only saw non-relevant specialists, if the patient has not seen a PCP and no "dominant" specialist can be identified, or if the patient has not had more than one visit with any individual PCP. Patients are then assigned at the Taxpayer Identification Number (TIN) level, which includes solo clinicians and groups of clinicians who have chosen to report their quality under a common TIN. • Patients "follow" their clinician to the TIN designated by the clinician (i.e. they are assigned to their clinician's TIN). Patients unassigned at the individual clinician-level, therefore, continue to be unassigned at the TIN level. Citations 1. National Quality Forum. Multiple Chronic Conditions Measurement Framework. http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71227. Accessed February 20, 2019."
Exclusions:	Denominator Exclusions: "The cohort excludes the following patients: 1) Patients without continuous enrollment in Medicare Part A or B during the measurement period. 2) Patients who were in hospice at any time during the year prior to the measurement year or at the start of the measurement year. 3) Patients who had no Evaluation & Management (E&M) visits to a MIPS-eligible clinician type. 4) Patients assigned to clinician who achieve QP status and therefore do not participate in MIPS. 5) Patients attributed to hematologists and oncologists. 6) Patients not at risk for hospitalization during the measurement year." Note: Exclusions 1-3 are applied prior to attribution, while exclusions 4-6 are applied after the attribution algorithm is run.
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	Administrative Claims

Category	Description
Measure-Specific Case Minimum/Performance Period:	MIPS eligible groups, subgroups*, virtual groups, and APM Entities with at least 16 clinicians / 18 case minimum / 1 year performance period (January 1st – December 31st) *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We proposed this risk-standardized hospital admission rate administrative claims outcome measure as patients with MCCs are at high risk for hospital admission, often for potentially preventable causes, such as exacerbation of pulmonary disease. Evidence from several Medicare demonstration projects suggests that care coordination results in decreased hospital admission rates among high-risk patients. In addition, studies have shown that the types of ambulatory care clinicians this measure targets (for example, primary care providers and specialists caring for patients with MCCs) can influence admission rates through team-based and enhanced access to care, found specifically in the patient-centered medical home (PCMH) model of interventions, and broadly through increased primary care supply and continuity of care. To expand the list of available reporting options for clinicians, we proposed the MCC measure for use in the MIPS program, as it is an administrative claims measure, which has no reporting burden. This measure was evaluated by the NQF MAP in 2019, who did not support for rulemaking with potential for mitigation, including applying the measure to clinician groups, not to individual clinicians, a higher reliability threshold (e.g., 0.7; 3), consideration of patient preference and selection as a method of attribution and NQF endorsement. While we agreed with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. This measure has been submitted for endorsement as part of the fall 2020 NQF cycle. The measure developer indicated the measure will be used for clinician group reporting with a mean reliability score for groups of >15 clinicians with at least 18 MCC patients at 0.873. While the developer indicated that the patient attestation is not yet available for testing, based on research of the available information presented at the MAP, we believe the measure is evidence-based and represents an important clinical practice addressing a large Medicare patient population. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

Comment: One commenter supported this new measure in the MIPS program.

Response: We thank the commenter for supporting this new measure.

Comment: Several commenters did not support measure A.4: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions.

Key concerns cited by commenters included:

- Less than desirable reliability thresholds and intraclass correlation coefficients for the minimum sample size/case volume
- Lack of inclusion of socioeconomic risk factors in the risk adjustment model, the adequacy of the risk adjustment model, and that dual eligibility should be included in the risk adjustment model.
- Population health measurement faces numerous challenges, including its concept and definition, reliability and validity, data collection and analysis, and accountability.
- CMS should select either this new measure or continue to pursue the individual condition-based measures rather than include both measures in MIPS, and this measure should not be included as a foundational layer to the program and/or a requirement.
- Lack of evidence to support attributing this measure to practices as evidenced from the NQF involved multiple partners such as a disease management program, health system, and/or hospital.
- Insufficient evidence to apply this measure at the TIN level to support that physicians or practices, in the absence of some coordinated program or payment offset (for example, care management fee), can implement structures or processes that can lead to improved outcomes for these patients. Attribution is also assigned retrospectively.
- Concern that PAs, NPs, and other mid-level providers could be attributed this measure, even if they do not practice in the measured specialties (primary care, cardiology, pulmonology, nephrology, neurology, endocrinology, and hematology/oncology).
- The minimum sample size and reliability threshold remain too low.
- Additional information on the validity of the measure is needed when applied at these levels is needed.
- CMS must ensure that data yields accurate scores.
- Concern related to unplanned admissions.
- Insufficient face validity.

Response: We have addressed the concerns raised on this measure with the measure developer.

- The intent of the MIPS MCC measure is to evaluate performance at the clinician group level so that the group can improve care quality across their practice. We will use the measure for clinician groups of >15 providers with at least 18 MCC patients, aligned with its minimum reliability threshold of 0.4. In setting a minimum reliability threshold, CMS, the measure steward, needed to balance measure reliability with the statutory requirement to make performance measures applicable to the broadest number of providers. However, when the measure is applied to groups of >15 clinicians with at least 18 MCC patients, the mean reliability is 0.873, greatly exceeding this minimum threshold. Beyond care coordination, evidence suggests that greater continuity of care and care comprehensiveness can reduce acute admissions[2]. Hospital admissions which do not reflect the quality of ambulatory care are excluded from the measure outcome (for example, admissions due to accidents or planned admissions). The measure is designed to mitigate concerns about use of retrospective attribution: admissions that occur prior to an initial visit to the clinician are not counted in the outcome and attribution is based on performance year to ensure that providers are not held responsible for patients who do not seek care from them during the measurement year.

We have carefully considered adjustment for social risk factors and this measure is adjusted for AHRQ SES Index and specialist density. While dual-eligible beneficiaries are likely to have fewer available health/healthcare supports and may also have other unmeasured social risk factors (for example, low health literacy), we are not adjusting the model for dual eligibility for several reasons: adjusting for dual eligibility can mask disparities in care for dual-eligible beneficiaries; the marginal impact of including dual eligibility is attenuated after accounting for demographic, clinical, and frailty risk factors, and the AHRQ SES Index and specialist density social risk factors; clinicians may have more ability to mitigate social risk associated with dual eligibility,

Category	Description
	especially if a dual-eligible beneficiary is living in a non-socially deprived community; and TEP members supported including only the AHRQ SES Index and specialist density social risk factors in the model. Finally, this measure was evaluated and endorsed as specified by the NQF. With respect to validity, the measure steward's contractor convened a national Technical Expert Panel (TEP) to seek detailed input from clinicians, patient advocates, and other stakeholders. The TEP guided the development of the attribution algorithm and supported its final version. Administrative data do not allow for the identification of the specialty areas of NPs, PAs, or other non-physician clinicians; these clinicians are included because they play key roles in primary care and specialty practice. Condition-specific measures focus on a narrow cohort, a narrow set of condition-specific outcomes, and a narrow set of providers who primarily manage the patient cohort. In contrast, the MIPS MCC measure is designed to capture a broad set of outcomes reflective of care quality for these complex patients. After consideration of public comments, we are finalizing the *Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions* measure as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

[1] This quality measure is a Population Health measure.

[2] Bazemore, A., et al. (2018). "Higher Primary Care Physician Continuity is Associated With Lower Costs and Hospitalizations." *Ann Fam Med.* 16(6): 492-497. O'Malley, A. S., et al. (2019). "New approaches to measuring the comprehensiveness of primary care physicians." *Health Serv Res.* 54(2): 356-366.

[3] Martsolf GR, Barnes H, Richards MR, Ray KN, Brom HM, McHugh MD. Employment of Advanced Practice Clinicians in Physician Practices. *JAMA Intern Med.* 2018;178(7):988-990.

TABLE Group AA: COVID-19 Vaccination by Clinicians

In addition to the new quality measures in Table Group A, we solicited comments on one quality measure for potential future inclusion within MIPS. We refer readers to the CY 2022 PFS proposed rule for our request for information pertaining to the COVID-19 Vaccination by Clinicians measure specifications (86 FR 39393 through 39394; and for reference, available in section IV.A.3.d.(1)(f) of this final rule. Please note that we inadvertently referred to the vaccine as "SARS-CoV-2" and not "COVID-19" throughout Table AA.1 in the CY 2022 PFS proposed rule (86 FR 39603). In order to correctly refer to the vaccine in this final rule, we have updated the references to the vaccine to reflect "COVID-19" throughout Table AA.1.

AA.1. COVID Vaccination by Clinicians

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older seen for a visit during the measurement period who have received a COVID-19 vaccination dose OR completed a COVID-19 vaccination series.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Patients who have received a COVID-19 vaccination dose OR completed a COVID-19 vaccination series.
Denominator:	All patients aged 18 years and older seen for a visit during the measurement period.
Exclusions:	Patient received hospice services any time during the measurement period. Exceptions: 1. COVID-19 vaccine dose or full COVID-19 vaccination series was not administered, as documented by clinician, due to patient contraindication. 2. COVID-19 vaccine dose or full COVID-19 vaccination series was not administered, as documented by clinician, due to patient refusal. 3. COVID-19 vaccine dose or full COVID-19 vaccination series was not administered, as documented by clinician, due to vaccine being unavailable.
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We solicited comment on this measure as it represents a promising effort to advance measurement of vaccination for an evolving pandemic. On December 19, 2020, the Advisory Committee on Immunization Practice (ACIP) made an interim recommendation on the use of the Moderna COVID-19 vaccine for people ages 18 and older. Earlier that month, on December 12, ACIP also granted use of the Pfizer-BioNTech COVID-19 vaccine for people ages 16 and older, as an interim recommendation. The benefits of both vaccines were classified as high certainty (Type 1) based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) evidence assessment. On February 28, 2021, ACIP issued an interim recommendation for use of the Janssen COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19. The benefit for this single dose vaccine was classified as moderate certainty (Type 2) based on the GRADE evidence assessment. Future versions of the measure will be updated as more evidence and guidelines emerge. This measure would add value to the MIPS quality measure set by providing visibility into an important intervention to limit COVID-19 infections. In addition, collecting information on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination coverage and providing feedback to clinicians, will facilitate performance benchmarking and drive quality improvement. Vaccination coverage will reduce transmission of COVID-19 and the associated mortality and morbidity. This measure was reviewed by the NQF MAP, who recommended conditional support for future rulemaking contingent on us bringing the measure back to MAP once the specifications are further refined. We are considering an expedited process for this measure recognizing the importance of a vaccine during a public health emergency and are exploring the inclusion of pediatric hospitals within this COVID-19 vaccination measure. Based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical topic. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.
While we are not summarizing or responding to specific comments submitted in response to the Request for Information regarding the draft COVID-19 Vaccination by Clinicians measure specifications in this final rule, we thank commenters for the feedback received. We may consider such information to inform future rulemaking.	

TABLE Group B: New Specialty Measures Set Finalized for Addition and Modifications to Previously Finalized Specialty Measures Sets Finalized for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

We proposed to add one new specialty measures set: Certified Nurse Midwife. This set is finalized to be added based in part on the finalized expanded definition of the MIPS eligible clinician to include certified nurse midwife under section IV.A.3.a of this final rule. Note: Clinical Social Work is also finalized as a MIPS eligible clinician type under section IV.A.3.a of this final rule. See Table B.7 for the finalized changes to the previously finalized Clinical Social Work specialty set.

We proposed to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, proposed the addition of new measures for inclusion in MIPS, and considered the feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table Group B as follows: NQF # / eCQM NQF #.

NOTE:

- In the instance a title and/or measure description had a substantive change finalized in Table Group D, the revised title and/or measure description is reflected in the specialty measure sets located in Table Group B.
- Under Table Group B, we respond to comments that are related to new measures that were proposed for addition to measure sets, and measures that were proposed for removal. Any comments received on previously finalized measures are out of scope and not included in this final rule. Commenters who requested additions or removals of quality measures to specific specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these updates must be proposed through rulemaking.
- Measures that were not finalized for removal in this final rule have been added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for their retention is addressed under Table Group C. For some specialty sets, this resulted in the Removal Table being removed in its entirety in this final rule if no measures proposed for removal were finalized for removal. The Removal Tables were removed from the following specialty sets: Cardiology, Emergency Medicine, Gastroenterology, Nephrology, Radiation Oncology, Ophthalmology, Rheumatology, and Urgent Care.

The definition of high priority at §414.1305 includes an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

It should be noted that in the 2021 PFS final rule (85 FR 84870), the CMS Web Interface measures as a collection type would have sunset starting with the CY 2022 performance period; however, in section IV.A.3.d.(1)(d) of this final rule, we finalized to extend the availability of the CMS Web Interface measures as a collection type for the CY 2022 performance period (CY 2024 for APM Entities reporting through the APM Performance Pathway) and sunset the CMS Web Interface measures starting with the CY 2023 performance period (CY 2025 for APM Entities reporting through the APM Performance Pathway). Therefore, we proposed to modify the CMS Web Interface Measure Specifications collection type as outlined in the applicable measures within the B tables. In conjunction with soliciting public comments to extend the availability of the CMS Web Interface measures as a collection type, we solicited public comment on the modifications proposed for the CMS Web Interface Measure Specifications collection type given that the CMS Web Interface Measure Specifications collection type has generally remained the same for three consecutive (CY 2019, CY 2020, and CY 2021) performance periods.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma**: The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Allergy/Immunology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE ANESTHESIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Anesthesiology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE AUDIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Audiology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communicati on and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation
§ ! (Efficiency)	N/A / N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology Foundation
! (Efficiency)	N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, we solicited comments on applicable measures for a Certified Nurse Midwife specialty set, which takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures because Certified Nurse Midwife is finalized for inclusion in the definition of a MIPS eligible clinician type.

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR ADDITION TO THE CERTIFIED NURSE MIDWIFE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028 / 0028e	226	CMS138v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.

B.5. Certified Nurse Midwife

MEASURES FINALIZED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention	We proposed to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
We received no comments on this proposed measure set; therefore, we are finalizing the new *Certified Nurse Midwife Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient- reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association / American Academy of Neurology

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association /American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS177v10	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v10	eCQM Specifications	Outcome	Community /Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v11	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.9. Dermatology

MEASURES FINALIZED FOR **ADDITION** TO THE DERMATOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A/ N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We proposed to include this measure in the Dermatology specialty set as it is clinically relevant to this clinician type. Previous stakeholder feedback resulted in an expanded list of acceptable medications, proposed in Table D.20, which now cover the broader dermatological patient population. With this expansion, and the clinical relevance to this clinician type, we proposed to add to the Dermatology specialty set.
We received no public comments on the measure proposed for addition to this specialty set; therefore, we are finalizing the above measure for addition to the *Dermatology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE DERMATOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Dermatology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Care Coordination)	N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ National Committee for Quality Assurance

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE DIAGNOSTIC RADIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0507/ N/A	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0509/ N/A	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

After consideration of public comments, we are finalizing the above measures for removal from the *Diagnostic Radiology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	N/A / 0104e	107	CMS161v10	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
*	N/A / N/A	254	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A / N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS645v5	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
*	N/A / N/A	009	CMS128v10	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	N/A / 0104e	107	CMS161v10	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
* ! (Opioid)	N/A / N/A	305	CMS137v10	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v10	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v4	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive stakeholder engagement and comprehensive reviews of the literature.	The American Board of Family Medicine	We proposed to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. This measure assesses the element of patient experience in care quality within the broad scope of primary care. Capturing the voice of the patient is an important component of delivering high-value primary care which is a focus of family medicine. Therefore, given the expansive purview of this specialty and applicability of this component in improving patient care, we proposed the inclusion of this measure within the Family Medicine specialty set. See Table A.3 for rationale.
Comment: One commenter supported inclusion of the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) in the Family Medicine set. **Response:** We thank the commenter for supporting the new Patient Reported Outcome Performance Measure (PCPCM PRO-PM) in the Family Medicine set. After consideration of public comments, we are finalizing the above measure for addition to the *Family Medicine Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE FAMILY MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Family Medicine Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
§	N/A / N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A/ N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	425	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association

B.15 General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
*	N/A / N/A	317	CMS22 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE GENERAL SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE GENERAL SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *General Surgery Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159 v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
§ ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
* ! (Outcome)	N/A / N/A	476	CMS771 v3	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE GERIATRICS SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GERIATRICS SET								
ote: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality easure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
QF # / CQM QF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

omment: One commenter stated that the removal of measure Q154: Falls: Risk Assessment would have a detrimental impact on the geriatric population. As an ternative or in addition to measure Q154, the commenter requested that CMS include measure Q318, Falls: Screening for Future Fall Risk in the Geriatrics set. Should easure Q318 also become topped out, the commenter believed this would suggest the need to develop a more rigorous measure of falls risk assessment.

esponse: We agree that falls prevention is an extremely important concept for this patient population and the Geriatric Specialty Set. The removal of measure Q154 does ot preclude clinicians in completing these tasks, however, by removing measures with high performance rates, we are attempting to reduce reporting burden where there little room for improvement. The performance for measure Q154 has an extremely high and unvarying performance rate. This does not allow meaningful benchmarks to e established. In addition, prior to rulemaking we solicit feedback from stakeholders with regards to measures that should be added to or removed from existing specialty ts as well as the development of new specialty sets. We encourage the commenter to submit this comment during the Solicitation for Specialty Sets for potential nplementation in future years. Lastly, we also encourage the commenter to reach out to measure developers/stewards to develop a more rigorous falls risk assessment easure for submission to the Call for Measures for possible future implementation.

fter consideration of public comments, we are finalizing the above measure for removal from the *Geriatrics Specialty Measure Set* as proposed for the CY 2022 erformance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) r any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v10	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery
	N/A / 0104e	107	CMS161v10	eCQM Measure Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Opioid)	N/A / N/A	305	CMS137v10	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v10	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v4	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	483	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive stakeholder engagement and comprehensive reviews of the literature.	The American Board of Family Medicine	We proposed to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. This measure assesses the element of patient experience in care quality within the broad scope of primary care. Capturing the voice of the patient is an important component of delivering high-value primary care which is a focus of internal medicine. Therefore, given the expansive purview of this specialty and applicability of this component in improving patient care, we proposed the inclusion of this measure within the Internal Medicine specialty set. See Table A.3 for rationale.

Comment: One commenter supported inclusion of the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) in the Internal Medicine set.

Response: We thank the commenter for supporting the new Patient Reported Outcome Performance Measure (PCPCM PRO-PM) in the Internal Medicine set.

After consideration of public comments, we are finalizing the above measure for addition to the *Internal Medicine Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERNAL MEDICINE SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

After consideration of public comments, we are finalizing the above measures for removal from the *Internal Medicine Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	MIPS CQMs Specifications, eCQM Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.21. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Mental/Behavioral Health specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v10	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
	N/A/ / 0104e	107	CMS161v10	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	366	CMS136v11	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS177v10	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication / Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE MENTAL/BEHAVIORAL HEALTH SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	This measure was proposed for removal from this specialty set beginning with the 2024 MIPS payment year. Specialty specific coding was not added to this quality measure for the 2022 performance period. In addition, the measure's limited existing mental/behavioral health coding has resulted in limited submissions of this measure historically. Therefore, this measure has minimal eligibility for this clinician type, and we proposed to remove it.
We received no public comments on removing measure Q374 from this specialty set; therefore, we are finalizing the above measure for removal from the *Mental/Behavioral Health Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for all Patients:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. Given the high rates that patients with kidney diseases are treated and managed within this specialty, we recommended the inclusion of this measure in the Nephrology specialty set. See Table A.2 for rationale.
Comment: One commenter did not support the inclusion of the new measure: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate in the Nephrology specialty set. See full comment under Table A.2. **Response**: Currently, the Nephrology Specialty Measure Set contains 11 measures allowing clinicians to choose to submit those measures that are meaningful to their scope of care. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. In addition, we encourage the commenter to submit this comment during the Solicitation for Specialty Sets for potential implementation in future years. See full response under Table A.2. After consideration of public comments, we are finalizing the above measure for addition to the *Nephrology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE NEUROLOGY SET								
Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Neurology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROSURGICAL SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

After consideration of public comments, we are finalizing the above measures for removal from the *Neurosurgical Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	239	CMS155v10	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

MEASURES FINALIZED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	0417/ N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation**: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We proposed to include this measure in the Nutrition/ Dietician specialty set as it is clinically relevant to this clinician type. Based on previous stakeholder feedback, many registered dietitians who are Medicare providers are certified diabetes educators, so these services will be very appropriate for them to perform and report on. As such, we agreed with the feedback and proposed to add to the Nutrition/Dietician specialty set.
	0416/ N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear**: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association	We proposed to include this measure in the Nutrition/ Dietician specialty set as it is clinically relevant to this clinician type. Based on previous stakeholder feedback, many registered dietitians who are Medicare providers are certified diabetes educators, so these services will be very appropriate for them to perform and report on. As such, we agreed with the feedback and proposed to add to the Nutrition/Dietician specialty set.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the above measures for addition to the *Nutrition/Dietician Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NUTRITION/DIETICIAN SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	This measure was proposed for removal from this specialty set beginning with the 2024 MIPS payment year. Nutrition/ Dietician specialty specific coding was not finalized for inclusion for the 2022 performance period. Therefore, we proposed to remove the measure from the Nutrition/Dietician specialty set as it is no longer relevant to this specialty.
After consideration of public comments, we are finalizing the above measure for removal from the *Nutrition/Dietician Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	309	CMS124v10	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v10	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v4	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Obstetrics/Gynecology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
*	0041 / 0041e	110	CMS147 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
* §	0028 / 0028e	226	CMS138 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology
§	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS645 v5	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE ONCOLOGY/HEMATOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	067	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Society of Hematology	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	070	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry**: Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	American Society of Hematology	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Oncology/Hematology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0086 / 0086e	012	CMS143v 10	eCQM Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Academy of Ophthalmology
*	0087 / N/A	014	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology
! (Care Coordiantion)	N/A / N/A	019	CMS142v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v10	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.29. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS13 8v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	375	CMS66 v10	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v10	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Orthopedic Surgery Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.30. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications. CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Otolaryngology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.31. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.32. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS 154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS 146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS 147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
* §	N/A / N/A	239	CMS 155v10	eCQM Specifications	Process	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS 117v10	eCQM Specifications	Process	Community/ Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	305	CMS 137v10	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	310	CMS 153v10	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	366	CMS 136v11	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS 159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	N/A / N/A	379	CMS 74v11	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / 1365e	382	CMS 177v10	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* § ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication /Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PEDIATRICS SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Pediatrics Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.33. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PHYSICAL MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101/ N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Physical Medicine Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.34. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient= Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type. Stakeholders encouraged the addition of this measure to the Physical Therapy/Occupational Therapy specialty set upon coding revisions to allow physical therapists to report.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the above measure for addition to the *Physical Therapy/Occupational Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101/ N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Physical Therapy/Occupational Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. We note that measure Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older was inadvertently included in the Removal table in the proposed rule (86 FR 39746) for this specialty set; however, it was not previously included in this specialty set. Measure Q050 has been moved to the correct table for measures finalized for Addition to this specialty set. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.35. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.35. Plastic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE PLASTIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A/ N/A	128	CMS69v10	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous 12 months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Plastic Surgery specialty set as it is clinically relevant to this clinician type. Stakeholders commented, and we agreed, that this is a measure consistently reported by their MIPS eligible clinicians. BMI does impact plastic surgery outcomes, therefore, is clinically relevant to the Plastic Surgery specialty set.
We received no public comments on the measure proposed for addition to this specialty set; therefore, we are finalizing the above measure for addition to the *Plastic Surgery Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PLASTIC SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Plastic Surgery Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.36. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PODIATRY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Podiatry Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.37. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Preventive Medicine Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.38. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PULMONOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma**: The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Pulmonology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.39. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
*	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v10	Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS 145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS 144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS 147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS 127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS 156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* §	1525 / N/A	326	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE SKILLED NURSING FACILITY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101/ N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measure for removal from the *Skilled Nursing Facility Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.41. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.42. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS 138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE THORACIC SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Thoracic Surgery Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Although we are retaining measure Q317 in the MIPS program, based on previous stakeholder feedback in prior rulemaking we are removing the measure from this specialty set. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.43. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.44. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
	0390 / N/A	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research
* §	0062 / N/A	119	CMS134 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
*	N/A / N/A	462	CMS645 v5	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	476	CMS771 v3	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUS) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.44. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Appropriate Use)	N/A/ N/A	481	CMS646 v2	eCQM Specifications	Process	Effective Clinical Care	**Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of initial diagnosis	Oregon Urology	We proposed to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. Given the high rates that patients are assessed, treated, and managed for this condition within this specialty, we recommended the inclusion of this measure within the Urology specialty set. See Table A.1 for rationale.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the above measure for addition to the *Urology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.									

B.44. Urology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE UROLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair**: Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Urology Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.45. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months.	National Committee for Quality Assurance

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
*	N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE VASCULAR SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268/ N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure was proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
After consideration of public comments, we are finalizing the above measures for removal from the *Vascular Surgery Specialty Measure Set* as proposed for the CY 2022 performance period/2024 MIPS payment year and future years. Note: Where applicable, see Table C in this section of the final rule (Appendix 1: MIPS Quality Measures) for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

TABLE Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal in the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

In this final rule, we are removing 13 previously finalized quality measures from the MIPS Program for the CY 2022 performance period/2024 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 PFS final rule (83 FR 59763 through 59765).

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion that we use for the removal of measures also includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent. Beginning with the 2020 performance period/2022 MIPS payment year, we also refer readers to the CY 2020 PFS final rule (84 FR 62957 through 62959) for additional quality measure removal criteria.

NOTE: Since publication of the measures in Table C in the CY 2022 PFS proposed rule, we have determined the following measures will be retained in the CY 2022 performance period/2024 MIPS payment year: Q014 (MIPS CQMs Specifications collection type only), Q019, Q050 (MIPS CQMs Specifications collection type only), Q137, Q144, and Q317. Our decisions not to finalize these measures for removal in this final rule are detailed in our responses to the public comments for these measures in Table Group C.

As noted in the introduction to Table Group B, measures that were not finalized for removal under Table Group C are added back to the Previously Finalized tables, where applicable, under the appropriate specialty set in Table Group B.

TABLE Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal in the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

C.1. Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
NQF # / eCQM NQF #:	0087 / NA
Quality #:	014
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 months performance period.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle. Given this measure continued topped out status (82 FR 53640), we believe it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

Comment: Many commenters opposed the removal of measure Q014: Age-Related Macular Degeneration (AMD): Dilated Macular Examination. Retinal imaging provides useful information and facilitates careful evaluation of these patients for initial diagnosis, monitoring of progression and managing treatment plans. However, adequate diagnostic evaluation of condition requires detailed examination of the retina, which can only be accomplished with a face-to-face visit, supplemented by additional examinations as needed when new symptoms or unexplained visual changes occur. This measure is essential to patient safety. In addition, this measure is important because blindness due to diabetes and AMD are significant public health concerns and this measure (in addition to measure Q019) calls attention to the importance of HbA1c control for vision and regular eye exams for those with non-neovascular (dry) AMD before they progress to neovascular (wet) AMD.

Additionally, commenters mentioned that most ophthalmic practices only have six measures to report and removing the measure would make it impossible for practices to succeed at MIPS. Removal of this measure would adversely impact performance scores. There was concern on the impact of removing this measure on small rural practices. Removing this measure would also make it difficult for retinal specialists to find relevant measures to report.

Response: We agree that this is an important concept and recognize that specialization within ophthalmology may make it difficult to identify meaningful measures to submit. However, we strive to ensure that all measures align with the Meaningful Measures Initiative, including the removal of measures that are at the end of the topped out lifecycle. Additionally, by removing measures at the end of the topped out lifecycle, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2021 Benchmark File. In addition, there are processes in place to address instances where clinicians do not have the ability to submit six quality measures. We will maintain the MIPS CQMs Specifications collection type as the 2021 Benchmark File that shows a potential gap in care with a performance rate of 89.42 percent. The Medicare Part B Claims Measure Specifications collection type will be removed for this measure as it shows a performance rate of 96.14 percent and does not align with the Meaningful Measures Initiative of moving towards all digital quality measures (dQMs).

After consideration of public comments, we are finalizing the removal of measure Q014 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years for the Medicare Part B Claims Measure Specifications type and are retaining the MIPS CQMs Specifications collection type.

C.2. Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	019
CMS eCQM ID:	CMS142v10
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative. This is a process measure that is a standard of care requiring only the that results were communicated, which by itself may not have a meaningful direct impact on patient care as no follow-up or confirmation of care coordination is required. Additionally, the MIPS CQMs Specifications collection type is in the third year of the topped out lifecycle (82 FR 53640).
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

Comment: Many commenters opposed the removal of measure Q019: Diabetic Retinopathy: Communication With the Physician Managing Ongoing Diabetes Care. An ophthalmologist is needed to inform a primary care clinician or endocrinologist about a particular patient's retinopathy severity, possible diabetic macular edema, or other ocular co-morbidities. Retinopathy serves as a strong predictor of other serious medical conditions such as heart attack, stroke, kidney failure, amputation, and others. Without regular reporting from the ophthalmologist on this issue, the primary care clinician lacks valuable information key to the overall management of the patient. This measure is essential to patient safety and completes the feedback essential for treating a deadly, common disease. Before this measure, patients were not being referred for retinal exams until the blinding stages of disease. Commenters also stated that most ophthalmic practices only have six measures to report and removing the measure would make it impossible for practices to succeed at MIPS.

There was also concern on the impact of removing this measure on small rural practices. It is also important to continue offering eCQM options for reporting since many providers do not want to pay for other reporting services. Also, removing this measure would make it difficult for retinal specialists to find measures to report.

Response: We agree that this is an important concept and recognize that specialization within ophthalmology may make it difficult to identify meaningful measures to submit. While we agree that care coordination is extremely important, this measure only ensures that the specialist has documentation that they communicated exam findings to the physician managing ongoing care but does not require any confirmation from the ongoing care physician to ensure care coordination and closure of the feedback loop. However, we will maintain this measure for the CY 2022 performance period for consistency and stability as it has not reached the end of the topped-out lifecycle and still in alignment with guidelines but may consider removal in the future.

After consideration of public comments, we are not finalizing the removal of measure Q019 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.3. Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin

Category	Description
NQF # / eCQM NQF #:	0268 / N/A
Quality #:	021
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.
Measure Steward:	American Society of Plastic Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure steward will not be further reviewing or updating the measure specifications. In addition, this measure has reached the end of the topped out lifecycle (82 FR 53640). Given this measure continued topped out status, we believe it has a limited opportunity to improve clinical outcomes and the measure has become standard of care. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

Comment: One commenter opposed the removal of measure Q021: Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin from the MIPS program and therefore from the General Surgery set. Measuring stand-alone metrics have not been effective in achieving the goal of informing quality improvement cycles and driving real improvements in care. Therefore, the commenter supported a transition toward measures that do move toward that goal. Removal of this measure will make it more difficult for some groups—including surgical specialties—to succeed in the program. CMS should retain this measure until the agency has a clear plan for how they will replace them to give surgeons who are still required to report via traditional MIPS enough reporting options to avoid a MIPS-related penalty.

Response: We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer up to date and is currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, we are finalizing the removal of measure Q021 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.4. Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	023
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.
Measure Steward:	American Society of Plastic Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure steward will not be further reviewing or updating the measure specifications. In addition, this measure has reached the end of the topped out lifecycle (82 FR 53640). Given this measure continued topped out status, we believe it has a limited opportunity to improve clinical outcomes and the measure has become standard of care. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
Comment: One commenter opposed the removal of measure Q023: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) from the MIPS program and therefore from the General Surgery set. Removal of this measure will make it more difficult for some groups—including surgical specialties—to succeed in the program. CMS should retain this measure until the agency has a clear plan for how they will replace them to give surgeons who are still required to report via traditional MIPS enough reporting options to avoid a MIPS-related penalty. **Response:** We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer up to date and is currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS. After consideration of public comments, we are finalizing the removal of measure Q023 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

C.5. Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	044
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle (82 FR 53640) and has a high performance rate of 96.08 percent for the MIPS CQMs Specifications collection type. Given this measure continued topped out status, we believe it has a limited opportunity to improve clinical outcomes and should be a standard of care. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
We received no public comments on this measure; therefore, we are finalizing the removal of measure Q044 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

C.6. Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	050
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it splits a clinical process into individual quality measures. In order to align with the Meaningful Measures Initiative, we plan to maintain measure Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older. We recognize measure Q048 does not quantify the completion of plan of care but includes the assessment for the presence or absence of urinary incontinence within a broader patient population. Measure Q050 is limited to patients that were screened positive for urinary incontinence which results in an incomplete patient population being evaluated; whether screened for urinary incontinence or being voluntarily verbalized by the patient. We believe as a stand-alone measure it is not a true reflection of the quality of care being given, but only reflects care to a subpopulation of patients with documented urinary incontinence. To truly ensure quality of care for these patients, we believe that clinicians should engage patients and perform this assessment for all denominator eligible patients at risk for the presence or absence of urinary incontinence. Additionally, the Medicare Part B Claims Specifications collection type is at the end of the topped out lifecycle (82 FR 53640).
In the Circumstance the Measure is Retained	We would update the denominator eligible encounters to add coding for Physical Therapy MIPS eligible clinician type and add the measure to the Physical Therapy/Occupational Therapy specialty measure set.

Comment: One commenter understood CMS' reasoning for removing measure Q050 but requested measure Q048 be added to the Physical Therapy/Occupational Therapy list in its place. Therapists treat patients with urinary incontinence and it would make sense to replace the topped out measure with the measure that allows therapists to most successfully report outcomes in that patient population.

Response: As currently specified the denominator eligible criteria within the measure does not include physical therapy/occupational therapy specific coding. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. In the instance the coding is included, we agree to consider adding this measure to the Physical Therapy/Occupational Therapy specialty set.

Comment: One commenter did not support removal of measure Q050 because a performance gap exists, treatments exist to create meaningful improvements in clinical outcomes/quality of life, and the benefits of reducing the patient disease burden outweigh the clinician measurement burden. A second commenter opposed removal of measure Q050 from MIPS and the Geriatrics set. Removing this measure may result in mere screening of urinary incontinence without development of an appropriate plan of care. An appropriate plan of care ensures proper follow-up assessment, referrals, and treatment depending on what matters most to the patient and the impact that urinary incontinence has on the patient's overall health status. The commenter believed that the measure does not split a single clinical process because detecting an issue (as measured by measure Q048) is different from treating the issue (as measured by measure Q050). There are different actions required by the two measures and denominators. The commenter recommended the development of a more rigorous quality measure rather than removing Q050, and instead revising measure Q048 to explicitly measure the establishment of an appropriate plan of care for patients identified through screening as having urinary incontinence so that it is an assessment as well as a plan of care measure. A similar comment stated that this measure may be better suited as a multi-strata measure with measure Q048.

Response: As currently specified, measure Q048 ensures patients were assessed for the presence or absence of urinary incontinence and would not capture outcomes for this patient population. We acknowledged the clinicians screening for incontinence may not be the subsequent treating clinician, however, keeping these measures separate does not allow for full accounting of quality care. We encourage the commenters to reach out to the measure steward to collaborate on development of a measure that not only captures a complete picture of patient care, but also allows clinicians to report outcomes in this patient population. We strive to ensure that all measures align with the Meaningful Measures Initiative, including the removal of measures that are at the end of the topped out lifecycle. Additionally, by removing measures at the end of the topped out lifecycle, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2021 Benchmark File. After careful consideration, we will maintain MIPS CQMs Specifications collection type as the 2021 Benchmark File shows a potential gap in care with a performance rate of 71.93 percent. However, we will remove the Medicare Part B Claims Measure Specifications collection type is at the end of the topped out lifecycle and does not align with the Meaningful Measures Initiative of moving towards all digital quality measures (dQMs).

After consideration of public comments, we are finalizing the removal of measure Q050 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years for the Medicare Part B Claims Measure Specifications type and are retaining the MIPS CQMs Specifications collection type.

C.7. Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	067
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.
Measure Steward:	American Society of Hematology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
We received no public comments on this measure; therefore, we are finalizing the removal of measure Q067 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

C.8. Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	070
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.
Measure Steward:	American Society of Hematology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
We received no public comments on this measure; therefore, we are finalizing the removal of measure Q070 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

C.9. Melanoma: Continuity of Care – Recall System

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	137
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as the measure is not advancing quality care but offers performance by simply establishing a recall system. Despite this structure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

Comment: Commenters opposed removal of measure Q137: Continuity of Care – Recall Systems.

Removal of this measure is a patient safety concern as regular skin exams for patients with a current or personal history of melanoma are extremely important. Commenters did not agree that this measure does not advance quality care to the patients, citing that many patients forget to make their next follow up visit and also do not call the practice when they receive their melanoma recall letter. Practices are able to catch melanoma diagnoses with these follow-up appointments. Removal of the measure is also unfair because measures related to cancer screenings for colorectal, breast, cervical cancers, etc., have been retained in the quality measure inventory.

Commenters stated that primary care clinicians cannot monitor the course of ocular melanoma, and this can only be accomplished via ocular imaging and diagnostic examination techniques of an ophthalmologist. These are the last patients who should become lost to follow-up as a result of inadequate tracking and call-back procedures.

Removal of measure Q137 would also be detrimental to small practices as they often rely on this measure for quality category score optimization as tracking and following up for patient safety reasons. Removing this measure would impact quality scoring for the Dermatology set. It was also cited that is not topped out.

Response: We agree that it is important to ensure regular skin exams for patients with a current diagnosis or history of melanoma, however, this measure does not assess if the patient gets annual skin exams or if the process to follow up for those patients who miss an appointment is effective and leading to compliance. Therefore, we will maintain this measure for consistency and stability as it is not topped out, aligns with current guidelines, and has a high adoption amongst the dermatology clinician type. However, we may consider removal in the future. We encourage the commenters to reach out to the measure steward for possible collaboration in revising the measure to better capture an outcome that results from a recall system and regular skin exams. We prioritize measures that express performance reflected as outcomes rather than measures that represent quality-based processes.

After consideration of public comments, we are not finalizing the removal of measure Q137 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.10. Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
NQF # / eCQM NQF #:	0383 / N/A
Quality #:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it splits a clinical process into individual quality measures. In order to align with the Meaningful Measures Initiative, we plan to maintain measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. We recognize measure Q144 does not quantify the completion of a plan of care but includes the assessment of pain for patients undergoing cancer treatment. Measure Q144 is limited to those patients that were screened positive for pain; whether screened for pain or being voluntarily verbalized by the patient. We believe as a stand-alone measure it is not a true reflection of the quality of care being given, but only reflects care to a subpopulation of oncology patients with documented pain. To truly ensure quality of care for these patients, we believe that clinicians should engage all denominator eligible patients and perform this assessment to identify the presence of pain in patients undergoing cancer treatment.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

Comment: One commenter supported removal of this measure and agreed that it does not align with the Meaningful Measures Initiative. The commenter, however, stated that retaining the measure in the Radiation Oncology Model runs contrary to reducing complexity and aligning programs.

Response: We thank the commenter for supporting removal of measure Q144 from the MIPS program.

Comment: Commenters disagreed with the proposed removal of measure Q144: Medical and Radiation – Plan of Care for Pain. Ensuring that physicians are creating a plan of care for any pain is necessary. Patients with cancer can have multiple painful side effects and managing a patient's pain is key to their quality of life. This, and its paired measure, Q143: Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology, have been utilized since the Physician Quality Reporting System (PQRS) was initiated and are reliable quality measures. Both measures are capturable by electronic systems and are meaningful to the holistic care of patients.

Commenters cited maintaining harmonization across quality reporting programs, and to maintain continuity between the paired measures. Additionally, measure Q144 is included in the proposed Oncology Care First Model and the Radiation Oncology Model and the measure has been in use for more than a decade in multiple programs and clinical settings. Removing measure Q144 from MIPS means that it will not align with other reporting programs. NQF also recently re-endorsed measure Q144.

Commenters cited that that this measure is often paired with measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. Only those patients identified as having pain by measure Q143 are included in the denominator of measure Q144 to ensure their pain is addressed. The commenter emphasized the critical importance of addressing pain appropriately and believed this emphasis should outweigh the measure's status as a paired measure. Quantifying pain is only helpful if clinicians establish a plan of care to address it. Pain research has resulted in more effective therapies for treating pain in people with cancer, which may include pharmacologic, psychological, and other approaches. Until a new measure is introduced to address the need for the establishment of a plan of care for pain, the commenters requested that measure Q144 be retained in the MIPS program.

Response: We acknowledge that a plan of care for pain is an important aspect of oncology care. However, we believe by splitting the clinical process into multiple quality measures, we are unable to obtain complete and meaningful performance data of pain management for patients receiving chemotherapy and/or radiation therapy. As measure Q144 only ensures that patients who have voiced having pain present receive a plan of care, it does not ensure that all patients are being screened for the presence or absence of pain. The removal of measure Q144 would not preclude development of a plan of care. Currently, the measure being proposed for the Oncology Care First Model is a pain assessment and management composite measure, which is more robust than measure Q144 in that it ensures all patients are being screened and those that screen positive for pain have a plan of care completed. The Radiation Oncology Model only addresses the documentation of a plan of care and is therefore missing the first piece, measure Q143, of assessing all applicable patients for the presence of pain. Additionally, the removal of measure Q144 would align with the Core Quality Measures Collaborative (CQMC). We encourage the commenter to reach out to the measure steward to collaborate on developing a measure that covers the entirety of the clinical topic being addressed via measure Q143 and measure Q144. After careful consideration, we will maintain this measure for consistency and stability as it has not reached the end of the topped out lifecycle and aligns with current guidelines, but may consider removal in the future.

After consideration of public comments, we are not finalizing the removal of measure Q144 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.11. Falls: Risk Assessment

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality #:	154
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle (82 FR 53640). Given this measure continued topped out status, we believe it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

Comment: One commenter supported removal of measure Q154: Falls: Risk Assessment.

Response: We thank the commenter for supporting removal of measure Q154 from the MIPS program.

Comment: One commenter cited that if measure Q154 is removed, measure Q155 Falls: Plan of Care becomes impossible for physical therapists to report because measure Q155 is a two-part measure that is paired with measure Q154. If measure Q154 is removed, then physical therapists should be able to report measure Q318 Falls: Screening for Future Falls Risk.

Response: We note that both measures Q155 and Q318 are included within the Physical Therapy/Occupational Therapy set. In regard to the comment about no longer being able to report measure Q155, the removal of measure Q154 would not impede a clinician's ability to submit measure Q155 as the denominator criteria of screening for future fall risk (CPT II code 1100F) could still be submitted on the Medicare Part B claims form if utilizing the Medicare Part B Claims Measure Specification collection type. The denominator for the MIPS CQM Specifications collection type for both measures is the same, in that each requires that the patient have been screened for future fall risk with documentation of two or more falls in the past year or any fall with injury in the past year.

Comment: Many commenters opposed the removal of measure Q154. Patients with visual impairment, such as the elderly, are much more prone to falls than those who have normal vision and may have age-related eye conditions such as cataract, glaucoma, diabetic retinopathy and age-related macular degeneration. Screening these patients in the office to identify high-risk situations, especially compounded by visual impairment, can be an effective preventive service. In addition, database-driven analytics can provide important insights into fall risk and prevention strategies. This measure is essential to patient safety and well-being.

Different specialties opposed removal of measure Q154. One commenter stated that removal of Q154 would impact the number of measures available to be reported by clinicians at cancer centers. Removal of Q154 would also negatively impact measures available in the Geriatrics and Physical Therapy/Occupational Therapy sets. Audiologists wanted retention of measure Q154 because the measure is reportable via Medicare Part B Claims.

One commenter stated that although the measure is topped out, falls prevention is an excellent and critical tool to measure the quality of occupational therapy services. The commenter suggested CMS to ensure sufficient falls risk assessment measures exist in the MIPS program to ensure that falls risks are assessed and addressed by therapists in both healthy and vulnerable populations.

Response: This measure is at the end of the topped-out lifecycle and the denominator eligible patient population is captured within measure Q155: Falls: Plan of Care. Measure Q154 requires a risk assessment be completed for those patients who have a history of falls, where measure Q155 requires a plan of care to address those risks and diminish the occurrence of future falls through balance, strength, and gait training. We believe that assessing for documentation of a risk assessment does not indicate that the patient has a plan in place to address future falls with mitigation strategies.

We agree that falls prevention is an extremely important concept and that both physical and occupational therapists play a critical role in this area, which is why we are maintaining measure Q155, which requires that a plan of care for falls be documented with two or more falls in the past year or any fall with injury in the past year. The removal of measure Q154 does not preclude clinicians in completing these tasks, however, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2021 Benchmark File. In addition, there are processes in place to address instances where clinicians do not have the ability to submit six quality measures.

Comment: One commenter questioned if measure Q154 would be removed from eCQM reporting as the collection type is not specifically identified.

Response: Measure Q154 was only reportable through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. Measure 318: Falls: Screening for Future Fall Risk remains available through the eCQM Specifications collection type.

After consideration of public comments, we are finalizing the removal of measure Q154 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.12. Radiology: Stenosis Measurement in Carotid Imaging Reports

Category	Description
NQF # / eCQM NQF #:	0507 / N/A
Quality #:	195
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.
Measure Steward:	American College of Radiology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle (82 FR 53640) and has a high performance rate of 95.62 percent for the Medicare Part B Claims Specifications collection type and 97.47 percent for the MIPS CQMs Specifications collection type. Given this measure continued topped out status, we believe it has a limited opportunity to improve clinical outcomes. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
Comment: Commenters opposed the removal of measure Q195: Radiology: Stenosis Measurement in Carotid Imaging Reports. Commenters cited the continued removal and lack of radiology, imaging, and neuroradiology measures and stated that radiology practices are struggling with measure selection. One commenter cited that this measure continues to be endorsed by NQF. During the recent NQF Neurology Committee Standing Committee endorsement period, the commenter discovered a variation in the measure denominator between those who submitted this measure and those who could have submitted it but did not. The commenter stated that given the adoption disparities with measure Q195 that CMS should remove its topped-out status and begin working with stakeholders to identify solutions for engaging those eligible radiologists to use it and reduce disparities in this area. **Response:** We acknowledge the difficulties non-patient facing clinicians encounter when submitting quality measures and continue to engage with stakeholders to develop strategies for addressing this gap. While we acknowledge the specializations found within radiology, the performance for measure Q195 has an extremely high and unvarying performance rate. This does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2021 Benchmark File. This measure also continues to receive multiple inquiries through the QPP Service Center desk, indicating the measure is difficult to implement. We encourage stakeholders to submit potential new measures that will align with the Meaningful Measures Initiative and allow MIPS eligible clinicians to maximize their potential performance within MIPS during the annual Call for Measures. After consideration of public comments, we are finalizing the removal of measure Q195 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

C.13. Radiology: Reminder System for Screening Mammograms

Category	Description
NQF # / eCQM NQF #:	0509 / N/A
Quality #:	225
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it represents a structure measure rather than a measure that supports direct patient care. In addition, the performance on the MIPS CQMs Specifications collection type is extremely high and unvarying, making this measure extremely topped out for this collection type as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.37 percent for the MIPS CQMs Specifications collection type. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
Comment: One commenter opposed removal of measure Q225 as it is the only MIPS measure applicable to breast imagers following removal of numerous applicable measures from the MIPS program. Data in publications has shown lower return to screening by patients during the	

COVID crisis, particularly in safety-net hospitals and underserved, rural, and minority populations. Removal of this measure may make it more difficult to create a potential mammography MVP in the future, as this MVP would certainly rely on existing MIPS mammography measures when establishing quality scoring. A second commenter indicated there have been no new radiology measures since 2017. Removing this measure would limit current measures to computed tomography, magnetic resonance imaging. and nuclear medicine, which does not fit their modality mix or patient population.

Response: While we acknowledge the importance of ensuring timely mammograms, the performance for measure Q225 MIPS CQM Specifications collection type has an extremely high and unvarying performance rate. This does not allow meaningful benchmarks to be established. Additionally, the measure does not require any follow-up for those patients who do not complete mammograms in accordance with their targeted due date, and therefore does not assess compliance only that a system is in place to notify patients. We encourage stakeholders to submit potential new measures that will align with the Meaningful Measures Initiative and allow MIPS eligible clinicians to maximize their potential performance within MIPS during the annual Call for Measures.

After consideration of public comments, we are finalizing the removal of measure Q225 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.14. Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	317
CMS eCQM ID:	CMS22v10
National Quality Strategy Domain:	Community/Population Health
Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it is low-bar and a frequently performed assessment. This is a process measure that only requires a blood pressure to be taken and if abnormal a follow-up plan of care be documented; however, the documented follow-up includes referring the patient to a primary care physician and does require confirmation of follow-up. Additionally, the measure does not strive to ensure adequate control of blood pressure as patients with an active diagnosis of hypertension are excluded from the denominator eligible patient population. While screening patients for high blood pressure is an important piece of quality care, it is the controlling of high blood pressure which reduces patient clinical risks and truly drives positive patient outcomes. This quality action is already available in measure Q236: Controlling High Blood Pressure.
In the Circumstance the Measure is Retained	We would update the description to replace 'pre-hypertensive' with 'elevated'. Additionally, the definition for all collection types would be revised to reflect 2017 ACC/AHA guidelines; including, changing blood pressure classifications, relevant thresholds, and applicable interventions. The eCQM Measure Specifications collection type would be revised to have the logic apply to exceptions based on blood pressure classification to more accurately capture a patient declining applicable intervention(s). This measure would also be removed from the Thoracic Surgery specialty measure set.

Comment: Several commenters supported the removal of measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

Response: We thank the commenters for supporting the removal of measure Q317 from the MIPS program.

Comment: Commenters cited concerns with being able to meet reporting requirements if this measure was removed. One commenter stated that it can no longer met the six measures minimum if measure Q317 (in addition to measure Q154) is removed. For groups that have limited measures and a high weighted quality category, CMS now requires 100 percent quality to meet the minimum threshold, otherwise resulting in a negative adjustment. Clinician in small practices without EHRs have difficulty reaching the minimum measure requirement and this measure is of benefit for many specialists to reach the required six measures.

Response: MIPS CQMs Specifications collection type may be reported without a third-party intermediary (see the '2021 MIPS Quality Quick Start Guide' at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1294/2021%20MIPS%20Quality%20Quick%20Start%20Guide.pdf). In addition, there are processes in place to address instances where clinicians do not have the ability to submit six quality measures.

Comment: Several commenters opposed the removal of measure Q317. Cardiovascular disease remains the number one killer and disabler of Americans, and without adequate clinical screening and follow-up, hypertensive patients can go unrecognized and untreated, running counter to the high priority CMS should place on prevention. This measure is essential to patient safety. Making primary care clinicians accountable for screening, documenting, and treating hypertension has saved many lives.

One commenter stated that the measure developer for measure Q317 has made major changes to this measure since publication in the 2022 PFS proposed rule. The measure developer has added more follow up and changed the definition for high BP. They have also modified what follow up is needed based on the blood pressure, ex, F/U appt, meds, labs or EKG and looks at multiple blood pressure visits. The commenter suggested CMS not to remove EHR reportable eCQM measures when alternative eCQM measures are not available to be reported. Proposed scoring changes moving into 2022 will also create difficulty for many providers to be able to achieve a positive adjustment.

Response: We acknowledge the importance of monitoring blood pressure, and the impact cardiovascular disease has on the population, however, this measure does not ensure that high blood pressure is being treated and brought under control, which drives positive patient outcomes. Although, we do agree that clinicians that screen for hypertension would be able to detect and treat this disease sooner which supports a positive health outcome for their patients. "In 2007 the USPSTF published a reaffirmation of its 2003 A recommendation to screen for hypertension among all adults aged 18 years and older. The Task Force found good evidence that treatment of high blood pressure in adults can substantially decrease risk of cardiovascular disease" (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5217841/). Therefore, we will maintain this measure for consistency and stability as it is not topped out, aligns with current guidelines, and has high adoption amongst MIPS eligible clinicians, but may consider removal in the future. We would like to make measure Q317 an outcome measure in the future.

After consideration of public comments, we are not finalizing the removal of measure Q317 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.15. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative to measure Q176: Tuberculosis Screening Prior to First Course Biologic Therapy because we proposed in Table D.20 substantive changes to measure Q176 that would broaden the denominator by including an expanded list of biologic therapies that capture much of the denominator patient population for this measure.
In the Circumstance the Measure is Retained	We would update the denominator to include only those patients who are on a biologic immune response modifier prescribed within the current measurement period. There is no specialty set movement proposed for this measure.

Comment: One commenter supported the removal of measure Q337: Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier.

Response: We thank the commenter for supporting the removal of measure Q337 from the MIPS program.

Comment: One commenter opposed removal of measure Q337 because removal would result in a Dermatology set where there will be a significant disadvantage when it comes to the quality scoring category.

Another commenter opposed the removal to measure Q337 and stated that the proposed revisions to measure Q176 would mean that denominator population would overlap with Q337. For full comments relating to measure Q176, see Table D.20. Another commenter stated that measure Q176 is not included in the Dermatology registry nor is it in the Dermatology measure set. The commenter also stated that the proposed changes to measure Q176 do not adequately encompass the biological response modifiers used in dermatology and listed in measure Q337. The commenter requested for measure Q337 to remain in MIPS to allow time for development of additional dermatology measures.

Response: As a result of the substantive changes being made to measure 176, this measure will now be available within the Dermatology Specialty Measure set and will take the place of measure 337, maintaining the clinical topic for the dermatology clinician type. Replacing measure Q337 with measure Q176 aligns with the Meaningful Measures Framework, as duplicative measures have no purpose in quality measurement, and we do not believe that this will disadvantage dermatologists.

We also appreciate the commenters for their comment regarding potential patient population overlap of measure Q176 with measure Q337 and agree this would lead to duplicity in measures.

After consideration of public comments, we are finalizing the removal of measure Q337 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.16. Pain Brought Under Control Within 48 Hours

Category	Description
NQF # / eCQM NQF #:	0209 / N/A
Quality #:	342
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.
Measure Steward:	National Hospice and Palliative Care Organization
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it does not align with the Meaningful Measures Initiative. This measure should be a standard of care given it represents a central pillar of quality palliative care by supporting effective pain management for patients. As currently specified, this measure only assesses if pain was brought to a comfortable level within 48 hours of the initial assessment and does not ensure treatment is aligned with patient goals, a plan of care for the duration of palliative care, and current guidelines; additionally, it may not be feasible dependent upon the medication and delivery method (i.e., procedural versus oral medication administration). It is important to incorporate shared-decision making and patient engagement while in palliative care, which may not always align with the time constraint of the measure.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

Comment: One commenter supported the removal of Q342: Pain Brought Under Control Within 48 Hours.

Response: We thank the commenter for supporting the removal of measure Q342 from the MIPS program.

Comment: Several commenters opposed the removal of Q342, stating there has been a substantial decline in the number of quality measures related to pain management in the past several years that limits the number of measures the practice is able to report. One commenter stated that only one measure will be left specific to pain management and they will no longer be able to report a minimum of six measures in their practice. One commenter stated that Q342 is a high-priority measure that assesses an important outcome in the care of patients receiving palliative care.

Response: We acknowledge that there are a limited number of quality measure related to pain management and encourage the commenter to reach out to measure stewards and developers to submit meaningful pain management measures to the MIPS Annual Call for Measures for potential future inclusion. We believe the goal of pain management for patients receiving palliative care is to improve quality of life for both the patient and the family and await a measure that is capable of assessing outcomes of quality care provided by these clinicians. We do not believe this measure fully represents quality care for pain management for patients receiving palliative care, as the assessment of pain under control only needs to occur once to meet performance of the measure. In addition, there are processes in place to address instances where clinicians do not have the ability to submit six quality measures. Additionally, the measure steward is no longer supporting the maintenance of this measure on an annual basis.

After consideration of public comments, we are finalizing the removal of measure Q342 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.17. Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	429
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it does not show meaningful measurement. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

We received no public comments on this measure; therefore, we are finalizing the removal of measure Q429 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

C.18. Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	434
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it is duplicative in denominator patient population to measure Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair with the quality action being completed concurrently. Additionally, the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
We received no public comments on this measure; therefore, we are finalizing the removal of measure Q434 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

C.19. Medication Management for People with Asthma

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	444
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.
Comment: One commenter did not support removal of measure Q444: Medication Management for People with Asthma because implementation may promote patient adherence to prescribed controller medication therapy and a 50 percent medication compliance rate is an achievable threshold. Medication adherence issues in patients with asthma and underuse of controller medication therapy is clearly a problem. **Response:** We agree that this is an important topic and would encourage the commenter to reach out to the measure developer to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward is no longer supporting the measure; therefore, we are unable to continue implementation within MIPS. After consideration of public comments, we are finalizing the removal of measure Q444 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Finalized for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

NOTE: Electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

The D Tables within this final rule provide the substantive changes proposed for the quality measures in CY 2022. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2022 may not be identified within the proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2022 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2023. The 2022 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/resources/resource-library. For eCQM Release Notes, see the eCQI Resource Center at https://ecqi.healthit.gov/ep-ec?globalyearfilter=2021.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believe are important to communicate to stakeholders. These changes align with the scope of the current coding; however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2022 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes. Language has also been added, to all applicable 2022 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, will the D table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

It should be noted that in the 2021 PFS final rule (85 FR 84870), the CMS Web Interface Measures Specifications collection type would have sunset starting with the CY 2022 performance period; however, in section IV.A.3.d.(1)(d) of this final rule, we finalized to extend the availability of the CMS Web Interface measures as a collection type for the CY 2022 performance period (CY 2024 for APM Entities reporting through the APM Performance Pathway) and sunset the CMS Web Interface measures starting with the CY 2023 performance period (CY 2025 for APM Entities reporting through the APM Performance Pathway). Therefore, we proposed substantive changes to the CMS Web Interface Measure Specifications collection type as outlined in the applicable measures within the D tables. In conjunction with soliciting public comments on the proposal to extend the availability of the CMS Web Interface measures as a collection type, we solicited public comments on the substantive changes proposed for the CMS Web Interface Measure Specifications collection type given that the CMS Web Interface Measure Specifications collection type has generally remained the same for three consecutive (CY 2019, CY 2020, and CY 2021) performance periods.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. 3. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Revised:** Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator confirmation: For the CMS Web Interface Measure Specifications collection type: Revised:** Determine if the patient has an active diagnosis of diabetes during the measurement period OR an active diagnosis of diabetes during the year prior. - If the patient has an active diagnosis of diabetes in the medical record, select "Yes" **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated guidance: For the CMS Web Interface Measure Specifications colleciton type: Added:** Do not include HbA1c levels reported by the patient. **Updated numerator guidance: For the CMS Web Interface Measure Specifications colleciton type: Removed:** - Patient Reported Requirement: Date and most recent value (distinct value required) **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** 1. Palliative care services provided to patient any time during the measurement period
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed that the denominator exclusion language be updated for all collection types, except for the CMS Web Interface Measure Specifications collection type, to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We proposed to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component. We proposed to update the denominator exclusion language for the CMS Web Interface Measure Specifications collection type, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, the denominator confirmation was updated to clarify that the diagnosis should be active during the performance period or year prior. We proposed to update the guidance for the CMS Web Interface Measure Specifications collection type to ensure that patient reported HbA1c levels should not be utilized for quality action assessment for the purposes of this measure.
Comment: One commenter stated that measure Q001 includes a denominator exclusion for any patient that has received hospice services at any time during the measurement period, but it does not include denominator exclusion for patients receiving palliative care. Many Medicare beneficiaries utilize palliative care prior to or in lieu of hospice care to promote quality of life and comfort near the end of life. Beneficiaries often choose palliative care over hospice care in order to	

Category	Description
continue to receive treatment or therapy that may improve their quality of life. The commenter supported this patient-centered care and requests that CMS/QPP include a palliative care exclusion for this measure to reflect that this service is regularly utilized in populations with high mortality rates, such as a long-term care institutional population. One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in this measure and supported CMS proposal to add palliative care exclusions or exceptions. **Response:** We agree that this patient population is not appropriate for assessment of the clinical quality action within this measure. **Comment:** One commenter noted that CMS proposed add Palliative Care to the denominator exclusions for this eCQM measure (as we as adding for measures Q112, Q113, and Q236). The commenter encouraged CMS to work with the measure stewards for all of the measures that correspond to the 10 in use by Web Interface to match the exclusions of hospice and palliative care, since these are automatically screened out of the denominator in the patient qualification review that is part of Web Interface reporting. Deceased patients are also excluded in this Web Interface approach, and the commenter encouraged CMS to standardize this exclusion for all CQMs and submission types. **Response:** We encourage the commenter to reach out to the measure stewards to discuss revisions for possible implementation in future years. Reporting for the CMS Web Interface Measure Specifications collection type excludes this patient population from the sampling process rather than specifying it within the Web Interface Measure specification. We make efforts to exclude patients that are not qualified for the sample, but because there are limitations in the claims data used to identify the sample, the CMS Web Interface Measure Specification collection type allows a patient to be skipped because they are not qualified for the sample. The patient must meet one of the following criteria to be considered not qualified for the sample and will be removed from all CMS Web Interface measure samples: (1) In hospice; (2) Moved out of the U.S.; (3) Deceased; or (4) Non-Fee-for-Service (FFS) Medicare. If any of those circumstances are true for a sampled patient, at any time during the measurement period, that patient is not qualified for the sample. This is specific to the CMS Web Interface Measure Specifications collection type. After consideration of public comments, we are finalizing the changes to measure Q001 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality#:	005
CMS eCQM ID:	CMS135v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated definition: For the eCQM Specifications collection type: Added:** The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients. **Updated value set/coding: For the eCQM Specifications collection type: Revised:** "Pregnancy" (2.16.840.1.113883.3.526.3.378) value set to more accurately capture pregnancy state
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type definition section to align the measure language with the logic to allow for quantitative or qualitative documentation of moderate or severe left ventricular systolic dysfunction (LVSD). Additionally, we proposed to update the eCQM Specifications "Pregnancy" value set to more accurately capture the state of pregnancy to ensure the denominator exclusion is being applied to the correct patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q005 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.3 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.
Substantive Change:	**Updated definition: For the eCQM Specifications collection type: Added:** LVEF < 40% corresponds to qualitative documentation of moderate dysfunction or severe dysfunction (LVSD). The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients. **Updated denominator logic: For the eCQM Specifications collection type: Revised:** Myocardial Infarction timing logic to use the start date for the myocardial infarction. **Updated value set/coding: For the eCQM Specifications collection type: Revised:** "Coronary Artery Disease No MI" (2.16.840.1.113883.3.526.3.369) to remove coding related to Dressler's Syndrome. **Updated denominator note: For the MIPS CQM Specifications collection type: Added:** Submission Criteria 1: LVEF < 40% corresponds to qualitative documentation of moderate dysfunction or severe dysfunction (LVSD). The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type definition section to align the measure language with the logic to allow for quantitative or qualitative documentation of moderate or severe left ventricular systolic dysfunction (LVSD). We proposed to update the denominator logic for the eCQM Specifications collection type to use the start date for the myocardial infarction. This will ensure those patients without a documented myocardial infarction end date within the medical record will be captured within the measure denominator as these patients would be appropriate for the denominator eligible patient population. Additionally, we proposed to remove 'Dressler's Syndrome' from the "Coronary Artery Disease No MI" value set for the eCQM Specifications collection type as this is not a conclusive diagnosis to indicate coronary artery disease and therefore, not appropriate for this value set.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q007 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.4 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality#:	008
CMS eCQM ID:	CMS144v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated definition: For the eCQM Specifications collection type: Added:** The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type definition section to align the measure language with the current measure logic to allow for quantitative or qualitative documentation of moderate or severe left ventricular systolic dysfunction (LVSD).
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q008 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.5 Anti-Depressant Medication Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	009
CMS eCQM ID:	CMS128v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**Updated denominator exclusion: Revised:** Exclude patients who are in hospice care for any part of the measurement period
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion to remove the term 'overlaps' and replace with plain language for clarity and to ensure consistency in implementation.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q009 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.6 Appropriate Treatment for Upper Respiratory Infection (URI)

Category	Description
NQF # / eCQM NQF #:	0069 / N/A
Quality#:	065
CMS eCQM ID:	CMS154v10
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude URI episodes when the patient had hospice care for any part of the measurement period. 2. Exclude URI episodes when the patient had an active prescription of antibiotics in the 30 days prior to the episode date, including the episode date up until the time of the encounter. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic so definitions point to the encounter as a basis for evaluating other clinical data. **Updated value set/coding: For the eCQM Specifications collection type: Added:** value sets "Observation care discharge day management", "Home Healthcare Services", "Medical Disability Exam", and "Observation". **Updated denominator: For the MIPS CQMs Specifications collection type:** Added: Home Health setting and coding for Work Related or Medical Disability Evaluation services. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Revised:** URI episodes when the patient had an active prescription of antibiotics (Table 1) in the 30 days prior to the episode date.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type denominator exclusion to remove the term 'overlapping' and replace with plain language for clarity and to ensure consistency in implementation. Additionally, we proposed to revise the denominator exclusion to align with the logic regarding the timing of the active prescription and the encounter for the purposes of this exclusion. We proposed to update the eCQM Specifications collection type logic so that the definitions point to the encounter as a basis for evaluation of other clinical data as this will align with the measure intent and ensure appropriate time intervals for implementation. Additionally, we proposed to add value sets to the eCQM Specifications collection type as these value sets are appropriate and applicable to this measure's denominator eligibility. We proposed to revise the MIPS CQMs Specifications collection type denominator exclusion to clarify that all patients with active antibiotic prescriptions up to the time of the encounter should be excluded from the denominator eligible patient population. Additionally, we proposed to update the denominator eligible coding to include home visits and disability evaluation services as these are appropriate and applicable clinical settings. In the event the proposed substantive change(s) are finalized, for the MIPS CQMs Specifications collection type, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q065 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.7 Appropriate Testing for Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	066
CMS eCQM ID:	CMS146v10
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude episodes where the patient is taking antibiotics in the 30 days prior to the episode date, or had an active prescription on the episode date. 3. Exclude episodes where the patient is in hospice care for any part of the measurement period. **Updated denominator logic: For the eCQM Specifications collection type: Revised:** definitions to point to the encounter as a basis for evaluating other clinical data **The measure guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. The intent is to determine whether antibiotics are being dispensed appropriately. Antibiotics should only be dispensed if a strep test has been performed to confirm a bacterial infection. Antibiotics should not be dispensed for viral infections. This eCQM is an episode-based measure. An episode is defined as each eligible encounter for patients aged 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event during the measurement period. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure initial patient population/denominator is revised to read: For all collection types:** Outpatient, telephone, online assessment (i.e. e-visit or virtual check-in), observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispensing event on or within 3 days after the episode date among patients 3 years or older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Revised:** Prescribed or dispensed antibiotic on or within 3 days after the episode date (Table 1). **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Revised:** Episodes where the patient is taking antibiotics (Table 1) in the 30 days prior to the episode date, or had an active prescription on the episode date.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type denominator exclusions to clarify timing of exclusion criteria and to remove the term 'overlap' and replace with plain language for clarity and to ensure consistency in implementation. We proposed to update the eCQM Specifications collection type logic so that the definitions point to the encounter as a basis for evaluation of other clinical data as this will align with the measure intent and ensure appropriate time intervals for implementation. We proposed to update the eCQM Specifications collection type guidance section to clarify the intent of the measure and appropriate antibiotic dispensing. Additionally, we proposed to update the eCQM Specifications collection type initial patient population to capture those patients with an antibiotic dispensing event on or within 3 days after the episode event to align with intent of the measure. We proposed to update the denominator and denominator criteria of the MIPS CQMs Specifications collection type to reflect that patients with an antibiotic dispensing event on or within 3 days after the episode event should be included within the denominator eligible population as this aligns with the intent of the measure to assess appropriate antibiotic dispensing. We proposed to revise the MIPS CQMs Specifications collection type denominator exclusion to clarify that all patients with active antibiotic prescriptions up to the time of the encounter should be excluded from the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q066 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.8 Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	0654 / N/A
Quality#:	093
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q093 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.9 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Category	Description
NQF # / eCQM NQF #:	0389 / 0389e
Quality#:	102
CMS eCQM ID:	CMS129v11
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**Updated denominator criteria: For the MIPS CQMs Specifications collection type: Revised:** Any patient, regardless of age **The measure instructions are revised to read: For the MIPS CQMs Specifications collection type:** This measure is to be submitted once per performance period for patients with a diagnosis of prostate cancer at low (or very low) risk of recurrence who receive interstitial prostate brachytherapy, external beam radiotherapy to the prostate, radical prostatectomy during the performance period. The quality-data code or equivalent needs to be submitted only once during the performance period. It is anticipated that Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the listed procedures as specified in the denominator coding will submit this measure. **Updated denominator note: For the MIPS CQMs Specification collection type: Added:** Most recent risk assessment of recurrence completed before the first prostate cancer treatment during the performance period will be used for denominator eligibility.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the MIPS CQMs Specifications collection type to remove the gender specificity from the denominator criteria to ensure a complete patient population. Additionally, we proposed to revise the measure instructions and denominator note for the MIPS CQMs Specifications collection type to reflect the update in measure submission frequency from once per episode to once per performance period utilizing the most recent risk assessment for purposes of denominator eligibility, as this is more aligned with the measure intent as well as bringing all collection types into alignment.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q102 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.9 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Category	Description
NQF # / eCQM NQF #:	0389 / 0389e
Quality#:	102
CMS eCQM ID:	CMS129v11
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**Updated denominator criteria: For the MIPS CQMs Specifications collection type: Revised:** Any patient, regardless of age **The measure instructions are revised to read: For the MIPS CQMs Specifications collection type:** This measure is to be submitted once per performance period for patients with a diagnosis of prostate cancer at low (or very low) risk of recurrence who receive interstitial prostate brachytherapy, external beam radiotherapy to the prostate, radical prostatectomy during the performance period. The quality-data code or equivalent needs to be submitted only once during the performance period. It is anticipated that Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the listed procedures as specified in the denominator coding will submit this measure. **Updated denominator note: For the MIPS CQMs Specification collection type: Added:** Most recent risk assessment of recurrence completed before the first prostate cancer treatment during the performance period will be used for denominator eligibility.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the MIPS CQMs Specifications collection type to remove the gender specificity from the denominator criteria to ensure a complete patient population. Additionally, we proposed to revise the measure instructions and denominator note for the MIPS CQMs Specifications collection type to reflect the update in measure submission frequency from once per episode to once per performance period utilizing the most recent risk assessment for purposes of denominator eligibility, as this is more aligned with the measure intent as well as bringing all collection types into alignment.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q102 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.10 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / 0041e
Quality#:	110
CMS eCQM ID:	CMS147v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** Patient self-report for procedures as well as immunizations should be recorded in 'Procedure, Performed' template or 'Immunization, Administered' template in QRDA-1. **Updated value set/coding: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types: Removed:** "Previous Receipt of Influenza Vaccine" (2.16.840.1.113883.3.526.3.1185) value set.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type in order to accurately capture those patients who had previously received the influenza immunization. The current logic definition does not capture the date of immunization receipt nor does it ensure the patient was assessed during the flu season and is not fully aligned with measure intent. Therefore, the value set "Previous Receipt of Influenza Vaccine" will be removed from the measure and the guidance section will be updated to outline the process for capturing those patients who have previously received the influenza immunization for the purposes of this measure. Additionally, the value set "Previous Receipt of Influenza Vaccine" will be removed from CMS Web Interface Measure Specifications collection type to align with the eCQM Specifications collection type, however, this will not impact the numerator of the measure. Medical record documentation of previous receipt of the influenza vaccine during the flu season will still suffice for completion of the quality action, though this value set will no longer be available for mapping purposes.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q110 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.11 Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	111
CMS eCQM ID:	CMS127v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.
Substantive Change:	**The measure description is revised from 'Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine' to:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine. **The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** Exclude patients who are in hospice care for any part of the measurement period. **Updated initial patient population: For the eCQM Specifications collection type: Revised:** patient age changed to 66 years of age or older. **The measure numerator is revised to read: For all collection types:** Patients who received a pneumococcal vaccination on or after their 60th birthday and before the end of the measurement period; or had an adverse reaction to the vaccine before the end of the measurement period. **Updated value set/coding: For the eCQM Specifications collection type: Revised:** **Removed:** "Pneumococcal Vaccine" (2.16.840.1.113883.3.464.1003.110.12.1027) and "Pneumococcal Vaccine Administered" (2.16.840.1.113883.3.464.1003.110.12.1034) **Added:** "Pneumococcal Polysaccharide 23 Vaccine" (2.16.840.1.113883.3.464.1003.110.12.1089) **The measure denominator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients 66 years of age and older with a visit during the measurement period **The measure denominator criteria is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients aged ≥ 66 years on date of encounter **The measure denominator note is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** This measure assesses whether patients 66 years of age or older have received one or more pneumococcal vaccinations. **The measure numerator options are revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Performance Met:** Pneumococcal vaccine administered on or after patient's 60th birthday and before the end of the measurement period **Performance Met:** Documentation of medical reason(s) for not administering pneumococcal vaccine (e.g., adverse reaction to vaccine) **Performance Not Met:** Pneumococcal vaccine was not administered on or after patient's 60th birthday and before the end of the measurement period, reason not otherwise specified **The measure numerator note is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** The measure provides credit for adults 66 years of age and older who have received the PPSV23 vaccine on or after the patient's 60th birthday. Patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description, initial patient population, denominator, denominator criteria, and denominator note (as applicable) for all collection types to assess patients aged 66 years and older as this allows time for clinicians to administer the pneumococcal vaccination in accordance with current Advisory Committee on Immunization Practices (ACIP) recommendations. Additionally, the numerator for all collection types is proposed to be revised to assess for the administration of the pneumococcal vaccine on or after the patients 60th birthday and before the end of the measurement period or documentation of medical reason(s) for not administering the pneumococcal vaccine. We proposed to update the eCQM Specifications collection type denominator exclusion to remove the term 'overlaps' and replace with plain language for clarity and to ensure consistency in implementation. Additionally, we proposed to update the value sets for the eCQM Specifications collection type to reflect the updates to the measure to align with current ACIP recommendations that all adults age 65 years and older receive one dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23). The MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection type will also be updated to only allow for the PPSV23 vaccine to suffice for numerator compliance. We proposed to update the numerator options for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for the receipt of the pneumococcal vaccine on or after the patient's 60th birthday or the documentation of medical reasons, such as an adverse reaction, to meet the quality action of this measure as it better aligns with current ACIP recommendations. Additionally, we proposed to update the MIPS CQMs Specifications and the Medicare Part B

Category	Description
	Claims Measure Specifications collection types by revising the Numerator Note in order to align with current ACIP recommendations and clarify that patient self-reporting is allowable for this measure's required clinical quality action.

Comment: One commenter stated that CMS indicated the updates to measure Q111: Pneumococcal Vaccination Status for Older Adults are intended to align with the current CDC's Advisory Committee on Immunization Practices (ACIP) recommendation that all adults aged 65 years and older receive one dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23).

However, the Pneumococcal Workgroup of the ACIP is currently reviewing the Pneumococcal Vaccine Recommendations and is expected to vote on a revised adult Pneumococcal Vaccine Recommendation in October 2021. A CDC MMWR with the finalized recommendation should be published in the months following the vote; therefore, a new recommendation is expected in early 2022. This may render the proposed measure changes out of alignment with the new guidelines almost immediately upon implementation in CY 2022.

Therefore, the commenter requested CMS to reconsider the proposed revisions at this time, and whether there will be unintended consequences of introducing new measure changes given it will likely not align with the forthcoming revised ACIP Pneumococcal Vaccine recommendation. Otherwise, the commenter requested CMS to consider how it will incorporate needed measure changes upon release of the revised ACIP recommendation in a timely fashion. The forthcoming ACIP Pneumococcal Vaccine Recommendation will be evaluating age-based and risk-based recommendations.

Response: We acknowledge that ACIP recommendations with regard to the pneumococcal vaccine may be revised in the year 2022. As currently specified, the measure does not fully align with current ACIP guidelines nor would it align with potential updated ACIP guidelines and therefore, requires revision for PY2022. The proposed revisions will allow the measure to work with any revisions in recommendation by ACIP as it gives credit to clinicians in situations where the PPSV23 vaccine is not administered due to medical reason(s), as long as there is documentation by the clinician. Each year the measures are reviewed and revised in accordance with updated clinical guidelines. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q111 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.12 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** 1. Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Palliative care services used by patient any time during the measurement period **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Patient reported mammograms, when recorded in the medical record, are acceptable for meeting the numerator. **For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We proposed to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component. Additionally, we proposed to add a numerator note to the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for patient self-report as this is appropriate to avoid overtreatment. We proposed to update the denominator exclusion language for the CMS Web Interface Measure Specifications collection type, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in this measures and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q112. After consideration of public comments, we are finalizing the changes to measure Q112 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.13 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** 1. Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** 1. Patient was provided palliative care services any time during the measurement period **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Patient reported procedures and diagnostic studies, when recorded in the medical record, are acceptable for meeting the numerator. **For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We proposed to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component. Additionally, we proposed to add a numerator note to the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for patient self-report as this is appropriate to avoid overtreatment. We proposed to update the denominator exclusion language for the CMS Web Interface Measure Specifications collection type, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in this measure and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q113. After consideration of public comments, we are finalizing the changes to measure Q113 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.14 Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis

Category	Description
NQF # / eCQM NQF #:	0058 / N/A
Quality#:	116
CMS eCQM ID:	N/A

Category	Description
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated denominator exclusion: Revised:** Acute bronchitis/bronchiolitis episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to the episode date. **Updated numerator instructions: Removed:** Ticarcillin clavulanate and Erythromycin sulfisoxazole from Table 1 - Antibiotic Medications
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion to clarify that all patients with active antibiotic prescriptions up to the time of the encounter should be excluded from the denominator eligible patient population. We proposed to update Table 1 – Antibiotic Medications to ensure the list includes current and appropriate medications for the purposes of this measure. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q116 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.15 Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality#:	117
CMS eCQM ID:	CMS131v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **The measure guidance is revised to read: For the eCQM Specifications collection type:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included. The eye exam must be performed by an ophthalmologist or optometrist, or there must be evidence that fundus photography results were read by a system that provides an artificial intelligence (AI) interpretation. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** 1. Palliative care services provided to patient any time during the measurement period **The measure numerator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients with an eye screening for diabetic retinal disease. This includes diabetics who had one of the following: • Diabetic with a diagnosis of retinopathy during the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period • Diabetic with no diagnosis of retinopathy during the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period or the year prior to the measurement period **The measure numerator note is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** The eye exam must be performed or reviewed by an ophthalmologist or optometrist, or there must be evidence that fundus photography results were read by a system that provides an artificial intelligence (AI) interpretation. Alternatively, results may be read by a qualified reading center that operates under the direction of a medical director who is a retinal specialist **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the description of the measure to remove the term 'overlaps' and replace with plain language for clarity and to ensure consistency in implementation. Additionally, we proposed to update the numerator for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to remove the terms 'overlaps' and 'overlapping' and replace with plain language for clarity and to ensure consistency in implementation. We proposed that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured.

Category	Description
	Additionally, we proposed to update the guidance for the eCQM Specifications collection type and numerator note for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for the use of artificial intelligence as it is applicable and clinically appropriate for numerator compliance for this measure. We proposed to revise the denominator note for the MIPS CQMs Specifications collection type and the numerator note for the Medicare Part B Claims Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component.

Comment: One commenter supported that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in these measures and supported CMS' proposal to add palliative care exclusions or exceptions. Another commenter supported the proposed change to clarify that the diagnosis must be active during the measurement period, rather than "overlapping the measurement period". This has been a long-standing source of confusion for people reporting this measure and this is a welcome clarification.

Response: We thank the commenters for their support of measure Q117 regarding the addition of a palliative care denominator exclusion and language to clarify timing of the denominator diagnosis.

Comment: For measure Q117: Diabetes: Eye Exam, one commenter cited the proposed revision of: "The eye exam must be performed by an ophthalmologist or optometrist, or there must be evidence that fundus photography results were read by a system that provides an artificial intelligence (AI) interpretation." The commenter recommended that a qualification be added to this revision requiring that an AI interpretation must be generated by an FDA-approved system to qualify. CMS proposed this revision to update the guidance to allow for the use of artificial intelligence as it is applicable and clinically appropriate for numerator compliance for this measure.

CMS proposed that the measure numerator note is revised to include the statement "Alternatively, results may be read by a qualified reading center that operates under the direction of a medical director who is a retinal specialist." The commenter believed that to maintain consistency and clarity, the measure guidance should include the CMS proposed additional statement directly above regarding the inclusion of a qualified reading center operating under a retinal specialist that is in the numerator note. In addition, the commenter recommended new language requiring use of an FDA-approved system when AI is referenced.

Response: We believe that allowing AI will increase the accessibility and therefore occurrence of yearly eye exams, leading to quality outcomes in this patient population (https://www.aao.org/eye-health/news/artificial-intelligence-trends-in-eye-care). While we agree that best practices would dictate the use of FDA-approved AI systems, that language is not currently included within the measure specification. This request has been communicated with the measure steward for future consideration. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter was concerned with the proposed revision to the measure numerator for the "Diabetes Eye Exam" quality measure that was proposed to indicate, "The eye exam must be performed by an ophthalmologist or optometrist, or there must be evidence that fundus photography results were read by a system that provides an artificial intelligence (AI) interpretation." The commenter stated that screenings with high sensitivity and specificity may help identify risk, which is a risk that only an in-person comprehensive eye examination can begin to valuate, mitigate, and/or address. Creating a measure where both a comprehensive eye exam, which is considered the gold standard of care, and an AI screening equally denote health care "quality" is not appropriate.

The commenter believes that a more appropriate approach may be to require that if an AI screening is used to meet the measure, the patient must have been identified as not being at risk for diabetic retinopathy. When AI screenings for diabetic retinopathy are used, if a patient is identified as being at risk for diabetic retinopathy, that patient is directed to a Doctor of Optometry or ophthalmologist for a comprehensive eye exam. For the quality measure, an AI screening conducted which identifies that the patient does not appear to be at risk for retinopathy would be a greater indicator of quality than just allowing the measure to be met just by acknowledging that the patient was screened for retinopathy without regard to the screening results.

The commenter suggested CMS to delay any changes to this quality measure for 2022 to evaluate commenters related to AI. Another alternative would be to develop a unique quality measure based on the use of AI to assess diabetic retinopathy.

Response: According to the AAO, it is estimated that 61 million adults in the United States are at high risk for vision loss although only half have visited an eye doctor sometime in the last 12 months. New technology, such as artificial intelligence, may be an important step to make initial screenings more convenient and accessible, reaching people who may have otherwise gone without. While it is not expected that artificial intelligence would replace physicians, it will increase efficiency. As artificial intelligence may be able to assist in the detection of diabetic retinopathy and macular degeneration, it may help to catch those patients that are currently being missed for this extremely important examination (https://www.aao.org/eye-health/news/artificial-intelligence-trends-in-eye-care). We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q117 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.16 Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality#:	119
CMS eCQM ID:	CMS134v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **Updated value set/coding: For the eCQM Specifications collection type: Removed:** coding related to transplant donors from "Kidney Transplant" (2.16.840.1.113883.3.464.1003.109.12.1012) value set. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications collection types:** **Added:** 1. Patients who use palliative care services any time during the measurement period
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. Additionally, we proposed to update the "Kidney Transplant" value set to remove coding related to kidney transplant donors as it would be appropriate for these patients to still receive a screening for nephropathy. We proposed to revise the denominator note for the MIPS CQMs Specifications collection type to clarify the timing for those exclusions that have an age-related component.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in this measure and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q119. After consideration of public comments, we are finalizing the changes to measure Q119 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.17 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	128
CMS eCQM ID:	CMS69v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.
Substantive Change:	**The measure denominator exclusion is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** 1. Documentation stating the patient has received or is currently receiving palliative or hospice care 2. Documentation of patient pregnancy anytime during the measurement period prior to and including the current encounter
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusions to increase clarity and add specificity to ensure the appropriate patient population is being excluded from the assessment of the quality action.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in this measure and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q128. After consideration of public comments, we are finalizing the changes to measure Q128 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.18 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**The measure description is revised to read: For the CMS Web Interface Measure Specifications collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **The measure guidance is revised to read: For the eCQM Specifications collection type:** The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the diagnosis or treatment of depression. This measure does not require documentation of a specific score, just whether results of the normalized and validated depression screening tool used are considered positive or negative. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. This eCQM is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. Screening Tools: * An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. * The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. * The depression screening must be reviewed and addressed by the provider filing the code, on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. * The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter. * The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. In order to satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Follow-Up Plan: The follow-up plan must be related to a positive depression screening, for example: "Patient referred for psychiatric evaluation due to positive depression screening." Examples of a follow-up plan include but are not limited to: * Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression * Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Should a patient screen positive for depression: * A clinician should only order pharmacological intervention when appropriate and after sufficient diagnostic evaluation. However, for the purposes of this measure, additional screening and assessment during the qualifying encounter will not qualify as a follow-up plan. * A clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool will not qualify as a follow-up plan. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **For the CMS Web Interface Measure Specifications collection type:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. This is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. This measure does not require documentation of a specific score, just whether results of the normalized and validated depression screening tool used are considered positive or negative. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. Screening Tools: * An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. * The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record * The depression screening must be reviewed and addressed by the provider, filing the code, on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention

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	as determined by the provider practice * The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter * The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Follow-Up Plan: The follow-up plan must be related to a positive depression screening, for example: "Patient referred for psychiatric evaluation due to positive depression screening." Examples of a follow-up plan include but are not limited to: * Referral to a provider practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression * Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Should a patient screen positive for depression, a clinician should: *Only order pharmacological intervention when appropriate and after sufficient diagnostic evaluation. However for the purposes of this measure, additional screening and assessment during the qualifying encounter will not qualify as a follow-up plan. *Opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool will not qualify as a follow-up plan. **Updated guidance denominator: For the CMS Web Interface Measure Specifications collection type: Revised:** The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Revised:** Patients who have been diagnosed with depression or with bipolar disorder. **The measure numerator instructions are revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Numerator Instructions: A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. This is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. This measure does not require documentation of a specific score, just whether results of the normalized and validated depression screening tool used are considered positive or negative. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. The depression screening must be reviewed and addressed by the provider on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. In order to satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Should a patient screen positive for depression, a clinician should: • Only order pharmacological intervention when appropriate and after sufficient diagnostic evaluation. However, for the purposes of this measure, additional screening and assessment during the qualifying encounter will not qualify as a follow-up plan. • Opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool, will not qualify as a follow-up plan **Updated definitions (numerator): For the CMS Web Interface Measure Specifications collection type: Revised:** Follow-Up Plan: Documented follow-up for a positive depression screening must include one or more of the following: • Referral to a provider for additional evaluation and assessment to formulate a follow-up plan for a positive depression screen • Pharmacological interventions • Other interventions or follow-up for the diagnosis or treatment of depression **Updated numerator submission guidance: For the CMS Web Interface Measure Specifications collection type: Removed:** If recommended follow-up is additional evaluation or assessment, the additional evaluation or assessment must occur at the eligible encounter. **Revised:** Submission Guidance: Numerator Submission, Guidance Note: Use most recent screening for depression which occurred either during the encounter or up to 14 days prior to the encounter

Category	Description
	Although the patient may have access to the depression screening tool in advance of the encounter, the depression screening results must be documented on the date of the encounter. The results must be reviewed/verified and documented by the eligible professional in the medical record on the date of the encounter to meet the screening portion of this measure. **Updated numerator option: For the CMS Web Interface Measure Specifications collection type: Revised:** Medical Reason(s) Documentation of medical reason for not screening patient for depression (e.g., cognitive, functional, or motivational limitations that may impact accuracy of results; patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status)
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications and CMS Web Interface Measure Specifications collection types guidance section to remove the requirement for an in-office review of the assessment as it is appropriate to allow this to be completed via telehealth encounter, clarify requirements as only documentation of a negative or positive depression screening is needed to align with the intent of the measure, and revise the numerator compliant follow-up plans based on stakeholder feedback to ensure clinical appropriateness. We proposed to update the CMS Web Interface Measure Specification collection type description, guidance sections, definitions, and numerator sections to provide clarity as to what constitutes a follow-up plan. Additionally, language throughout the measure specification was updated allowing for alignment with clinical workflow. The measure assesses the most recent depression screening completed either during the encounter or up to 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening to count towards a follow-up, since that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Additionally, suicide risk assessments have been removed as a numerator compliant follow-up plan option as this should be completed when appropriate and based on the assessment by the clinician regarding the severity of the patient's symptoms of depression at the time of depression screening. We also proposed to update the measure language and denominator exclusions to reflect that this measure is screening of depression for patients who have not been previously diagnosed or have an active diagnosis of depression or bipolar disorder. This preventive measure assesses screening and follow up plan for patients that are screened positive for depression. The denominator exception was revised in order to streamline the language. We proposed to update the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types numerator instructions to clarify requirements as only documentation of a negative or positive depression screening is needed to align with the intent of the measure and revise instructions for the numerator compliant follow-up plans based on stakeholder feedback to ensure clinical appropriateness.
Comment: One commenter stated that measure Q134 includes a denominator exclusion for any patient that has received hospice services at any time during the measurement period, but it does not include denominator exclusion for patients receiving palliative care. Many Medicare beneficiaries utilize palliative care prior to or in lieu of hospice care to promote quality of life and comfort near the end of life. Beneficiaries often choose palliative care over hospice care in order to continue to receive treatment or therapy that may improve their quality of life. The commenter supported this patient-centered care and requested that CMS include a palliative care exclusion for this measure to reflect that this service is regularly utilized in populations with high mortality rates, such as a long-term care institutional population. **Response:** We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, we are finalizing the changes to measure Q134 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.19 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v10
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**The measure guidance is revised to read: For the eCQM Specifications collection type:** This eCQM is an episode-based measure. An episode is defined as each eligible encounter for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face or telehealth interaction. Due to the nature of some applicable coding related to radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face or telehealth encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face or telehealth encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face or telehealth encounter occurring on the actual billing date or within the 6 days prior to the billing date. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face or telehealth encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy on the same day as the encounter or during the 30 days before the date of the encounter AND during the 30 days after the date of the encounter. Pain intensity should be quantified using a standard instrument, such as a 0-10 numerical rating scale, visual analog scale, a categorical scale, or pictorial scale. Examples include the Faces Pain Rating Scale and the Brief Pain Inventory (BPI). This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM **Updated value set/coding: For the eCQM Specifications collection type: Removed:** Topical chemotherapy from value set "Chemotherapy Administration" (2.16.840.1.113883.3.526.3.1027) and coding for neurofibromatosis from value set "Cancer" (2.16.840.1.113883.3.526.3.1010). **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** **Removed:** Submission critiera one coding related to neurofibromatosis. **Revised:** Patient procedure on or within 30 days before denominator eligible encounter AND Patient procedure on or within 30 days after denominator eligible encounter **Updated instructions: For the MIPS CQMs Specifications collection type: Revised:** NOTE: For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter, where the patient and physician have a face-to-face or telehealth interaction. Due to the nature of some applicable coding related to the radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face or telehealth encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face or telehealth encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face or telehealth encounter occurring on the actual billing date or within the 6 days prior to the billing date. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face or telehealth encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy on the same day as the encounter or during the 30 days before the date of the encounter AND during the 30 days after the date of the encounter
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the eCQM Specifications guidance section to align the statement regarding timing of chemotherapy to ensure alignment with the logic timing constraints and added language for telehealth encounters as they are appropriate for inclusion for assessment of quality action completion. Additionally, we proposed to remove topical chemotherapy from the "Chemotherapy Administration" value set and neurofibromatosis from the "Cancer" (2.16.840.1.113883.3.526.3.1010) value set as these patient populations are not appropriate for inclusion within the initial patient population for the purposes of clinical quality action assessment. We proposed to remove coding related to neurofibromatosis from the MIPS CQMs Specifications collection type denominator criteria for Submission Criteria One as this patient population is not appropriate for inclusion with the denominator eligible patient population for the purposes of clinical quality action assessment. Additionally, the denominator criteria was revised to clarify the timing of the chemotherapy and align with the intent of the measure. We proposed to update the MIPS CQMs Specifications collection type instructions note to add clarity in timing of chemotherapy and ensure alignment throughout the measure specification in accordance with measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q143 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.20 Tuberculosis Screening Prior to First Course Biologic Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**Updated denominator instructions:** **Revised:** Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and also have not been prescribed DMARD biologic therapy in the 15 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes **Added:** Guselkumab (Tremfya), Infliximab-axxq (Avsola), Ixekizumab (Taltz), Upadacitinib (RINVOQ) **Added:** To be included in the denominator, patient must have an encounter and a prescription for DMARD biologic therapy in the measurement period (1/1/2022-12/31/2022) WITHOUT a prior prescription for DMARD biologic therapy within the 15 months prior to the DMARD prescribed during the measurement period. **Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator instructions to include a 15-month lookback period in response to stakeholder feedback to align with clinical workflow for more established patients and to add clarity regarding the denominator eligible patient population. Additionally, the medications list was updated to align with current DMARD medications available to treat rheumatic disease. We proposed to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians. This revision is not a reflection of any policy update and was made to allow those clinicians who bill exclusively through a FQHC to track their performance on the measure. This payment method is still not eligible for payment adjustments under MIPS.

Comment: As indicated in comments on the removal of measure Q337 (Table C.15), one commenter stated that the proposed revisions to measure Q176 would mean that denominator population would overlap with measure Q337. Instead of the measure being specific to rheumatoid arthritis (measure Q176) or psoriasis patients (measure Q337), it looks to assess all patients prescribed a first course biologic DMARD therapy. The revision to measure Q176 does not sufficiently cover the patients that dermatologists treat or the medications that are used, as are currently reported under Q337. If measures Q176 and Q337 are to be combined, to avoid confusion and to be as inclusive as possible, the commenter prefers that a new number and title be assigned.

The commenter suggested CMS again to make the following edits to measure Q176:

- The new measure should be added to the Dermatology Specialty Set.
- The description must explicitly include psoriasis and psoriatic arthritis.
- The language in the denominator should be modified so that its more inclusive and does not specify "anti-rheumatic therapy." DMARDs is not a term used by most dermatologists. This should be listed as "biologic immune response modifier".
- The list of medications should be expanded to include biologics dermatologists use and that are included in measure Q337.
- The new measure must be applicable to all patients regardless of age.
- Additional biologics to be added to the list of covered therapies.

Response: While we acknowledge that these revisions may not perfectly align with what is specific to dermatology, it is important to ensure duplicative measures are removed from the MIPS program in accordance with the Meaningful Measures Initiative as this ensures clinicians are not utilizing one quality action to achieve numerator compliance for multiple measures. The denominator eligible patient population is not limited to a diagnosis(es) in order to allow a broad range of clinician types to submit it as different specialties utilize biologic therapies for the treatment of their patients. Regardless of the diagnosis, clinical recommendations support tuberculosis screening prior to the initiation of a biologic therapy for patient safety, and therefore should not be limited to patients suffering from psoriasis and psoriatic arthritis. The denominator criteria would apply to any patients aged 18 years and older receiving one of the listed biologic therapies for the first time (or have not been prescribed in the 15 months preceding the encounter where a biologic was newly started). This request has been communicated with the measure steward for future consideration. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q176 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.20 Tuberculosis Screening Prior to First Course Biologic Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**Updated denominator instructions:** **Revised:** Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and also have not been prescribed DMARD biologic therapy in the 15 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes **Added:** Guselkumab (Tremfya), Infliximab-axxq (Avsola), Ixekizumab (Taltz), Upadacitinib (RINVOQ) **Added:** To be included in the denominator, patient must have an encounter and a prescription for DMARD biologic therapy in the measurement period (1/1/2022-12/31/2022) WITHOUT a prior prescription for DMARD biologic therapy within the 15 months prior to the DMARD prescribed during the measurement period. **Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator instructions to include a 15-month lookback period in response to stakeholder feedback to align with clinical workflow for more established patients and to add clarity regarding the denominator eligible patient population. Additionally, the medications list was updated to align with current DMARD medications available to treat rheumatic disease. We proposed to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians. This revision is not a reflection of any policy update and was made to allow those clinicians who bill exclusively through a FQHC to track their performance on the measure. This payment method is still not eligible for payment adjustments under MIPS.

Comment: As indicated in comments on the removal of measure Q337 (Table C.15), one commenter stated that the proposed revisions to measure Q176 would mean that denominator population would overlap with measure Q337. Instead of the measure being specific to rheumatoid arthritis (measure Q176) or psoriasis patients (measure Q337), it looks to assess all patients prescribed a first course biologic DMARD therapy. The revision to measure Q176 does not sufficiently cover the patients that dermatologists treat or the medications that are used, as are currently reported under Q337. If measures Q176 and Q337 are to be combined, to avoid confusion and to be as inclusive as possible, the commenter prefers that a new number and title be assigned.

The commenter suggested CMS again to make the following edits to measure Q176:

- The new measure should be added to the Dermatology Specialty Set.
- The description must explicitly include psoriasis and psoriatic arthritis.
- The language in the denominator should be modified so that its more inclusive and does not specify "anti-rheumatic therapy." DMARDs is not a term used by most dermatologists. This should be listed as "biologic immune response modifier".
- The list of medications should be expanded to include biologics dermatologists use and that are included in measure Q337.
- The new measure must be applicable to all patients regardless of age.
- Additional biologics to be added to the list of covered therapies.

Response: While we acknowledge that these revisions may not perfectly align with what is specific to dermatology, it is important to ensure duplicative measures are removed from the MIPS program in accordance with the Meaningful Measures Initiative as this ensures clinicians are not utilizing one quality action to achieve numerator compliance for multiple measures. The denominator eligible patient population is not limited to a diagnosis(es) in order to allow a broad range of clinician types to submit it as different specialties utilize biologic therapies for the treatment of their patients. Regardless of the diagnosis, clinical recommendations support tuberculosis screening prior to the initiation of a biologic therapy for patient safety, and therefore should not be limited to patients suffering from psoriasis and psoriatic arthritis. The denominator criteria would apply to any patients aged 18 years and older receiving one of the listed biologic therapies for the first time (or have not been prescribed in the 15 months preceding the encounter where a biologic was newly started). This request has been communicated with the measure steward for future consideration. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q176 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.21 Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF # / eCQM NQF #:	2523 / N/A
Quality#:	177
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q177 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.22 Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	178
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q178 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.23 Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	180
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q180 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.24 Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type. **Updated numerator definition: Added:** EAT-10: A Swallowing Screening Tool, Health Partners Hearing Assessment and Tinneti Performance Oriented Mobility Assessment (POMA) as eligible standardized tools. **Revised:** Standardized Tool definition note to include speech and language capacity. Functional Outcome Deficiencies – Impairment or loss of function related to musculoskeletal/neuromusculoskeletal capacity, including but are not limited to: restricted flexion, extension and rotation, back pain, neck pain, pain in the joints of the arms or legs, and headaches OR Impairment or loss of function related to speech and language capacity, including but not limited to: swallowing, hearing, and balance disorders
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type. We proposed to update the numerator definition to include concepts of swallowing, hearing, and balance to the measure as it is appropriate to assess this patient population for impairment or loss of function and create a follow-up plan of care based upon any identified loss of function or impairment. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.

Comment: One commenter supported the addition of swallowing to measure Q182: Functional Outcome Assessment. Occupational therapists often treat patients with swallowing and feeding dysfunction. The commenter did not support removing the Medicare Part B Claims Specification collection type as many small therapy practices are still reporting via claims and there is currently a limited number of high priority measures available in this specialty set. Another commenter supported the proposed update to the measure numerator for measure Q182: Functional Outcomes Assessment but suggested the following revisions for clarity:

- Added: Health Partners Hearing Assessment and Tinneti Performance Oriented Mobility Assessment (POMA) as an eligible standardized tool.
- Revised: Standardized Tool definition note to include speech and language capacity. Functional Outcome Deficiencies – Impairment or loss of function related to speech and language capacity, including but not limited to swallowing, **OR impairment or loss of function related to hearing and/or balance disorders**~~. hearing, and balance disorders.~~[2] (Note, request to add the Bold text and remove the strikethrough text).

The commenter also encouraged CMS to maintain the Medicare Part B Claims Specifications collection type.

The commenter also believes that measure Q182 should remain limited to a subset of audiology codes for vestibular function, including:

- CPT 92540 (Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal and peripheral stimulation, with recording, and oscillating tracking test, with recording);
- CPT 92542 (Positional nystagmus test, minimum of 4 positions, with recording);
- CPT 92546 (Sinusoidal vertical axis rotational testing - rotary chair);
- CPT 92548 (Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (i.e., eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway) including interpretation and report).

These CPT codes represent audiology procedures that are most consistent with the functional capacity of patients referenced in measure Q182.

Response: We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years.

The Medicare Part B Claims Measure Specifications collection type has reached the end of the topped-out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2021 Benchmark File.

After consideration of public comments, we are finalizing the changes to measure Q182 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.25 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v10

Category	Description
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type: Added:** coding for homonymous bilateral field defects and generalized contraction of visual field to the "Visual Field Defects" (2.16.840.1.113883.3.526.3.1446) value set and coding for disorders of visual cortex in (due to) inflammatory disorders to the "Disorders of Visual Cortex" (2.16.840.1.113883.3.526.3.1458) value set. **Updated denominator exclusion: For all collection types:** **Removed:** episcleritis. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type:** **Added:** diagnoses codes to the Significant Ocular Conditions 'Visual Fields Defects' for sector or arcuate defects, other localized visual field defect, homonymous and heteronymous bilateral field defects, and generalized contraction of visual field.
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the eCQM Specifications collection type denominator exclusion coding to add appropriate coding for other relevant "disorders of visual field defects" and "disorders of visual cortex" diagnosis codes as these patients should not be included in the initial patient population for the assessment of the clinical quality action. The denominator exclusion coding was updated for all collection types removing diagnosis of episcleritis as a denominator exclusion as the measure steward's Technical Expert Panel (TEP) advised that this would not affect central visual acuity and as such, should not be a criteria for denominator exclusion as it would be appropriate for these patients to be assessed for best-corrected visual acuity following cataract surgery. We proposed to update the denominator exclusion for the MIPS CQMs Specifications collection type to include appropriate coding for conditions to ensure the appropriate patient population is being included in the eligible denominator patient population for assessment of the clinical quality action.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q191 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.26 Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The measure description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure description to align language across Focus on Therapeutic Outcomes, Inc. (FOTO) measures in order to provide clarity to clinicians.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q217 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.27 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The measure description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient- reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure description to align language across Focus on Therapeutic Outcomes, Inc. (FOTO) measures in order to provide clarity to clinicians.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q219 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.28 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. **For the CMS Web Interface Measure Specifications collection type:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months. **Updated guidance:** **For the eCQM Specifications collection type: Revised:** To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the measurement period. If a patient has multiple tobacco use screenings during the measurement period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. **For the CMS Web Interface Measure Specifications collection type: Revised:** To reflect a shortened timeframe of 12 months. **Updated value set/coding: For the eCQM Specifications and CMS Web Interface Measure Specifications collection type:** **Removed:** passive smoker from "Tobacco User" (2.16.840.1.113883.3.526.3.1170) value set. **The measure instructions are revised to read: For the MIPS CQMs Specifications collection types:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. For implementation of the measure, the denominator eligible encounter should be used to determine if the numerator action for the tobacco cessation intervention was performed within the 12 month look back period from the date of the denominator eligible encounter. This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period 2) Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months 3) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months **For the Medicare Part B Claims Measure Specifications collection types:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. For implementation of the

Category	Description
	measure, the denominator eligible encounter should be used to determine if the numerator action for the tobacco cessation intervention was performed within the 12 month look back period from the date of the denominator eligible encounter. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period 2) Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months 3) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months **Updated submission criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** The language "on the date of the encounter or within the previous 12 months" to submission criteria 2 and 3. **Updated numerator: For the eCQM Specifications collection types: Revised:** NUMERATOR (SUBMISSION CRITERIA 1): Patients who were screened for tobacco use at least once within the measurement period NUMERATOR (SUBMISSION CRITERIA 3): Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user **For the MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications, and CMS Web Interface Measure Specifications collection types: Revised:**NUMERATOR (SUBMISSION CRITERIA 1): Patients who were screened for tobacco use at least once within the measurement period NUMERATOR (SUBMISSION CRITERIA 2): Patients who received tobacco cessation intervention on the date of the encounter or within the previous 12 months NUMERATOR (SUBMISSION CRITERIA 3): Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Replaced "12 months" with "the measurement period" for submission criteria 1 and 3. **Added:** The language "on the date of the encounter or within the previous 12 months" to submission criteria 2 and 3 in reference to tobacco cessation intervention. **Updated guidance numerator note: For the CMS Web Interface Measure Specifications collection type: Updated:** Revised language to reflect that the tobacco screening is once per performance period and tobacco cessation intervention if necessary must be completed during the encounter or previous 12 months. **Updated numerator options: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Submission Criteria 2: **Performance Met:** Patient identified as a tobacco user received tobacco cessation intervention on the date of the encounter or within the previous 12 months (counseling and/or pharmacotherapy) **Denominator Exception:** Documentation of medical reason(s) for not providing tobacco cessation intervention on the date of the encounter or within the previous 12 months (e.g., limited life expectancy, other medical reason) **Performance Not Met:** Patient identified as tobacco user did not receive tobacco cessation intervention on the date of the encounter or within the previous 12 months (counseling and/or pharmacotherapy), reason not given Submission Criteria 3: **Denominator Exception:** Documentation of medical reason(s) for not providing tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user (e.g., limited life expectancy, other medical reason)
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the language for the MIPS CQMs Specifications, the Medicare Part B Measure Specifications, and CMS Web Interface Measure Specifications collection types to clarify the timing for tobacco use screening and tobacco cessation intervention for those patients identified as tobacco users. The intent of the measure is to ensure all patients are screened for tobacco use on an annual basis (each performance period) and receive tobacco cessation intervention, if identified as a tobacco user on the date of the encounter or within the previous 12 months. We proposed to update the eCQM Specifications collection type to reflect that both the tobacco use screening and tobacco use intervention for those patients identified as tobacco users should occur annually (each performance period). We understand that causes a slight misalignment between the different collection types, which is due to the annual update timeline differences between the collection types. This misalignment will be reviewed in future annual update cycles. Additionally, we proposed to update the eCQM Specifications and CMS Web Interface Measure Specifications collection type to "Tobacco User" value set to remove passive smoker coding as these patients are not appropriate for inclusion in the tobacco user identified patient population as they do not meet the intent of the measure and the clinical quality action would not be applicable to them. In the event the proposed substantive change(s) are finalized, for the CMS Web Interface Measure Specifications collection type, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of the substantive changes. Under MIPS, the CMS Web Interface measures are scored in comparison to quality measure benchmarks established under the Medicare Shared Savings Program. The benchmarks established for the CMS Web Interface measures are based on historical data. If a benchmark is able to be established for a CMS

Category	Description
	Web Interface measure with the proposed substantive changes, then such benchmark would be used for scoring purposes. If a benchmark is not able to be established for a CMS Web Interface measure, then the following would apply for such CMS Web Interface measure: excluded from MIPS scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the data completeness requirement is met and the applicable measure data is submitted via the CMS Web Interface.

Comment: Several commenters stated that if all substantive changes are finalized as proposed it will likely mean these measures will be capped at 3 points as they would not have a historical benchmark for comparison. This means that the majority of dermatology measures available within this specialty set are not eligible to score up to 10 full points and therefore is significantly limiting a clinician's ability to score well in the Quality category. The commenters specifically mentioned this in relation to substantive changes proposed for measures Q226, Q238, Q265, Q317, and Q374.

Response: The substantive changes above would only impact the CMS Web Interface Measure Specifications collection type benchmark. Under MIPS, the CMS Web Interface measures are scored in comparison to quality measure benchmarks established under the Medicare Shared Savings Program. The benchmarks established for the CMS Web Interface measures are based on historical data. If a benchmark is able to be established for a CMS Web Interface measure with the proposed substantive changes, then such benchmark would be used for scoring purposes. If a benchmark is not able to be established for a CMS Web Interface measure, then the following would apply for such CMS Web Interface measure: excluded from MIPS scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the data completeness requirement is met and the applicable measure data is submitted via the CMS Web Interface. There would be no policy related impacts to the benchmark for the eCQM Specifications, MIPS CQMs Specifications, or Medicare Part B Claims Measure Specifications collection types.

After consideration of public comments, we are finalizing the changes to measure Q226 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.29 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients 81 and older with an indication of frailty for any part of the measurement period. 2. Exclude patients receiving palliative care during the measurement period. **Revised:** Logic to allow ESRD encouncter to be on or before the end of the measurement period. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** 1. Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. 2. Patients 66 – 80 years of age with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. 3. Patients 66 - 80 years of age with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. **Added:** 1. Patients 81 years of age and older with at least one claim/encounter for frailty during the measurement period. **Updated value set/coding: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types:** **Revised:** "Pregnancy" (2.16.840.1.113883.3.526.3.378) value set to more accurately capture pregnancy state. **Removed:** coding related to transplant donors from "Kidney Transplant" (2.16.840.1.113883.3.464.1003.109.12.1012) value set. **The measure guidance is revised to read: For the eCQM Specifications collection type:** In reference to the numerator element, only blood pressure readings performed by a clinician or a remote monitoring device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by a remote monitoring device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the remote monitoring device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. Do not include BP readings: -Taken during an acute inpatient stay or an ED visit -Taken on the same day as a diagnostic test or diagnostic or therapeutic procedure that requires a change in diet or change in medication on or one day before the day of the test or procedure, with the exception of fasting blood tests. -Taken by the patient using a non-digital device such as with a manual blood pressure cuff and a stethoscope. If no blood pressure is recorded during the measurement period, the patient's blood pressure is assumed "not controlled." If there are multiple blood pressure readings on the same day, use the lowest systolic and the lowest diastolic reading as the most recent blood pressure reading. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure initial patient population is revised to read: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types:** Patients 18-85 years of age who had a visit and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period.

Category	Description
	The measure denominator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Patients 18-85 years of age who had a visit and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Palliative care services given to patient any time during the measurement period **Updated denominator confirmation: For the CMS Web Interface Measure Specifications collection type: Revised:** The language to reflect the diagnosis for essential hypertenision must start before and continue into, or start during the first six months of the measurement period. **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Revised:** The diagnosis of essential hypertension must be present some time between 1 year prior to the measurement period and the first six months of the measurement period (January 1, 2021 - June 30, 2022). **For the MIPS CQMs Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **The measure instructions note, numerator note, and narrative guidance are revised to read: For the MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications, and CMS Web Interface Measure Specifications collection types:** In reference to the numerator element, only blood pressure readings performed by a clinician or a remote monitoring device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by a remote monitoring device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the remote monitoring device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. Do not include BP readings: • Taken during an acute inpatient stay or an ED visit • Taken on the same day as a diagnostic test or diagnostic or therapeutic procedure that requires a change in diet or change in medication on or one day before the day of the test or procedure, with the exception of fasting blood tests. BP readings taken on the same day that the member receives a common low-intensity or preventive procedure are eligible for use. For example, the following procedures are considered common low intensity or preventive (this list is just for reference, and is not exhaustive): • Vaccinations. • Injections (e.g., allergy, vitamin B-12, insulin, steroid, toradol, Depo-Provera, testosterone, lidocaine). • TB test. • IUD insertion. • Eye exam with dilating agents. • Wart or mole removal. • Taken by the patient using a non-digital device such as with a manual blood pressure cuff and a stethoscope. If no blood pressure is recorded during the measurement period, the patient's blood pressure is assumed "not controlled." If there are multiple blood pressure readings on the same day, use the lowest systolic and the lowest diastolic reading as the most recent blood pressure reading. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the measure description to remove the term 'overlapping' and add clarity to the timing associated with the hypertension diagnosis. We proposed that the denominator exclusion language be updated for all but the CMS Web Interface Measure Specifications collection type to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replace with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We proposed to update the CMS Web Interface Measure Specifications collection type denominator exclusions language to clarify that, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the CMS Web Interface Measure Specifications collection type denominator exclusions, we proposed to update the ages for the frailty and advanced illness exclusions and add an exclusion specific to those patients 81 years and older to ensure the appropriate patients are being assessed for the quality action. We proposed to update the eCQM Specifications and CMS Web Interface Measure Specifications collection types "Pregnancy" value set to more accurately capture the state of pregnancy to ensure the denominator exclusion is being applied to the correct patient population and revised the logic for the end stage renal disease (ESRD) encounter to align with the intent of the measure.

Category	Description
	Additionally, we proposed to update the "Kidney Transplant" value set to remove coding related to kidney transplant donors as it would be appropriate for these patients to still be assessed for blood pressure control if diagnosed with essential hypertension. We proposed to revise the eCQM Specifications guidance section to provide clarification that patient obtained blood pressure readings captured via non-digital devices are not acceptable for this measure as they may not provide an accurate reading and therefore do not meet the intent of the measure, as well as the addition of clarifying language for what suffices as an acceptable blood pressure reading. Additionally, we proposed to update the initial patient population for the eCQM Specifications collection type to align with clarification for the timing of the hypertension diagnosis. We proposed to update the MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications, and CMS Web Interface Measure Specifications collection types denominator, denominator note, and denominator confirmation to align with clarification for the timing of the hypertension diagnosis. Additionally for the MIPS CQMs Specifications, the Medicare Part B Claims Measure Specifications, and the CMS Web Interface Measure Specifications collection types, we proposed to update the instructions note, numerator note, and narrative guidance to better clarify acceptable blood pressure readings for the purposes of clinical quality action assessment and examples of low intensity or preventive procedures that would not preclude the use of a blood pressure reading from that day or the day prior. We proposed to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component.

Comment: One commenter stated measure Q236 includes a denominator exclusion for any patient that has received hospice services at any time during the measurement period, but it does not include denominator exclusion for patients receiving palliative care. Many Medicare beneficiaries utilize palliative care prior to or in lieu of hospice care to promote quality of life and comfort near the end of life. Beneficiaries often choose palliative care over hospice care in order to continue to receive treatment or therapy that may improve their quality of life. The commenter supported this patient-centered care and requests that CMS/QPP include a palliative care exclusion for this measure to reflect that this service is regularly utilized in populations with high mortality rates, such as a long-term care institutional population.

Another commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in these measures and supported CMS' proposal to add palliative care exclusions or exceptions.

Response: We agree that this patient population is not appropriate for assessment of the clinical quality action within this measure.

After consideration of public comments, we are finalizing the changes to measure Q236 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.30 Use of High-Risk Medications in Older Adults

Category	Description
NQF # / eCQM NQF #:	0022/ N/A
Quality#:	238
CMS eCQM ID:	CMS156v10
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.
Substantive Change:	**The measure description is revised to read:** **For the eCQM Specifications collection type:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. Three rates are reported. 1. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. 2. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class, except for appropriate diagnoses. 3. Total rate (the sum of the two numerators divided by the denominator, deduplicating for patients in both numerators). **For the MIPS CQMs Specifications collection type:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. **Updated definition: For the eCQM Specifications collection type: Added:** Index prescription start date. The start date of the earliest prescription ordered for a high-risk medication during the measurement period. **The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients receiving palliative care during the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Removed:** the 90-day supply criterion to the non-benzodiazepine hypnotics. **Updated value set/coding: For the eCQM Specifications collection type:** **Added:** drug classes methscopeolamine and pyrilamine. **Removed:** drug class Diphenhydramine hydrochloride. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Rate 1: Patients with at least two orders of the same high-risk medication to avoid from the same drug class. Rate 2: Patients with at least two orders of high-risk medications from the same medication class (i.e., antipsychotics and benzodiazepines), except for appropriate diagnoses. Total rate (the sum of the two previous numerators, deduplicated). **Updated numerator exclusion: For the eCQM Specifications collection type: Added:** Rate 2: For patients with two or more antipsychotic prescriptions ordered, exclude patients who did have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the Index Prescription Start Date (IPSD) for antipsychotics. For patients with two or more benzodiazepine prescriptions ordered, exclude patients who did have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated instructions: For the MIPS CQMs Specifications collection type:** **Added:** This measure will be calculated with 2 performance rates: 1. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. 2. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class, except for appropriate diagnoses. For accountability reporting in the CMS MIPS program, the rate for submission criteria 1 is used for performance. **The measure denominator is revised to read: For the MIPS CQMs Specifications collection type:** SUBMISSION CRITERIA 1: PERCENTAGE OF PATIENTS 65 YEARS OF AGE AND OLDER WHO WERE ORDERED AT LEAST TWO HIGH-RISK MEDICATIONS FROM THE SAME DRUG CLASS Denominator (Submission Criteria 1): Patients 65 years and older who had a visit during the measurement period SUBMISSION CRITERIA 2: PERCENTAGE OF PATIENTS 65 YEARS OF AGE AND OLDER WHO WERE ORDERED AT LEAST TWO HIGH-RISK MEDICATIONS FROM THE SAME DRUG CLASS, EXCEPT FOR APPROPRIATE DIAGNOSES Denominator (Submission Criteria 2): Patients 65 years and older who had a visit during the measurement period **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Added:** Submission Criteria 2 Denominator Criteria: Patient aged ≥ 65 years on date of encounter. Patient encounter during performance period (in alignment with submission criteria 1). Denominator exclusions for hospice and palliative care during the measurement period. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Added:** Submission Criteria 1: Patients receiving palliative care during the measurement period.

Category	Description
	The measure numerator is revised to read: For the MIPS CQMs Specifications collection type: Numerator (Submission Criteria 1): Patients ordered at least two high-risk medications from the same drug class during the measurement year. Numerator (Submission Criteria 2): Patients with at least two orders of high-risk medications from the same drug class (i.e., antipsychotics and benzodiazepines), except for appropriate diagnoses. **Updated numerator definition: For the MIPS CQMs Specifications collection type: Revised:** Numerator (Submission Criteria 1): Definitions: The intent of the measure is to assess if the eligible clinician ordered high-risk medication(s).The intent of the numerator is to assess if the patient has either been ordered: • At least two high-risk medications from the same drug class (grouped by row) in Table 1 on different dates of service, or • At least two high-risk medications from the same drug class (grouped by row) in Table 2 on different dates of service, where the sum of days supply exceeds 90 days If the patient had a high-risk medication previously prescribed by another provider, they would not be counted towards the numerator unless the submitting provider also ordered a high-risk medication for them from the same drug class. Cumulative Medication Duration – an individual's total number of medication days over a specific period; the period counts multiple prescriptions with gaps in between, but does not count the gaps during which a medication was not dispensed. To determine the cumulative medication duration, determine first the number of the Medication Days for each prescription in the period: the number of doses divided by the dose frequency per day. Then add the Medication Days for each prescription without counting any days between the prescriptions. For example, there is an original prescription for 30 days with 2 refills for thirty days each. After a gap of 3 months, the medication was ordered again for 60 days with 1 refill for 60 days. The cumulative medication duration is (30 x 3) + (60 x 2) = 210 days over the 10 month period. Table 1 - High-Risk Medications at any dose or duration: **Removed:** Orphenadrine from Anticholinergics, first-generation antihistamines **Revised:** Antithrombotics – Dipyridamole, oral short-acting **Added:** Nonbenzodiazepine hypnotics – Eszopiclon, Zolpidem, Zaleplon Table 2 - High-Risk Medications With Days Supply Criteria **Removed:** Nonbenzodiazepine hypnotics **Added:** Numerator (Submission Criteria 2): Definitions: The intent of the numerator is to assess if the patient has been ordered at least two high-risk medications form the same drug class (grouped by row) in Table 3 on different dates or service. The intent of the measure is to assess if the submitting provider ordered the high-risk medication(s). If the patient had a high-risk medication previously prescribed by another provider, they would not be counted towards the numerator unless the submitting provider also ordered a high-risk medication for them from the same drug class. Index Prescription Start Date - the start date of the earliest prescription ordered for a high-risk medication during the measurement period. Table 3 - High-Risk Medications: Antipsychotics, first (conventional) and second (atypical) generation and Benzodiazepines, long, short, and intermediate acting. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Added:** Submission Criteria 2: INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control. A high-risk medication is identified by: • A prescription for medications classified as high risk at any dose and for any duration listed in Table 3 **Updated numerator note: For the MIPS CQMs Specifications collection type: Removed:** numerator note. **Updated numerator options: For the MIPS CQMs Specifications collection type: Revised:** Submission Criteria 1: **Performance Met:** At least two orders for high-risk medications from the same drug class **Performance Not Met:** At least two orders for high-risk medications from the same drug class not ordered **Added:** Submission Criteria 2: **Performance Met:** At least two orders for high-risk medications from the same drug class **Performance Not Met:** At least two orders for high-risk medications from the same drug class not ordered **Performance Not Met:** Two or more antipsychotic prescriptions ordered for patients who had a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the Index Prescription Start Date (IPSD) for antipsychotics **Performance Not Met:** Two or more benzodiazepine prescriptions ordered for patients who had a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines

Category	Description
	Updated measure analytic: For all collection types: Revised: performance rate 1 will be utilized for benchmarking purposes.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to restructure all of the collection types to introduce new performance rates based upon the American Geriatric Society Beers Criteria and expert panel recommendations, with performance rate one being utilized for benchmarking purposes as it is more comprehensive in assessment and aligns across the collection types. These revisions allow for the inclusion of antipsychotics and benzodiazepines to ensure alignment with most recent recommendations. The description for the measure is being updated for all collection types to align with the revisions in the measure and reflect the restructuring within multiple components of the specifications. Additionally, there will be multiple performance rates: three performance rates for the eCQM Specifications collection type and two performance rates for the MIPS CQMs Specifications collection type. We proposed that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and consistency in implementation. The eCQM Specifications collection type's value sets were revised to add and remove drug classes and the logic for the non-benzodiazepine hypnotics was revised to remove the 90-day supply criterion to align with the American Geriatric Society Beers Criteria guidelines. We proposed to revise the MIPS CQMs Specifications collection type to add a second performance rate and submission criteria as the measure is restructured to align with the American Geriatric Society Beers Criteria guidelines. Additionally, the medication tables have been revised to align with the current guidelines and intent of the measure revisions. Multiple components of the MIPS CQMs Specifications collection type were updated to align with revised structure and the American Geriatric Society Beers Criteria guidelines to ensure consistent language throughout and alignment with the measure intent.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in these measures and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q238. After consideration of public comments, we are finalizing the changes to measure Q238 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.31 Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	239
CMS eCQM ID:	CMS155v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.
Substantive Change:	**The measure title is revised from 'Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents' to:** Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents **Updated denominator exclusion: Revised:** Exclude patients who are in hospice care for any part of the measurement period. **Updated value set/coding: Revised:** "Pregnancy" (2.16.840.1.113883.3.526.3.378) value set to more accurately capture pregnancy state.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the title for alignment across programs. We proposed to update the "Pregnancy" value set to more accurately capture the state of pregnancy to ensure the denominator exclusion is being applied to the correct patient population and remove the term 'overlaps' and replace with plain language for clarity and consistency in implementation.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q239 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.32 Childhood Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	240
CMS eCQM ID:	CMS117v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.
Substantive Change:	**The measure denominator exclusion is revised to read:** Exclude patients who are in hospice care for any part of the measurement period. **The measure guidance is revised to read:** Numerator criteria includes evidence of receipt of the recommended vaccine or the following: -- DTaP: Adverse reaction to the DTaP or Td vaccine; or encephalopathy due to DTaP or Td vaccination -- Polio (IPV) vaccine: Adverse reaction to the IPV vaccine, streptomycin, polymyxin B, or neomycin -- MMR Vaccination: Immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; history of measles, mumps, or rubella; or a seropositive result for the antigens -- Hib: Adverse reaction to the Hib vaccine -- Hepatitis B: Seropositive result for the antigen, adverse reaction to the hepatitis B vaccine, adverse reaction to common baker's yeast, or a history of hepatitis B illness -- Chicken pox (varicella zoster): Seropositive result for the antigen; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; or a history of varicella zoster -- Pneumococcal: Adverse reaction to the pneumococcal vaccine -- Hepatitis A: Seropositive result for the antigen, adverse reaction to the hepatitis A vaccine, or a history of hepatitis A illness -- Rotavirus: Adverse reaction to the rotavirus vaccine, severe combined immunodeficiency, or a history of intussusception -- Influenza: Adverse reaction to the influenza vaccine; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; or adverse reaction to neomycin The measure allows a grace period by measuring compliance with these recommendations between birth and age two. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated logic and logic definitions: Added:** influenza LAIV vaccination as numerator compliant.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. The measure guidance is updated to reflect the intent of the measure and clarify the criteria for numerator compliance more accurately. Additionally, we proposed to update the logic and logic definitions to include the influenza LAIV vaccination to align with current clinical guidelines.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q240 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.33 Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	254
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type. **Updated denominator criteria: Revised:** Patient has any emergency department encounter during the performance period with Place of Service Indicator 23 (The claim form Place of Service field must indicate emergency department) OR Patient encounter during the performance period (CPT)
Steward:	American College of Emergency Physicians
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria to capture all patients with an encounter with a Place of Service indicator 23 to ensure that all applicable patients are being assessed for the quality action as it is appropriate for those patients who meet all other denominator criteria and are seen at any emergency department encounter. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q254 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.34 Biopsy Follow-Up

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	265
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.
Substantive Change:	**The measure denominator note is revised to read:** *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for MIPS CQMs. Only the first biopsy results for new patients should be reported for this measure. Do not include specimens sent for debridement.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator note to clarify which biopsy, if multiple biopsies are performed, should be utilized for assessment of the clinical quality action and that only new patients should be reported for the purposes of this measure.
Comment: One commenter supported CMS' proposed clarifications to this measure that if multiple biopsies are performed, only the first biopsy is used for this measure and that only new patients should be reported for this measure. **Response:** We thank the commenter for supporting the substantive changes to measure Q265. After consideration of public comments, we are finalizing the changes to measure Q265 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.35 Dementia: Cognitive Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 2872e
Quality#:	281
CMS eCQM ID:	CMS149v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**Updated logic and logic definitions: Revised:** dementia and qualifying encounter logic to clarify timing of during the measurement period.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the technical definition names and logic to provide clarity and ensure alignment with measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q281 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.36 Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	290
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months
Substantive Change:	**The measure title is revised from 'Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease' to:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease. **The measure description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period. **Updated denominator criteria: Removed:** coding related to Hospital Inpatient Services. **The measure numerator is revised to read:** Patients who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period. **The measure numerator definition is revised to read:** Assessed – use of a screening tool or discussion with the patient or care partner. Please see "Opportunity for Improvement" section below for suggestions on possible screening tools. Psychosis: includes hallucinations, illusions, delusions, paranoia **Updated numerator instructions:** **Added:** For Depression: Patient Health Questionnaire 2 (PHQ2), Patient Health Questionnaire 9 (PHQ9), Montgomery-Asberg Depression Rating Scale (MADRS) For Anxiety: Parkinson Anxiety Scale (PAS) **Removed:** For Impulse Control Disorder (9): Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease-Rating Scale (QUIP-RS) Minnesota Impulsive Disorders Interview **Updated numerator note: Removed:** the Numerator Note. **The measure numerator options are revised to read:** **Performance Met:** Depression, anxiety, apathy, AND psychosis assessed **Performance Not Met:** Depression, anxiety, apathy, AND psychosis not assessed
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure to lessen the requirements necessary for numerator compliance to balance quality patient care and clinician burden based upon feedback and recommendations from the measure steward's expert work group. The measure title, description, numerator, and numerator options will have updates to align with the proposed change to the measure's clinical quality action requirement. We proposed to remove Hospital Inpatient Services from the denominator criteria as patients seen in the inpatient setting are not appropriate for inclusion within the denominator eligible patient population for the clinical quality action being assessed, as this is to address care for patients seen during outpatient encounters. Additionally, we proposed to revise the numerator definition to more clearly define what "assessed" means for the purposes of this measure and what components are included within the term "psychosis". We proposed to revise the list of tools available for use in the Parkinson's disease patient population to align with current availability and applicability. We proposed to remove the numerator note to align with the updated time frame to ensure annual assessment.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q290 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.37 Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	291
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months.
Substantive Change:	**The measure title is revised from 'Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease' to:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease. **The measure description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once during the measurement period. **Updated denominator criteria: Removed:** coding related to Hospital Inpatient Services. **The measure numerator is revised to read:** Patients (or care partner as appropriate) who were assessed for cognitive impairment or dysfunction once during the measurement period. **The measure numerator definition is revised to read:** Assessed – Is defined as a discussion with the patient or care partner or use of a screening tool OR referral to neuropsychologist for testing. **Updated numerator instructions: Added:** Neuro-QoL and Patient-Reported Outcomes Measurement Information System (PROMIS). **Updated numerator note: Removed:** the Numerator Note. **Updated numerator options: Added:** **Denominator Exception:** Patient or care partner decline assessment **Denominator Exception:** On date of encounter, patient is not able to participate in assessment or screening, including non-verbal patients, delirious, severely aphasic, severely developmentally delayed, severe visual or hearing impairment and for those patients, no knowledgeable informant available.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure's title to remove redundancy in wording. We proposed to remove Hospital Inpatient Services from the denominator criteria as patients seen in the inpatient setting are not appropriate for inclusion within the denominator eligible patient population for the clinical quality action being assessed, as this is to address cares for patients seen during outpatient encounters. We proposed to update the measure numerator and numerator definition to include the care partner within the assessment of the clinical quality action as patients who have severe cognitive impairment may be unable to accurately respond to questions, leaving clinicians to rely on care partners for accurate information. We proposed to add the PROMIS and Neuro-QoL (Quality of Life) to the list of tools in the numerator instructions as these are applicable to the intent of the measure. Additionally, we proposed to update the numerator options to add denominator exceptions as the measure steward's expert work group felt it was important not to penalize clinicians for patients/care partners who are unable to participate in or decline the assessment. Additionally, we proposed to update the description and numerator to reflect that the quality action should be completed annually to ensure timely capture of cognitive impairment or dysfunction. To align with these revisions, we proposed to remove the numerator note.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q291 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.38 Parkinson's Disease: Rehabilitative Therapy Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months.
Substantive Change:	**The measure title is revised from 'Parkinson's Disease: Rehabilitative Therapy Options' to: Rehabilitative** Therapy Referral for Patients with Parkinson's Disease. **The measure description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period. **Updated denominator criteria: Added:** Physical and Occupational Therapy, Speech Language Pathology **The measure numerator is revised to read**: Patients who were referred to physical, occupational, speech, or recreational therapy once during the measurement period. **Updated numerator note: Removed:** the Numerator Note. **The measure numerator options is revised to read:** **Performance Met:** Referral to physical, occupational, speech, or recreational therapy **Denominator Exception:** Patient and/or care partner decline referral **Denominator Exception:** Clinician determines patient does not require referral **Denominator Exception:** Patient already receiving physical/occupational/speech/recreational therapy during the measurement period **Performance Not Met:** Patient not referred, reason not otherwise specified
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure title to remove redundancy in wording. We proposed to update the measure description and numerator to include recreational therapy as it is clinically relevant and can be beneficial to the Parkinson's disease patient population. We proposed to update and expand the denominator coding to include additional MIPS eligible clinician types as this measure may be appropriate to their scope of care. We proposed to remove the numerator note to align with the updated time-frame to ensure annual assessment. Additionally, we proposed to update the numerator options to align with the addition of recreational therapy as numerator compliant and allowing for denominator exceptions for those patients that decline a referral, do not need a referral based on the stage of the disease, or for those patients who are already receiving one or more of the services, as clinicians should not be penalized in these situations.

Comment: One commenter questioned the changes to measure Q293: Parkinson's Disease: Rehabilitative Therapy Options, as the commenter does not believe recreational therapy qualifies as rehabilitative therapy. The commenter appreciates that the measure includes referrals to OT, PT, and SLP but asserts that the measure would be more effective if it was linked back to a specific therapy evaluation code rather than simply a referral. This would ensure that the patients were receiving medically necessary rehabilitative therapy rather than receiving a referral and not acting upon it.

Response: Recreational therapy may provide physical, social, emotional, and cognitive benefits and incorporates the interests of the patient, which may better align with the patient's goals. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q293 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.39 Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	305
CMS eCQM ID:	CMS137v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.
Substantive Change:	**The measure denominator exclusion is revised to read:** 1. Exclude patients with a negative diagnosis history, defined as an encounter or medication treatment for a diagnosis of alcohol, opioid or other drug abuse or dependence in the 60 days prior to the first episode of alcohol or drug dependence. 2. Exclude patients who are in hospice care for any part of the measurement period. **Updated initial patient population: Revised:** logic for timing associated with the timing of the first dependence diagnosis. **Updated numerator logic: Revised:** timing attribute associated with orders of medications to 'authorDatetime'. **The measure stratification is revised to read:** Report a total score, and each of the following strata: Stratum 1: Patients age 13-17 at the start of the Measurement Period Stratum 2: Patients age >=18 at the start of the Measurement Period
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion to more accurately represent the intent to exclude patients with prior and recent history of substance abuse treatment as this patient population is not appropriate for the clinical quality action being assessed. The term 'overlaps' was removed from the denominator exclusion and replaced with plain language for clarity and consistency in implementation. We proposed to revise the logic for the timing associated with the first dependence diagnosis timing to align with the intent of the measure to correctly capture all diagnoses during the measurement period through November 14. We proposed to update the datatype for "Medication, Order" to use 'authorDatetime' as this is the preferred timing attribute. We proposed to revise the anchor for age calculations of the stratifications to align with those within the initial patient population for alignment.

Comment: One commenter proposed an additional numerator change for measure Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment. For the percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis, currently, the guidance states "within 14 days of diagnosis" while the CQL implementation does not include "within 14 days" including the day of the encounter. Greenway recommends that CMS review and include the day of the encounter as "within the 14 days" to meet the numerator action since treatment can often clinically occur the same day as diagnosis. The commenter did not believe that providers should be penalized for providing treatment on the same day as the diagnosis, which does not meet the intent of the guidance.

Response: The numerator definitions for population criteria 1 have different timings, with one including the day of diagnosis and one not including the day of diagnosis. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q305 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.40 Cervical Cancer Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	309
CMS eCQM ID:	CMS124v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years
Substantive Change:	**Updated denominator exclusion:** **Revised:** Exclude patients who are in hospice care for any part of the measurement period. **Added:** Exclude patients receiving palliative care during the measurement period. **Updated value set/coding: Updated:** replaced "Congenital absence of cervix (disorder)" ("SNOMEDCT Code (37687000)") with "Congenital or Acquired Absence of Cervix" (2.16.840.1.113883.3.464.1003.111.12.1016) value set.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed and the term 'overlaps' was removed and replaced with plain language for clarity and consistency in implementation. We proposed to update the value sets for the denominator exclusion to include acquired absence of cervix as this patient population is not appropriate for the clinical quality action being assessed.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in these measures and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q309. After consideration of public comments, we are finalizing the changes to measure Q309 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.41 Chlamydia Screening for Women

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	310
CMS eCQM ID:	CMS153v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.
Substantive Change:	**Updated denominator exclusion: Revised:** Exclude patients whose who are in hospice care for any part of the measurement period. **Updated value set: Added:** Clutton's joints "Diagnoses Used to Indicate Sexual Activity" value set.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the term 'overlaps' and replace with plain language for clarity and consistency in implementation. We proposed to update the "Diagnoses Used to Indicate Sexual Activity" value set to align with coding utilized in other programs, however, this code set will undergo further refinements in future years.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q310 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.42 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v10
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications | CMS Web Interface Measure Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** Exclude patients who are in hospice care for any part of the measurement period. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Removed:** Exclude patients who were assessed to be non-ambulatory during the measurement period. **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Removed:** Denominator Exclusion, count as non-ambulatory only if non-ambulatory at the most recent encounter during the measurement period (i.e., patient is not ambulatory, bed ridden, immobile, confined to chair, wheelchair bound, dependent on helper pushing wheelchair, independent in wheelchair or minimal help in wheelchair).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed for the eCQM Specifications collection type to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We proposed for the CMS Web Interface Measure Specifications collection type to remove the denominator exclusion for non-ambulatory patients to address implementation challenges as there is a lack of available documentation for a non-ambulatory status. Additionally, the denominator guidance has been updated to reflect this revision.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q318 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.43 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525 / N/A
Quality#:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type. **The measure description is revised to read:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period. **Updated denominator exclusion: Added:** 1. Patients with moderate or severe mitral stenosis 2. Patients with mechanical prosthetic heart valve
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type. We proposed to revise the measure description to align with the language revisions in the measure to no longer explicitly state the valve types. We proposed to add denominator exclusions that align with language revisions to remove those patients for whom the clinical quality action being assessed would not be appropriate. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q326 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.44 Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	335
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication.
Substantive Change:	**The measure title is revised from 'Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)' to:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) **The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor. **The measure numerator options are revised to read:** **Performance Met:** Elective delivery (without medical indication) by cesarean birth or induction of labor performed (<39 weeks of gestation) **Denominator Exception:** Medical indication for delivery by cesarean birth or induction of labor (<39 weeks of gestation) [Documentation of reason(s) for elective delivery (e.g., hemorrhage and placental complications, hypertension, preeclampsia and eclampsia, rupture of membranes (premature or prolonged), maternal conditions complicating pregnancy/delivery, fetal conditions complicating pregnancy/delivery, late pregnancy, prior uterine surgery, or participation in clinical trial)] **Performance Not Met:** Elective delivery (without medical indication) by cesarean birth or induction of labor not performed (<39 weeks of gestation) **Updated performance calculation: Revised:** Measure analytic was updated to be inverse.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the measure analytic to be inverse to better align with the intent of the measure as this is an overuse measure. We proposed to update the measure title, description, and numerator options to align with the revision in analytic as a lower calculated performance rate will now indicate better clinical care for the purposes of this measure. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q335 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.45 Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	336
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. **The measure denominator is revised to read:** All patients, regardless of age, who gave birth during a 12-month period and were seen for postpartum care at a visit before or at 12 weeks of giving birth. **Updated denominator criteria: Revised:** Postpartum care visit before or at 12 weeks of giving birth. **Updated instructions:** This measure is to be submitted a minimum of once per performance period for all patients seen for postpartum care before or at 12 weeks of giving birth during the performance period. **Updated numerator definition: Revised:** to align with the measure change from 8 weeks to 12 weeks postpartum.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the timeframe for the postpartum care visit from before or at 8 weeks of giving birth to before or at 12 weeks of giving birth, which is reflected in revisions to multiple components of the measure for alignment. This revision aligns with American College of Obstetricians and Gynecologists (ACOG) guidance and better aligns with current clinical workflows. This also ensures a more complete patient population is addressed to drive quality care.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q336 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.46 HIV Medical Visit Frequency

Category	Description
NQF # / eCQM NQF #:	2079 / N/A
Quality#:	340
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.
Substantive Change:	**The measure denominator note is revised to read:** In order to determine denominator eligibility, patients should be diagnosed with HIV during the first 3 months of the 24-month measurement period or have a diagnosis prior to the 24- month measurement period. The 24-month measurement period is defined as the 24 months prior to and including the date of the first qualifying encounter during the performance period (i.e., January 1, 2022 through December 31, 2022). Performance of the measure is met when there is at least one medical visit in each 6 month interval with 60 days between denominator eligible encounters for patients with HIV within the 24-month measurement period.
Steward:	Health Resources and Services Administration
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator note to clarify the 24-month period to ensure alignment with the measure intent and consistency in implementation.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q340 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.47 Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	350
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.
Substantive Change:	**The measure title is revised from 'Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy' to:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy. **The measure description is revised to read:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure. **Updated instructions: Revised:** This measure is to be submitted each time a procedure for total knee or total hip replacement is performed during the performance period. **Updated denominator: Added:** Total hip replacement.
Steward:	American Association of Hip and Knee Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure to include total hip replacements as denominator eligible as the clinical quality action being assessed is applicable to this procedure as well. This will ensure that a broader patient population is being assessed as it is important to for the patient and clinician to engage in shared decision making to ensure that joint replacement therapy is the best treatment option. Multiple components of the measure will be updated to reflect the additional procedure of total hip replacement. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q350 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.48 Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	351
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).
Substantive Change:	**The measure title is revised from 'Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation' to:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation. **The measure description is revised to read:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke). **Updated instructions: Revised:** This measure is to be submitted each time a procedure for total knee or total hip replacement is performed during the performance period. **Updated denominator: Added:** Total hip replacement.
Steward:	American Association of Hip and Knee Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure to include total hip replacements as denominator eligible as the clinical quality action being assessed is applicable to this procedure as well. This will ensure that a broader patient population is being assessed as it is important to evaluate this patient population for venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure to ensure that joint replacement therapy is the best treatment option. Multiple components of the measure will be updated to reflect the additional procedure of total hip replacement. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q351 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.49 Patient-Centered Surgical Risk Assessment and Communication

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	358
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.
Substantive Change:	**Updated denominator criteria: Added:** Coding related to 'Ablation, irreversible electroporation; 1 or more tumors per organ'
Steward:	American College of Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria to add a procedure that is appropriate for the measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q358 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.50 Follow-Up Care for Children Prescribed ADHD Medication (ADD)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	366
CMS eCQM ID:	CMS136v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.
Substantive Change:	**Updated denominator exclusion: Revised:** For all denominators: Exclude patients who are in hospice care for any part of the measurement period. **The measure guidance is revised to read:** This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure numerator is revised to read:** Numerator 1: Patients who had at least one visit with a practitioner with prescribing authority within 30 days after the IPSD. Numerator 2: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase, and at least two follow-up visits during the Continuation and Maintenance Phase. **Updated performance calculation: Revised:** Performance Rate 2 will be used for benchmarking purposes.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We proposed to update the guidance to remove the language regarding how cumulative medication duration is calculated as this is outdated and no longer in alignment with the measure intent. We proposed to revise the numerator language to allow for telehealth visits as these are appropriate for inclusion when assessing for the clinical quality action. We proposed to update the performance calculation for the measure to utilize the performance rate for submission criteria 2 as this is more indicative of quality care during and after the Initiation Phase. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q366 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.51 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Updated logic definitions: For the eCQM Specifications collection type: Revised:** timing of denominator exclusion elements; 'Global."ToDate" {element} on or before end of "Measurement Assessment Period". **Updated denominator criteria: For all collection types: Added:** coding for mental and behavioral health MIPS eligible clinicians to both submission criteria. **Updated initial population: For the CMS Web Interface Measure Specifications collection type: Revised:** Adolescent patients 12 to 17 years of age and adult patients 18 years of age and older with a diagnosis of major depression or dysthymia and an initial Patient Health Questionnaire-9 item version (PHQ-9) or Patient Health Questionnaire-9 Modified for Teens and Adolescents (PHQ-9M) score greater than nine during the index event. Patients may be assessed using PHQ-9 or PHQ-9M on the same date or up to 7 days prior to the encounter (index event). **Updated guidance: For the CMS Web Interface Measure Specifications collection type: Added:** When a baseline assessment is conducted with PHQ 9M, the follow-up assessment can use either a PHQ 9M or PHQ 9. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Added:** Patients with a diagnosis of personality disorder emotionally labile.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the eCQM Specifications collection type to revise the timing of the denominator exclusion elements to ensure the full 12 months + 60 days after the index event date is allowed in order to align with the measure intent and language. We proposed to expand the denominator eligible encounters for all collection types to include mental and behavioral health MIPS eligible clinicians as this measure is applicable to their scope of care. We proposed to update the CMS Web Interface Measure Specification collection type as the measure steward believes that allowing flexibility for the timeframe in which a PHQ-9/PHQ-9M can be obtained will accommodate pre-visit planning or distribution of a PHQ-9/PHQ-9M tool prior to the encounter (office visit, psychiatry or psychotherapy visit, telephone or online encounter). The intent of this change includes the following principles: (1) The patient must have the corresponding diagnosis at the time of the index encounter. (2) The patient must have completed the PHQ-9/PHQ-9M and have a score greater than 9. (3) That same PHQ-9/PHQ-9M is directly tied to and used during the index encounter. We proposed to revise the denominator exclusion language for the CMS Web Interface Measure Specifications collection type for a diagnosis of personality disorder to further clarify ensuring the correct patient population is being excluded from quality action assessment. We proposed to update the guidance for CMS Web Interface Measure Specifications collection type to add clarity regarding the assessment that may be used for the follow-up assessment for the purposes of meeting performance for this measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q370 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.52 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v10
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Substantive Change:	**The measure numerator note is revised to read: For the MIPS CQMs Specifications collection type:** The consultant report that will successfully close the referral loop should be related to the first referral for a patient during the measurement period. If there are multiple consultant reports received by the referring provider which pertain to a particular referral, use the first consultant report to satisfy the measure. The provider to whom the patient was referred is responsible for sending the consultant report that will fulfill the communication. Note: this is not the same provider who would report on the measure.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the numerator note for the MIPS CQMs Specification collection type to add clarifying language that the first referral for a patient should be utilized for the purposes of assessing whether the referral loop was closed and the clinical quality action completed, as this aligns with the intent of the measure.
Comment: One commenter supported CMS' proposed change clarifying that the first referral during the measurement period is the one that will count toward this measure. **Response:** We thank the commenter for supporting the substantive change to measure Q374. After consideration of public comments, we are finalizing the changes to measure Q374 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.53 Functional Status Assessment for Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	375
CMS eCQM ID:	CMS66v10
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Substantive Change:	**The measure denominator exclusion is revised to read:** 1. Exclude patients with two or more fractures indicating trauma at the time of the total knee arthroplasty or patients with severe cognitive impairment that starts before or in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period. **Updated value set/coding: Revised:** 'Primary TKA Procedure' (2.16.840.1.113883.3.464.1003.198.12.1007) value set to include revisions of one component of total prosthetic replacement of knee joint.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We proposed to expand the 'Primary TKA Procedure' value set to include revisions of one component of total prosthetic replacement of knee joint to create a more complete denominator eligible patient population as completing a functional status assessment would be appropriate for this patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q375 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.54 Functional Status Assessment for Total Hip Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	376
CMS eCQM ID:	CMS56v10
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Substantive Change:	**The measure denominator exclusion is revised to read:** 1. Exclude patients with two or more fractures indicating trauma at the time of the total hip arthroplasty or patients with severe cognitive impairment that starts before or in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q376 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.55 Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	377
CMS eCQM ID:	CMS90v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**The measure title is revised from 'Functional Status Assessments for Congestive Heart Failure' to:** Functional Status Assessments for Heart Failure. **The measure description is revised to read:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments. **The measure denominator exclusion is revised to read:** 1. Exclude patients with severe cognitive impairment in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period. **The measure guidance is revised to read:** Initial functional status assessment (FSA) and encounter: The initial FSA is an FSA that occurs two weeks before or during an encounter, in the 180 days or more before the end of the measurement period. Follow-up FSA: The follow-up FSA must be completed at least 30 days but no more than 180 days after the initial FSA. The same FSA instrument must be used for the initial and follow-up assessment. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure initial patient population is revised to read:** Patients 18 years of age and older who had two outpatient encounters during the measurement period and a diagnosis of heart failure that starts before and continues into the measurement period. **Updated logic and logic definitions: Updated:** restructured the logic to ensure the patient meets the denominator criteria by 1) had multiple assessments in the year and that 2) there is sufficient time for them to have had repeat assessments in the year 3) there is sufficient time between assessments for their condition to have changed or for them to have responded to treatment (30-180days).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the term 'congestive' from the measure title and description based upon the expert work group recommendations in order to align the language with the denominator eligible patient population to ensure all appropriate patients are included in the initial patient population. We proposed to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We proposed to revise the measure guidance to aid in measure implementation, align with measure intent and the timing constraints within the logic of the measure. We proposed to update the initial patient population to clarify timing of the heart failure diagnosis and ensure alignment with the logic. Additionally, we proposed to revise the logic to more clearly reflect relationships between the encounter and assessment(s), as identifying the first encounter without ensuring a relationship with an assessment does not meet the intent of the measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q377 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.56 Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 6 months - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period. **The measure denominator exclusion is revised to read:** Exclude patients who are in hospice care for any part of the measurement period. **The measure numerator is revised to read:** Children who had a diagnosis of cavities or decayed teeth in any part of the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the measure description to be more explicit of the timing associated with the patient's age. We proposed to remove the term 'overlaps' from the denominator exclusion and numerator and replace with plain language for clarity and consistency in implementation.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q378 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.57 Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	379
CMS eCQM ID:	CMS74v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The measure denominator exclusion is revised to read:** Exclude patients who are in hospice care for any part of the measurement period
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q379 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.58 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
NQF # / eCQM NQF #:	1879 / N/A
Quality#:	383
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator criteria: Added:** Filled at least two prescriptions for any of the qualifying antipsychotic medications listed under "Denominator Note" during the performance period **Added:** outpatient mental health encounters ocurring at federally qualified health centers for the 'Patient encounter during the performance period determination Outpatient Setting Option 1'. **Updated denominator note: Added:** lumateperone to 'Atypical Antipsychotic Medications'
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to add denominator criteria to ensure that only those patients who fill at least two prescriptions for any of the qualifying antipsychotic medications are included within the denominator eligible patient population as this aligns with the intent of the measure and protects clinicians from being held accountable for non-established patients. We proposed to add outpatient mental health encounters ocurring at FQHCs as denominator eligible as schizophrenia may be diagnosed at these encounters. This revision is not a reflection of any policy update and was made to allow those clinicians who bill exclusively through a FQHC to track their performance on the measure. This payment method is still not eligible for payment adjustments under MIPS. We proposed to update the 'Atypical Antipsychotic Medications' to align with current Food and Drug Administration (FDA) approved treatments for adults with schizophrenia.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q383 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.59 Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576 / N/A
Quality#:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Substantive Change:	**The measure description is revised to read:** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the description to utilize the term provider in place of practitioner for alignment within the specification.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q391 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.60 Lung Cancer Reporting (Biopsy/Cytology Specimens)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	395
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.
Substantive Change:	**The measure description is revised to read: For all collection types:** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report. **The measure numerator is revised to read: For all collection types:** Lung biopsy and cytology specimen reports with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following IASLC guidance (see below) (including but not limited to squamous cell carcinoma or adenocarcinoma) OR classified as NSCLC-NOS with an explanation included in the pathology report IASLC Guidance: The IASLC recommends the following regarding terminology for small biopsy and cytology specimens: 1. Do not use the term "large cell carcinoma" 2. Do not use the term "AIS (adenocarcinoma in situ)" or "MIA (minimally invasive adenocarcinoma)"—if a noninvasive pattern is present in a small biopsy, the term "lepidic growth" should be used instead 3. Do not use the term "BAC (bronchioloalveolar carcinoma)" All three recommendations must be followed in order for a case to be considered Met (ie if any one of these terms is present, the case is Not Met) **The measure numerator options are revised to read: For all collection types:** **Performance Met:** Primary non-small cell lung cancer lung biopsy and cytology specimen report documents classification into specific histologic type following IASLC guidance OR classified as NSCLC- NOS with an explanation **Denominator Exception:** Documentation of medical reason(s) for not including the histological type OR NSCLC-NOS classification with an explanation (e.g. Specimen insufficient or non-diagnostic, specimen does not contain cancer, or other documented medical reasons) **Performance Not Met:** Primary non-small cell lung cancer lung biopsy and cytology specimen report does not document classification into specific histologic type OR histologic type does not follow IASLC guidance OR is classified as NSCLC-NOS but without an explanation
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure description to add clarity in alignment with the measure intent. We proposed to update the numerator and numerator options to add guidance regarding what phrases should be avoided within the pathology reports to align with IASLC guidance and to clarify what is acceptable for numerator compliance.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q395 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.61 Lung Cancer Reporting (Resection Specimens)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	396
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.
Substantive Change:	**The measure description is revised to read: For all collection types:** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure description to include the term 'lung' for clarity and alignment within the specification.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q396 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.62 Melanoma Reporting

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	397
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.
Substantive Change:	**The measure description is revised to read: For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors. **The measure instructions are revised to read: For all collection types:** This measure is to be submitted each time a patient's pathology report addresses specimens with a diagnosis of malignant cutaneous melanoma; however, only one quality-data code (QDC) per date of service for a patient is required. In instances where multiple specimens from different/unique lesions are submitted and resulted in a single report, each eligible specimen must be Met in order for the case to be considered Met (Denominator Exclusions and Denominator Exceptions are not considered eligible specimens). If any eligible specimen is Not Met, the quality data code for Not Met should be submitted for this report. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The measure numerator is revised to read: For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the pT category thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors **The measure numerator options are revised to read: For all collection types:** **Performance Met:** Pathology report includes the pT Category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors **Denominator Exception:** Documentation of medical reason(s) for not including pT Category,thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors (e.g., negative skin biopsies, insufficient tissue, or other documented medical reasons) **Performance Not Met:** Pathology report does not include the pT Category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure for all collection types to require new data elements for numerator compliance to align with updated American Academy of Dermatology (AAD) guideline recommendations. This revision is reflected in the proposed description, numerator, and numerator options language revisions to ensure the measure is aligned with the current clinical recommendations. Additionally, we proposed to revise the instructions for all collection types to clarify how to handle instances where there are multiple samples included within one report.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q397 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.63 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	400
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.
Substantive Change:	**The measure title is revised from 'One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk' to:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients. **The measure description is revised to read:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection. **The measure instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients > =18 years of age seen during the performance period AND who were seen twice for any visits or who had at least one preventive visit within the 12-month performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The measure denominator is revised to read:** All patients >= 18 years of age who had at least one preventive visit OR were seen at least twice within the 12-month reporting period. **Updated denominator criteria: Removed:** Patients who were born in the years 1945 to 1965 OR History of receiving blood transfusions prior to 1992 OR Receiving maintenance hemodialysis (CPT) OR History of injection drug use
Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update this measure to align with current clinical recommendations which no longer require at-risk conditions for HCV screening. The measure will be updated to require one-time HCV screening for all patients aged 18 years and older, in accordance with current clinical recommendations. We proposed to revise the measure title, description, instructions, and denominator to reflect the removal of the at-risk criteria. Additionally, we proposed to remove the at-risk criteria from the denominator criteria. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q400 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.64 Clinical Outcome Post Endovascular Stroke Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	409
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.
Substantive Change:	**The measure description is revised to read:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention. **Updated instructions: Revised:** This measure is to be submitted a minimum of once per performance period for patients undergoing an endovascular stroke intervention procedure during the performance period. This measure is intended to reflect the success of the endovascular intervention inclusive of appropriate patient selection. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure- specific denominator coding. Include only patients that have cerebrovascular accidents through September 18 of the performance period. This will allow the evaluation of clinical outcome 90 days after the cerebrovascular accident within the performance period. Assessment of the mRS between 75 and 105 days is considered acceptable for reporting this measure. **Added:** Unique to this measure is the Minimum Process of Care Performance Threshold Requirement. This measure based threshold requires that at least 90% of all eligible patients have an mRS score assessed 90 days following endovascular stroke intervention. Therefore, if the performance rate for Submission Criteria 1 is below 90%, the MIPS eligible clinician would not be able to meet the denominator of the Submission Criteria 2 and this measure CANNOT BE SUBMITTED. CMS anticipates the performance rate for Submission Criteria 2 will be calculated using 100% of patients that met performance in Submission Criteria 1. This measure contains two submission criteria which together measure the outcome following an endovascular stroke intervention. Submission Criteria 1 evaluates whether an appropriate percentage of patients received the applicable clinical follow-up assessment using mRS. Submission Criteria 2 evaluates the rate of achieving an mRS score of 0 to 2 in those patients for whom an mRS score was obtained (during clinical follow-up, Submission Criteria 1). The rate of achieving an mRS of 0 to 2 at 90 days (Submission Criteria 2) can be used to compare this measure to performance prior to the 2021 performance year, when the measure had a single performance rate. For accountability reporting in the CMS MIPS program, the rate for Submission Criteria 2 is used for performance. For the purposes of submitting this measure Data Completeness has been determined in Submission Criteria 1. THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1) Percentage of patients with mRS score assessed at 90 days following endovascular stroke intervention AND 2) Percentage of patients with mRS score of 0 to 2 assessed at 90 days following endovascular stroke intervention **Updated denominator: Revised:** **Submission Criteria 1:** Percentage of patients with clinical follow-up and mRS score assessed at 90 days following endovascular stroke intervention. **Denominator (Submission Criteria 1):** All patients with CVA undergoing endovascular stroke treatment. **Submission Criteria 2**: Percentage of patients with Performance Met for Submission Criteria 1 with an mRS score of 0 to 2 assessed at 90 days following endovascular stroke intervention therapy. **Denominator (Submission Criteria 2):** Patients with Performance Met for Submission Criteria 1 who received clinical follow-up and mRS score assessed at 90 days following endovascular stroke intervention therapy. **Updated denominator criteria: Revised:** Denominator (Submission Criteria 1) • All patients • Diagnosis for ischemic stroke • Patient procedure (endovascular stroke treatment) Denominator (Submission Criteria 2) • Minimum Process of Care Threshold Requirement: At least 90% of all eligible patients had an mRS score assessed at 90 days following endovascular stroke intervention (GXXXX submitted for Submission Criteria 1) **Updated numerator: Revised:** **Numerator (Submission Criteria 1):** Patients who received clinical follow-up and mRS score assessed at 90 days. **Numerator (Submission Criteria 2):** Patients with Performance Met for Submission Criteria 1 with 90 day mRS score of 0-2. **Updated numerator note: Added:** For the purposes of submitting this measure Data Completeness has been determined in Submission Criteria 1. The performance rate calculated for Submission Criteria 2 of this measure is calculated using the subset of patients identified in the Performance Met Numerator Option of Submission Criteria 1 (GXXXX). **Updated numerator options:** **Added:** Numerator Options (Submission Criteria 1): **Performance Met:** Clinical follow-up and mRS score assessed at 90 days following endovascular stroke intervention **Performance Not Met:** Clinical follow-up and mRS score not assessed at 90 days following endovascular stroke intervention **Revised:** Numerator Options (Submission Criteria 2): **Performance Met:** Patients with 90 day mRS score of 0 to 2

Category	Description
	Performance Not Met: Patients with 90 day mRS score greater than 2
Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed an update to the measure that includes a new submission criterion to assess whether a clinical follow-up and mRS score is being completed post endovascular stroke treatment. Additionally, this new submission criterion will ensure that the denominator eligible patient population being assessed for an mRS score of 0 – 2 is representative of the assessed population post treatment to determine the degree of disability or dependence in daily activities for patient suffering stroke. We proposed to add an additional denominator criterion for submission criteria 2 that requires a 'Minimum Process of Care Threshold Requirement' of 90%. This ensures that patients are receiving post treatment follow-ups as a standard of care being and assessed for good outcomes following a stroke. This update is reflected with the restructure of multiple components of the specification to ensure clarity on the implantation of the measure change. We also proposed to update the measure instructions to clarify what timeframe constitutes the 90-day follow-up and to align with the revisions to add a submission criterion. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q409 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.65 Door to Puncture Time for Endovascular Stroke Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	413
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.
Substantive Change:	**The measure description is revised to read:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less. **The measure numerator is revised to read:** Patients with CVA undergoing endovascular stroke treatment who have a door to puncture time of less than 90 minutes. **Updated numerator options: Revised:** To align with door to puncture time of 90 minutes or less.
Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to revise the measure to reflect an updated door to puncture time of 90 minutes or less to more closely align with Target Stroke (a national initiative organized by the American Heart Association/American Stroke Association) which has an initial goal of achieving a door-to-puncture time of no more than 60 minutes for at least 50 percent of acute ischemic stroke patients. Additionally, The Joint Commission has set an ambitious goal of 80 percent of patients treated within 1 hour for primary stroke centers. This revision will drive quality care for this patient population as every delay in time from onset to arterial puncture will result in significant decreases in likelihood of a good outcome.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q413 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.66 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Updated numerator options: For all collection types: Added:** **Performance Met:** Pediatric patient with minor blunt head trauma and PECARN prediction criteria are not assessed.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to add a Performance Met numerator option to this measure to ensure those patients without a documented PECARN prediction score are correctly submitted as a Performance Met. As the PECARN prediction should be assessed for all patients seen for minor blunt head trauma, those patients without a documented PECARN predication score would not meet the intent of the measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q416 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.67 Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053 / N/A
Quality#:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**The measure description is revised to read: For all collection types:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For all collection types:** **Added:** Patients who receive palliative care services any time during the intake period through the end of the measurement year **Added:** Donzepezil-memantine to Dementia medication list. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the description for alignment with other programs. We proposed that the denominator exclusion language be updated to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, the medications were update for the Dementia medication list to include Donzepezil-memantine as this is an applicable medication for the purposes of the denominator exclusion. We proposed to revise the denominator note for the MIPS CQMs Specifications collection type and the numerator note for the Medicare Part B Claims Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in these measures and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q418. After consideration of public comments, we are finalizing the changes to measure Q418 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.68 Photodocumentation of Cecal Intubation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	425
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications collection type
Steward:	American Society for Gastrointestinal Endoscopy
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped-out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.

Comment: One commenter opposed removal of Medicare Part B Claims Measure Specifications collection type for measure Q425: Photodocumentation of Cecal Intubation, although the commenter appreciated retaining the MIPS CQMs Specifications collection type for this measure as the measure is recognized by the gastroenterology specialty as an important quality indicator for colonoscopy. Removing the Medicare Part B Claims Measure Specifications collection type disadvantages gastroenterologists in small and rural practices who provide screening colonoscopy services and do not participate in registry reporting from having a meaningful, specialty-specific measure to report. If this measure is removed the only other gastroenterology measure available for the Medicare Part B Claims Measure Specifications collection type would be Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients, which is considered topped out with a seven-point cap. Measure Q425 illustrates the commenter's concern with removal of quality measures from MIPS regardless of whether the measure is truly topped out and not just representative of top performers or one data source. Gastroenterologists have been challenged over the years in being able to meaningfully report across a broad array of QPP and QCDR specialty-specific quality measures with available measures changing each performance year.

Response: The Medicare Part B Claims Measure Specifications collection type has reached the end of the topped-out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2021 Benchmark File. In addition, there are processes in place to address instances where clinicians do not have the ability to submit six quality measures. MIPS CQMs Specifications collection type may be reported without a third-party intermediary (see the '2021 MIPS Quality Quick Start Guide' at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1294/2021%20MIPS%20Quality%20Quick%20Start%20Guide.pdf).

After consideration of public comments, we are finalizing the changes to measure Q425 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.69 Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	430
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.
Substantive Change:	**Updated numerator definition: Added:** Propofol for induction and maintenance of anesthesia
Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the numerator definition to add propofol as this is a commonly used prophylactic antiemetic and aligns with current clinical recommendations.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q430 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.

D.70 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v5
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes **The measure definition is revised to read: For the eCQM Specifications collection type:** Clinical atherosclerotic cardiovascular disease (ASCVD) includes: * Acute coronary syndromes * History of myocardial infarction * Stable or unstable angina * Coronary or other arterial revascularization * Stroke or transient ischemic attack (TIA) * Peripheral arterial disease of atherosclerotic origin Lipoprotein density cholesterol (LDL-C) result: * A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available on the same day, the direct LDL-C test result should be used. Statin therapy: * Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Statin Medication Therapy List (NOTE: List does NOT include dosage): [Generic name] (Brand or trade name) and (-) Medication type, if applicable: [Atorvastatin] (Lipitor) - Statin [Fluvastatin] (Lescol XL or Lescol) - Statin [Lovastatin (Mevinolin)](Mevacor or Altoprev) -Statin [Pitavastatin] (Livalo or Zypitamag or Nikita) - Statin [Pravastatin Sodium] (Pravachol) - Statin [Rosuvastatin Calcium] (Crestor) - Statin [Simvastatin] (Zocor) - Statin [Amlodipine Besylate/Atorvastatin Calcium] (Caduet) – Fixed Dose Combination [Ezetimibe/Simvastatin] (Vytorin) – Fixed Dose Combination Statin-Associated Muscle Symptoms (SAMS) – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. **Updated denominator exception:** **For the eCQM Specifications CMS Web Interface Measure Specifications collection types:** **Revised:** Patients with statin-associated muscle symptoms or an allergy to statin medication **Removed:** Patients with diabetes who have the most recent fasting or direct LDL-C laboratory test result < 70 mg/dL and are not taking statin therapy **For the MIPS CQM Specifications collection type:** **Revised:** Documentation of medical reason(s) for not currently being a statin therapy user or receiving an order (prescription) for statin therapy (e.g., patients with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice care, patients with active liver disease or hepatic disease or insufficiency, and patients with end stage renal disease [ESRD]) **Removed:** Submisstion Criteria Three: Documentation of patients with diabetes who have a most recent fasting or direct LDL-C laboratory test result < 70 mg/dL and are not taking statin therapy **Updated denominator exclusion: For all collection types: Added:** Timeframe of 'at any time during the measurement period' to all denominator exclusions. **The measure guidance is revised to read: For the eCQM Specifications collection type:** Initial Population Guidance: The initial population covers three distinct populations. Use the following process to prevent counting patients more than once. Initial Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure, before the end of the measurement period.

Category	Description
	-If YES, meets Initial Population 1 risk category -If NO, screen for next risk category Initial Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had a laboratory test result of LDL-C >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia -If YES, meets Initial Population 2 risk category -If NO, screen for next risk category Initial Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with an active diagnosis of Type 1 or Type 2 diabetes at any time during the measurement period -If YES, meets Initial Population 3 risk category -If NO, patient does NOT meet Initial Population criteria and is NOT eligible for measure inclusion Initial Population Guidance for Encounter: -In order for the patient to be included in the Initial Population, the patient must have ONE initial population-eligible visit, defined as follows: outpatient visit, initial or established office visit, face-to-face interaction, preventive care services, or annual wellness visit. LDL-C Laboratory test result options: The measure can be reported for all patients with a documented LDL-C level recorded as follows: To meet Initial Population 1: There is no LDL-C result required. To meet Initial Population 2: If a patient has ANY previous laboratory result of LDL-C >= 190 mg/dL, report the highest value >= 190 mg/dL. To meet Initial Population 3: There is no LDL-C result required. Numerator instructions and guidance: -Current statin therapy use must be documented in the patient's current medication list or ordered during the measurement period. -ONLY statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). -Prescription or order does NOT need to be linked to an encounter or visit; it may be called to the pharmacy. -Statin medication "samples" provided to patients can be documented as "current statin therapy" if documented in the medication list in health/medical record. -Patients who meet the denominator criteria for inclusion, but are not prescribed or using statin therapy, will NOT meet performance for this measure unless they have an allowable denominator exception. Patients with an allowable denominator exception should be removed from the denominator of the measure and reported as a valid exception. -There is only one performance rate calculated for this measure: the weighted average of the three populations. -Adherence to statin therapy is not calculated in this measure. -It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions for the complete list) Intensity of statin therapy in primary and secondary prevention: The expert panel of the 2018 ACC/AHA/MS Guidelines (Grundy et al., 2019) defines recommended intensity of statin therapy on the basis of the average expected LDL-C response to specific statin and dose. Although intensity of statin therapy is important in managing cholesterol, this measure assesses prescription of ANY statin therapy, irrespective of intensity. Assessment of appropriate intensity and dosage documentation added too much complexity to allow inclusion of statin therapy intensity in the measure at this time. Lifestyle modification coaching: A healthy lifestyle is important for the prevention of cardiovascular disease. However, lifestyle modification monitoring and documentation added too much complexity to allow its inclusion in the measure at this time. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated guidance/denominator confirmation: For the CMS Web Interface Measure Specifications collection type: Revised:** Language within all of the guidance/confirmation sections was updated to reflect the changes to the initial patient poulations. **The measure initial patient population is revised to read: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types:** Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes **Updated denominator:** **For the eCQMs Specifications collection type: Revised:** Equals Initial Population **For the CMS Web Interface Measure Specifications collection types: Revised:** Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of ASCVD, including an ASCVD procedure, Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had laboratory result of LDL-C >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes

Category	Description
	The measure rate aggregation is revised to read: For the eCQM Specifications collection type: This measure is intended to have one reporting rate, which aggregates the following populations into a single performance rate for reporting purposes: Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure, before the end of the measurement period. Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had a laboratory test result of LDL-C >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with an active diagnosis of Type 1 or Type 2 diabetes at any time during the measurement period. For the purposes of this measure, a single performance rate can be calculated as follows: Performance Rate = (Numerator 1 + Numerator 2 +Numerator 3)/ [(Denominator 1 - Denominator Exclusions 1- Denominator Exceptions 1) + (Denominator 2 - Denominator Exclusions 2 - Denominator Exceptions 2) +(Denominator 3 - Denominator Exclusions 3 - Denominator Exceptions 3)] **Updated definition: For the MIPS CQMs Specifications collection type:** **Revised:** Lipoprotein Density Cholesterol (LDL-C) result – A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available, the direct LDL-C test result should be used. **Added:** - Statin-Associated Muscle Symptoms (SAMS) – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define SAMS: G72.0, G72.9, M60.9, M79.10. - Zypitamag and Nikita to statin medication therapy list. **Revised:** Caduet and Vytorin to 'Fixed Dose Combination'. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage): [Generic name] (Brand or trade name) and (-) Medication type, if applicable: [Atorvastatin] (Lipitor) - Statin [Fluvastatin] (Lescol XL or Lescol) - Statin [Lovastatin (Mevinolin)](Mevacor or Altoprev) -Statin [Pitavastatin] (Livalo or Zypitamag or Nikita) - Statin [Pravastatin Sodium] (Pravachol) - Statin [Rosuvastatin Calcium] (Crestor) - Statin [Simvastatin] (Zocor) - Statin [Amlodipine Besylate/Atorvastatin Calcium] (Caduet) – Fixed Dose Combination [Ezetimibe/Simvastatin] (Vytorin) – Fixed Dose Combination Statin-Associated Muscle Symptoms (SAMS) – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. Lipoprotein Density Cholesterol (LDL-C) result - A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available on the same day, the direct LDL-C test result should be used. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Submission Criteria: 1) All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure. 2) Patients aged ≥ 20 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. 3) Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. **Updated denominator criteria is revised to read: For the MIPS CQMs Specifications collection type:** **Updated:** Submission Criteria 1: **Revised:** - All patients, regardless of age - Previously diagnosed or have an active diagnosis of clinical ASCVD, including ASCVD procedure. Submissiont Criteria 2: **Revised:** - Patient aged ≥ 20 years at the beginning of the measurement period - Any LDL-C laboratory test result ≥ 190 mg/dL - History of or active diagnosis of familial hypercholesterolemia Submission Criteria 3: **Removed:**

Category	Description
	Patient's highest fasting or direct LDL-C laboratory test result in the measurement period or two years prior to the beginning of the measurement period is 70 –189 mg/dL **Updated numerator guidance: For the CMS Web Interface Measure Specifications collection type: Revised:** These drugs may be used as a Denominator Exception if present in the patient's record accompanied by an appropriate conditional reason why the patient is not taking the drug (e.g. statin-associated muscle symptoms or an allergy to statin medication) - Documentation of statin therapy prescribed or being taken during the measurement period can be completed during a telehealth encounter.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure to align with 2018 American College of Cardiology (ACC)/American Heart Association (AHA) cholesterol guidelines and recommendations. These revisions are reflected in multiple components of the measure specifications for all collection types. The measure definitions and/or guidance sections for all collection types were revised to align with and add clarity to the revisions within the measure to align with current clinical guidelines and recommendations. We proposed to remove the denominator exception found in submission criteria 3 for patients with diabetes not taking statin therapy who have the most recent fasting or direct LDL-C laboratory test result < 70 mg/dL as it is no longer applicable as the denominator criteria was revised to remove LDL-C laboratory testing criteria. Additionally, we propse to add statin-associate muscle symptoms to the denominator exception for documentation of medical reason(s) for all submission criteria and all collection types as it would not be appropriate to prescribe statin therapy for this patient population. We proposed to update the numerator guidance for the CMS Web Interface Measure Specifications collection type to allow for the documentation of statin therapies prescribed or taken during the measurement period to be completed during a telehealth encounter as this aligns with the intent of the measure and clinical workflow. We proposed to revise the statin medication therapy list for all collection types to reflect current clinical guidelines and recommendations. Additionally, we proposed to update the denominator exclusions for all submission criterias and collection types to include a timing component in order to clarify when it must occur and for consistency in implementation.
Comment: One commenter agreed that patients receiving palliative care are not appropriate for the clinical quality actions being assessed in these measures and supported CMS' proposal to add palliative care exclusions or exceptions. **Response:** We thank the commenter for supporting the substantive change to measure Q438. After consideration of public comments, we are finalizing the changes to measure Q438 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.71 Appropriate Workup Prior to Endometrial Ablation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	448
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.
Substantive Change:	**The measure denominator definition is revised to read:** Index Date –Date of first endometrial ablation during the performance period. **Updated denominator exclusion: Revised:** Patients who had an endometrial ablation procedure during the 12 months prior to the index date (exclusive of the index date). **The measure numerator is revised to read:** Patients who received endometrial sampling or hysteroscopy with biopsy and results were documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation. **The measure numerator options are revised to read:** **Performance Met:** Endometrial sampling or hysteroscopy with biopsy and results documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation **Performance Not Met:** Endometrial sampling or hysteroscopy with biopsy and results not documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure denominator definition to reference the first endometrial ablation as the index date. This change aligns with the measure intent as the timing of the quality action should be assessed based on the date of the endometrial ablation procedure. We proposed to revise the denominator exclusion for clarity in timing of previous endometrial ablations that may suffice for this exclusion. Additionally, we proposed to revise the numerator and numerator options for clarity in timing of the quality action as well as to align with the revised definition for Index Date to ensure alignment with measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q448 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.72 Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer

Category	Description
NQF # / eCQM NQF #:	1858 / N/A
Quality#:	450
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.
Substantive Change:	**Updated denominator criteria: Added:** exclusion for telehealth
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add an exclusion for telehealth as adjuvant therapy would require an in-person encounter and this will ensure only the appropriate patients are being pulled into the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q450 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.73 Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient at three months (6 - 20 weeks) after the date of procedure. Assessment scores obtained via a telephone screening or prior to six weeks and after 20 weeks postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the six to 20 weeks following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q459 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.74 Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained via a telephone screening or prior to 9 months and after 15 months postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q460 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.75 Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months pre-operatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient three months (6 to 20 weeks) after the date of the procedure. Assessment scores obtained via a telephone screening or prior to 6 weeks and after 20 weeks postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the six to 20 weeks following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q461 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.76 Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	462
CMS eCQM ID:	CMS645v5
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**Updated logic definitions:** **Revised:** First Androgen Deprivation Therapy' to 'Androgen Deprivation Therapy Start Date'. **Added:** 'Androgen Deprivation Therapy for Urology Care Medication Active Start Dates' and 'Androgen Deprivation Therapy for Urology Care Medication Order Start Dates.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the logic to include order for androgen deprivation therapy as an option to meet eligibility for the initial patient population as these patients would be appropriate for inclusion to be assessed for the quality action.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q462 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.77 Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	463
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Substantive Change:	**Updated numerator definition: Added:** Propofol for induction and maintenance of anesthesia.
Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the numerator definition to add Propofol as this is a commonly used prophylactic antiemetic and aligns with current clinical recommendations.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q463 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.78 Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.
Substantive Change:	**The measure description is revised to read:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively. **Updated instructions: Revised: NOTE**: This measure is a target-based measure with two ways to meet the numerator; either a postoperative ODI score that is less than or equal to 22 OR an improvement of 30 points or greater from the preoperative to postoperative score. It is expressed as a proportion or rate. Patients having received a lumbar fusion procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures for performance calculation. **The measure numerator is revised to read:** All eligible patients whose functional status is less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI Version 2.1a) patient reported outcome tool at one year (9 to 15 months) postoperatively **Updated numerator definition: Revised:** Preoperative Assessment Oswestry Disability Index (ODI version 2.1a)- A preoperative ODI functional assessment score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative ODI was obtained, use the ODI that is the most recent and prior to the procedure. Postoperative Assessment Oswestry Disability Index (ODI version 2.1a) - A postoperative ODI functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to nine months and after fifteen months postoperatively will not be used for measure calculation. If more than one postoperative ODI was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the improvement is greater than or equal to 30 points. **The measure numerator note is revised to read:** NUMERATOR NOTE: It is recommended that both a preoperative and postoperative tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 or G2143 is submitted. • ODI is not administered postoperatively at one year (9 to 15 months) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure improvement • Postoperative ODI was greater than 22 and preoperative ODI (to measure improvement) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure.) **The measure numerator options are revised to read:** **Performance Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 30 points or greater. **Performance Not Met:** Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively. **Performance Not Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of less than 30 points.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered. Additionally, we proposed to update multiple components of the measure specifications to remove 'a change' and replace it with 'an improvement' as the intent of the measure is to assess if there was improvement in a patient's functional status.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q469 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.79 Functional Status After Primary Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	470
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Measure Assessment Period (Performance Period) - The period of time following the procedure date that is in which a postoperative Oxford Knee Score (OKS) or KOOS, JR. functional status score can be obtained reflecting a one year post operative assessment with a 9 to 15 month window. If more than one postoperative assessment was obtained during the 9 to 15 month window, use the most recent score during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q470 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.80 Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure description is revised to read:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively. **The measure numerator is revised to read:** All eligible patients whose functional status is less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively. **Updated numerator definition: Revised:** Preoperative Assessment Oswestry Disability Index (ODI version 2.1a) - A preoperative ODI functional assessment score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative ODI was obtained, use the ODI that is the most recent and prior to the procedure. Postoperative Assessment Oswestry Disability Index (ODI version 2.1a) - A postoperative ODI functional assessment score can be obtained from the patient three months (6 to 20 weeks) after the date of procedure. Assessment scores obtained prior to six weeks and after twenty weeks postoperatively will not be used for measure calculation. If more than one postoperative ODI was obtained during the 6 to 20 weeks following the procedure, use the most recent score obtained during the allowable timeframe. ODI can be obtained below or at the following link https://eprovide.mapi-trust.org/instruments/oswestry-disability-index. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the improvement is greater than or equal to 30 points. **Updated instructions: Revised:** NOTE: This measure is a target-based measure with two ways to meet the numerator; either a postoperative ODI score that is less than or equal to 22 OR an improvement of 30 points or greater from the preoperative to postoperative score. It is expressed as a proportion or rate. Patients having received a lumbar discectomy/laminectomy procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures to be utilized for performance calculation. **The measure numerator note is revised to read:** NUMERATOR NOTE: It is recommended that both a preoperative and postoperative be administered to the patient increasing chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1049 or G2145 is submitted. • ODI is not administered postoperatively at three months (6 to 20 weeks) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 6 weeks or greater than 20 weeks (3 month window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure improvement • Postoperative ODI is greater than 22 and preoperative ODI (to measure improvement) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure) **The measure numerator options are revised to read:** **Performance Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at three months (6 – 20 weeks) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within three months preoperatively AND at three months (6 - 20 weeks) postoperatively demonstrated an improvement of 30 points or greater. **Performance Not Met:** Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at three months (6 - 20 weeks) postoperatively. **Performance Not Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at three months (6 – 20 weeks) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within three months preoperatively AND at three months (6 - 20 weeks) postoperatively demonstrated an improvement of less than 30 points.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered. Additionally, we proposed to update multiple components of the measure specifications to remove 'a change' and replace it with 'an improvement' as the intent of the measure is to assess if there was improvement in a patient's functional status.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q472 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.81 Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF # / eCQM NQF #:	N/A / 3475e
Quality#:	472
CMS eCQM ID:	CMS249v4

Category	Description
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Substantive Change:	**Updated denominator exclusion: Revised:** The following risk factors may occur at any time in the patient's history or during the measurement period: Rheumatoid arthritis Hyperthyroidism Malabsorption Syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption Chronic liver disease Chronic malnutrition Osteoporotic fracture The following risk factors may occur any time in the patient's history prior to the start of the measurement period but do not need to be active at the start of the measurement period: Documentation of history of hip fracture in parent Glucocorticoids [cumulative medication duration >= 90 days]
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exclusion to remove the dosage requirements associate with glucocorticoid usage calculation to more accurately capture patients with relevant exposure and to exclude patients who had an osteoporotic fracture at any point in time, based upon stakeholder feedback. This will ensure that only patients appropriate for the assessment of the quality action are being included within the initial patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q472 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.82 Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained via a telephone screening or prior to 9 months and after 15 months postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q473 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.83 Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v3
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**Updated logic definitions: Revised:** the denominator exclusion "Patients with an initial BPH diagnosis that starts during, or within 30 days of hospitalization" logic has been updated to identify the encounter for the first diagnosis. **Updated value set/coding: Updated:** the denominator exclusion "Patients with a diagnosis of morbid obesity, or with a BMI Exam >40 before the follow up urinary symptom score" value set was updated to allow only calculated BMIs
Steward:	Large Urology Group Practice Association and Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise the logic of the denominator exclusion to ensure that the first encounter is being utilized to correctly identify the initial Benign Prostatic Hyperplasia (BPH) diagnosis to align with the intended timing component of the exclusion. Additionally, we proposed to update the body mass index (BMI) denominator exclusion value set to allow for calculated BMIs to align with the measure intent and ensure only applicable patients are being excluded.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q476 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.84 Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	478
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).
Substantive Change:	**The measure description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update the measure description to align language across Focus on Therapeutic Outcomes, Inc. (FOTO) measures.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q478 as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

D.85 Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
NQF # / eCQM NQF #:	0087 / N/A
Quality#:	014
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 month performance period.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type.
Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640.
After consideration of public comments received under Table C.2, we are finalizing the removal of measure Q014 as indicated for the CY 2022 performance period/2024 MIPS payment year and future years for the Medicare Part B Claims Specifications collection type only. Measure Q014 will remain in the MIPS program for the CY 2022 performance period/2024 MIPS payment year for the MIPS CQMs Specifications collection type.	

D.86 Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	050
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type. **Updated denominator:** Added Physical Therapy MIPS eligible clinician.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640.
After consideration of public comments received under Table C.6, we are finalizing the removal of measure Q050 as indicated for the CY 2022 performance period/2024 MIPS payment year and future years for the Medicare Part B Claims Specifications collection type only. Measure Q050 will remain in the MIPS program for the CY 2022 performance period/2024 MIPS payment year for the MIPS CQMs Specifications collection type.	

D.87 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.

Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
	
	The measure definition is revised to read: For the eCQM Specifications collection type: Blood Pressure (BP) Classification: BP is defined by four (4) BP reading classifications: Normal, Elevated, First Hypertensive, and Second Hypertensive Readings
	* Normal BP: Systolic BP (SBP) < 120 mmHg AND Diastolic BP (DBP) < 80 mmHg
	* Elevated BP: SBP of 120-129 mmHg AND DBP < 80 mmHg
	* First Hypertensive Reading: SBP of >= 130 mmHg OR DBP of >= 80 mmHg without a previous SBP of >= 130 mmHg OR DBP of >= 80 mmHg during the 12 months prior to the encounter
	* Second Hypertensive Reading: Requires a SBP >= 130 mmHg OR DBP >= 80 mmHg during the current encounter AND a most recent BP reading within the last 12 months SBP >= 130 mmHg OR DBP >= 80 mmHg
	
	Recommended BP Follow-Up:
	The 2017 Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults from the American College of Cardiology and American Heart Association (2017 Guideline) recommends BP screening thresholds as defined under Blood Pressure Classifications and recommends interventions based on the current BP reading as listed in the ""Recommended Blood Pressure Follow-Up Interventions"" below
	
	The types of Recommended Nonpharmacologic Interventions, such as lifestyle modifications, are listed following the section on Recommended Follow-Up Interventions based on BP Classification.
	
	Recommended Blood Pressure Follow-Up Interventions:
	* Normal BP: No follow-up required for SBP < 120 mmHg AND DBP < 80 mmHg
	* Elevated BP: Patients with SBP of 120-129 mmHg AND DBP < 80 mmHg:
	  * Referral to Alternate/Primary Care Health Care Professional
	  OR
	  * Follow-up with rescreen in 2 to 6 months AND recommend nonpharmacologic interventions
	* First Hypertensive BP Reading: Patients with one elevated reading of SBP >= 130 mmHg OR DBP >= 80 mmHg:
	  * Referral to Alternate/Primary Care Health Care Professional
	  OR
	  * Follow-up with rescreen > 1 day and < 4 weeks AND recommend nonpharmacologic interventions
	* Second Hypertensive BP Reading:
	  - Second Hypertensive BP Reading: Patients with second elevated reading of SBP of 130-139 mmHg OR DBP of 80-89 mmHg:
	  * Referral to Alternate/Primary Care Healthcare Professional
	  OR
	  * Nonpharmacologic intervention AND reassessment in 2-6 months AND an order for a laboratory test or ECG for hypertension
	  - Second Hypertensive BP Reading: SBP>=140 or DBP>=90:
	  * Referral to Alternate/Primary Care Healthcare Professional
	  OR
	  * Nonpharmacologic intervention AND BP-lowering medication AND reassessment within 4 weeks AND an order for a laboratory test or ECG for hypertension
	
	The 2017 Guideline outlines nonpharmacologic interventions (lifestyle modifications) which must include one or more of the following as indicated:
	* Weight Reduction
	* Dietary Approaches to Stop Hypertension (DASH) Eating Plan
	* Dietary Sodium Restriction
	* Increased Physical Activity
	* Moderation in alcohol (ETOH) Consumption
	
	Updated numerator logic: For the eCQM Specifications collection type: Revised: logic to apply exceptions based on blood pressure classification.
	
	Updated value set/coding: For the eCQM Specifications collection type: Removed: Hypertensive encephalopathy from Diagnosis of Hypertension (2.16.840.1.113883.3.600.263) value set.
	
	The measure numerator definition is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Definitions:

Category	Description
	Blood Pressure (BP) Classification – BP is defined by four (4) BP reading classifications: Normal, Elevated, First Hypertensive, and Second Hypertensive Readings • Normal BP: Systolic BP (SBP) < 120 mmHg AND Diastolic BP (DBP) < 80 mmHg • Elevated BP: SBP of 120-129 mmHg AND DBP < 80 mmHg • First Hypertensive Reading: SBP of >= 130 mmHg OR DBP of >= 80 mmHg without a previous SBP of >= 130 mmHg OR DBP of >= 80 mmHg during the 12 months prior to the encounter • Second Hypertensive Reading: Requires a SBP >= 130 mmHg OR DBP >= 80 mmHg during the current encounter AND a most recent BP reading within the last 12 months SBP >= 130 mmHg OR DBP >= 80 mmHg Recommended BP Follow-Up – The 2017 Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults from the American College of Cardiology and American Heart Association (2017 Guideline) recommends BP screening and thresholds as defined under Blood Pressure Classifications and recommends interventions based on the current BP reading as listed in the "Recommended Blood Pressure Follow- Up Table" below. Recommended Nonpharmacologic Interventions (Lifestyle Modifications) – The 2017 Guideline outlines nonpharmacologic interventions which must include one or more of the following as indicated: • Weight Reduction • Dietary Approaches to Stop Hypertension (DASH) Eating Plan • Dietary Sodium Restriction • Increased Physical Activity • Moderation in alcohol (ETOH) Consumption Patients with a Documented Reason for not Screening or no Follow-Up Plan for High Blood Pressure (Denominator Exceptions) – • Documentation of medical reason(s) for not screening for high blood pressure (for example, patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). • Documentation of patient reason(s) for not screening for blood pressure measurements or for not ordering an appropriate follow-up intervention if patient BP is elevated or hypertensive (e.g., patient refuses). **Updated numerator definition: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Recommended Blood Pressure Follow-Up Table' to reflect the updated blood pressure classifications. **Revised:** Recommended follow-up for Elevated BP Reading - Rescreen BP in 2 to 6 months AND recommended nonpharmacologic interventions OR Referral to Alternate/Primary Care Provider First Hypertensive BP Reading - Rescreen BP > 1 day and < 4 weeks AND recommended nonpharmacologic interventions OR Referral to Alternate/Primary Care Provider Second Hypertensive BP Reading (130 - 139 systolic OR 80-89 diastolic) - Recommended nonpharmacologic intervention AND reassessment in 2 to 6 months AND an order for laboratory test or ECG for hypertension OR Referral to Alternate/Primary Care Provider **Added:** Second Hypertensive BP Reading (over 140 systolic OR over 90 diastolic) - Recommended nonpharmacologic intervention AND BP-lowering medication AND reassessment within 4 weeks AND an order for laboratory test or ECG for hypertension OR Referral to Alternate/Primary Care Provider.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the description to replace 'pre-hypertensive' with 'elevated'. Additionally, the definition for all collection types was revised to reflect 2017 ACC/AHA guidelines; including, changing blood pressure classifications, relevant thresholds, and applicable interventions. The eCQM Measure Specifications collection type was revised to have the logic apply to exceptions based on blood pressure classification to more accurately capture a patient declining applicable intervention(s).
After consideration of public comments, as outlined in Table C.14, the substantive change above to measure Q317 is finalized as proposed for the CY 2022 performance period/2024 MIPS payment year and future years.	

Table A: New Improvement Activities for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_AHE_8**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Create and Implement an Anti-Racism Plan
Proposed Activity Description:	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools.[1] The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.
Proposed Weighting:	High
Rationale:	The proposed activity aimed to address systemic inequities, including systemic racism, as called for in Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, published January 20, 2021.[2] This activity began with the premise that it is important to acknowledge systemic racism as a root cause for differences in health outcomes between socially-defined racial groups.[3] [4] We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, per the improvement activity definition at § 414.1305, because it supports MIPS eligible clinicians in identifying health disparities and implementing processes to reduce racism and provide equitable quality health care. This activity is intended to help MIPS eligible clinicians move beyond analyzing data to taking real steps to naming and eliminating the causes of the disparities identified. We also proposed making this activity high-weighted because MIPS eligible clinicians will need considerable time and resources to develop a thorough anti-racism plan that is informed by data, and to implement it throughout the practice or system. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	Several commenters expressed support for the proposal to adopt this improvement activity, and for the high weight that we assigned to it. One commenter stated that this activity would be easier for larger, more established practices than smaller or solo practices to adopt. Another commenter stated that CMS should encourage MIPS eligible clinicians to implement this and other new equity-related activities for longer than 90 days to track and impact real improvement.
Response:	We appreciate the commenters' support. We disagree that this activity would be more appropriate for larger, more established practices to adopt. A small or new practice could tailor the activity to their context, fulfilling the requirements within their constraints in the same way as a larger, more established practice. MIPS eligible clinicians will be encouraged to fit these requirements to their specific context. We currently require a minimum of 90 days for the implementation period of this activity, but we support MIPS eligible clinicians who wish to implement this activity for longer periods of time. MIPS eligible clinicians could also attest to this activity in multiple years as they make steady progress towards intended outcomes. As mentioned in the Disparities Impact Statement, CMS offers technical assistance on health equity which a MIPS-eligible clinician can access by emailing healthequityTA@cms.hhs.gov.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_8**
Subcategory:	Achieving Health Equity

Activity Title:	Create and Implement an Anti-Racism Plan
Activity Description:	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools.[1] The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.
Weighting:	High
New Improvement Activity	
Proposed Activity ID:	**IA_AHE_9**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
Proposed Activity Description:	Create or improve, and then implement, protocols for identifying and providing appropriate support to: a) patients with or at risk for food insecurity, and b) patients with or at risk for poor nutritional status. (Poor nutritional status is sometimes referred to as clinical malnutrition or undernutrition and applies to people who are overweight and underweight.) Actions to implement this improvement activity may include, but are not limited to, the following: • Use Malnutrition Quality Improvement Initiative (MQii) or other quality improvement resources and standardized screening tools to assess and improve current food insecurity and nutritional screening and care practices. • Update and use clinical decision support tools within the MIPS eligible clinician's electronic medical record to align with the new food insecurity and nutrition risk protocols. • Update and apply requirements for staff training on food security and nutrition. • Update and provide resources and referral lists, and/or engage with community partners to facilitate referrals for patients who are identified as at risk for food insecurity or poor nutritional status during screening. Activities must be focused on patients at greatest risk for food insecurity and/or malnutrition—for example patients with low income who live in areas with limited access to affordable fresh food, or who are isolated or have limited mobility.
Proposed Weighting:	Medium
Rationale:	Food insecurity is a widespread and worsening issue in the United States. Estimates indicate that the number of food insecure people in the United States increased from 35.2 million people (1 in 9 people) in 2019 to 45 million people (1 in 7 people) in 2020.[5] Older adults are particularly at risk because of low income, mobility issues, dementia, and other factors such as social isolation. Food insecurity also disproportionately affects Black and Latinx households.[6] Malnutrition is also widespread in the United States.[7] Both food insecurity and malnutrition are associated with worse health outcomes and higher spending on healthcare.**Error! Bookmark not defined.** For example, adults who are malnourished at the time of hospitalization or surgery are more likely to have worse hospitalization, surgical, and recovery outcomes.[8] The improvement activity would fill a gap in the inventory, which does not currently include an improvement activity related to food insecurity or malnutrition. We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because ameliorating food insecurity and malnutrition leads to better health outcomes.[9] [10] This activity would create an opportunity for MIPS eligible clinicians to help address food insecurity and malnutrition, and provide the Malnutrition Quality Improvement Initiative as a resource.[11] Evidence indicates that they can help patients by increasing enrollment in the Supplemental Nutrition Assistance Program (SNAP) (https://www.fns.usda.gov/snap/supplemental-nutrition-assistance-program), which is associated with reduced food insecurity[12] or connecting their patients to other community resources. This activity also created an opportunity for MIPS eligible clinicians to help address malnutrition by ensuring patients in need receive a detailed nutritional assessment and appropriate nutritional care.

	We proposed weighting this activity medium, because this activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. The estimated level of effort for MIPS eligible clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	Several commenters expressed support for the proposal to adopt this improvement activity. One commenter stated that this activity would be easier for larger, more established practices than smaller or solo practices to adopt. Another commenter reminded CMS that malnutrition in food insecure individuals can present as either undernutrition or overnutrition.
Response:	We appreciate the commenters' support. We disagree that this activity would be more appropriate for larger, more established practices to adopt. A small or new practice could tailor the activity to their context, fulfilling the requirements within their constraints in the same way as a larger, more established practice. We agree with the commenter who stated that malnutrition in food insecure individuals can present as either undernutrition or overnutrition. We also note that CMS offers technical assistance on health equity which a MIPS eligible clinician can access by emailing healthequityTA@cms.hhs.gov.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_9**
Subcategory:	Achieving Health Equity
Activity Title:	Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
Activity Description:	Create or improve, and then implement, protocols for identifying and providing appropriate support to: a) patients with or at risk for food insecurity, and b) patients with or at risk for poor nutritional status. (Poor nutritional status is sometimes referred to as clinical malnutrition or undernutrition and applies to people who are overweight and underweight.) Actions to implement this improvement activity may include, but are not limited to, the following: • Use Malnutrition Quality Improvement Initiative (MQii) or other quality improvement resources and standardized screening tools to assess and improve current food insecurity and nutritional screening and care practices. • Update and use clinical decision support tools within the MIPS eligible clinician's electronic medical record to align with the new food insecurity and nutrition risk protocols. • Update and apply requirements for staff training on food security and nutrition. • Update and provide resources and referral lists, and/or engage with community partners to facilitate referrals for patients who are identified as at risk for food insecurity or poor nutritional status during screening. Activities must be focused on patients at greatest risk for food insecurity and/or malnutrition—for example patients with low income who live in areas with limited access to affordable fresh food, or who are isolated or have limited mobility.
Weighting:	Medium
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_11**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
Proposed Activity Description:	Create and implement a plan for trauma-informed care (TIC) that recognizes the potential impact of trauma experiences on patients and takes steps to mitigate the effects of adverse events in order to avoid re-traumatizing or triggering past trauma. Actions in this plan may include, but are not limited to, the following: • Incorporate trauma-informed training into new employee orientation • Offer annual refreshers and/or trainings for all staff • Recommend and supply TIC materials to third party partners, including care management companies and billing services • Identify patients using a screening methodology • Flag charts for patients with one or more adverse events that might have caused trauma • Use ICD-10 diagnosis codes for adverse events when appropriate TIC is a strengths-based healthcare delivery approach that emphasizes physical, psychological, and emotional safety for both trauma survivors and their providers.[13] Core components of a TIC approach are: awareness of the prevalence of trauma; understanding of the impact of past trauma on services utilization and engagement; and a commitment and plan to incorporate that understanding into training, policy, procedure, and practice.[14]
Proposed Weighting:	Medium

Rationale:	We proposed this activity because the psychological impact of trauma influences the clinical care needs of a large population in the United States and adopting a TIC approach could help all MIPS eligible clinicians avoid retraumatizing affected patients and support providers and staff who have experienced trauma themselves.[15] Research indicates that MIPS eligible clinicians have a positive view of TIC but need more resources and support to apply the concepts to practice.[16] For the purposes of this proposed improvement activity, trauma is the experience of a harmful or life-threatening event or series of events and their longer-term psychological impact, which can include development of post-traumatic stress disorder (PTSD) and changes to brain functioning and even genetics.[17] Approximately 60 percent of men and 50 percent of women in the U.S. have experienced trauma in their lifetimes and 7-8 percent of the population will have PTSD at some point in their lives.[18] Multi-generational trauma, whereby experiences that traumatized earlier generations, such as the genocide of Native American tribes, are passed down, impact many families and communities.[19] Clinicians (and not just mental health clinicians) who take a TIC approach anticipate and avoid institutional processes and individual practices that are likely to retraumatize individuals who have histories of trauma.[20] We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because trauma-informed approaches in healthcare are associated with improved outcomes for patients.[21] We proposed weighting this activity medium, because this activity may be accomplished by conducting a training, providing resources, or incorporating new procedures into a MIPS eligible clinician's practice. The estimated level of effort for MIPS eligible clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	Several commenters expressed support for the proposal to adopt this improvement activity. One commenter stated that this activity would be easier for larger, more established practices than smaller or solo practices to adopt.
Response:	We appreciate the commenters' support. We disagree that this activity would be more appropriate for larger, more established practices to adopt. A small or new practice could tailor the activity to their context, fulfilling the requirements within their constraints in the same way as a larger, more established practice. They can also consider using the Substance Abuse and Mental Health Services Administration's resource for providers who seek additional information about Trauma-Informed Care at: https://www.samhsa.gov/sites/default/files/programs_campaigns/childrens_mental_health/atc-whitepaper-040616.pdf.[16]
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BMH_11**
Subcategory:	Behavioral and Mental Health
Activity Title:	Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
Activity Description:	Create and implement a plan for trauma-informed care (TIC) that recognizes the potential impact of trauma experiences on patients and takes steps to mitigate the effects of adverse events in order to avoid re-traumatizing or triggering past trauma. Actions in this plan may include, but are not limited to, the following: • Incorporate trauma-informed training into new employee orientation • Offer annual refreshers and/or trainings for all staff • Recommend and supply TIC materials to third party partners, including care management companies and billing services • Identify patients using a screening methodology • Flag charts for patients with one or more adverse events that might have caused trauma • Use ICD-10 diagnosis codes for adverse events when appropriate TIC is a strengths-based healthcare delivery approach that emphasizes physical, psychological, and emotional safety for both trauma survivors and their providers.[13] Core components of a TIC approach are: awareness of the prevalence of trauma; understanding of the impact of past trauma on services utilization and engagement; and a commitment and plan to incorporate that understanding into training, policy, procedure, and practice.[14]
Weighting:	Medium

New Improvement Activity	
Proposed Activity ID:	**IA_BMH_12**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Promoting Clinician Well-Being
Proposed Activity Description:	Develop and implement programs to support clinician well-being and resilience—for example, through relationship-building opportunities, leadership development plans, or creation of a team within a practice to address clinician well-being—using one of the following approaches: • Completion of clinician survey on clinician well-being with subsequent implementation of an improvement plan based on the results of the survey. • Completion of training regarding clinician well-being with subsequent implementation of a plan for improvement.
Proposed Weighting:	High
Rationale:	We believe this activity would help MIPS eligible clinicians prioritize and improve their own well-being and the well-being of their staff and colleagues. Focusing on improving clinician well-being is especially critical now, given the stress that the COVID-19 public health emergency has exerted on clinicians. Many organizations, including the National Academies of Sciences, Engineering, and Medicine,[22] have prioritized interventions to improve clinician well-being. Studies indicate that clinician burnout, including emotional exhaustion, depersonalization, and reduced personal accomplishment, is associated with poorer quality healthcare and reduced safety for patients.[23] [24] Studies also indicate that some interventions have been shown to reduce burnout and improve well-being.[25] This improvement activity would fill a gap in the inventory because it does not currently include an improvement activity related to clinician well-being. We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because promoting clinician well-being and mitigating burnout leads to better quality health care and increased patient safety.[25] Given the impact of the COVID-19 pandemic on the medical community and the considerable time and resources required to mitigate its effects and promote well-being among clinicians, we believe that this activity should be weighted as high, in alignment with our definition in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	One commenter expressed support for the proposal to adopt this improvement activity but recommended that CMS modify it so that both the survey and training are required components of the activity; surveys contain relevant questions by role; and that the survey be conducted annually. The commenter also suggested that MIPS eligible clinicians implementing this activity combine the clinician well-being survey with all other essential workforce themed surveys to minimize survey fatigue.
Response:	We appreciate the commenter's support. The option to choose between a clinician survey and a training on clinician well-being provides two ways a MIPS eligible clinician could meet the requirements for this activity, tailored to the clinician's practice's needs and abilities. The requirement to implement a plan for improvement with either the survey or training further ensures that a MIPS eligible clinician selecting this activity take action towards improving clinician well-being. A clinician may also conduct surveys annually and attest to this activity in multiple years as they make steady progress towards intended outcomes.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BMH_12**
Subcategory:	Behavioral and Mental Health
Activity Title:	Promoting Clinician Well-Being
Activity Description:	Develop and implement programs to support clinician well-being and resilience—for example, through relationship-building opportunities, leadership development plans, or creation of a team within a practice to address clinician well-being—using one of the following approaches: • Completion of clinician survey on clinician well-being with subsequent implementation of an improvement plan based on the results of the survey. • Completion of training regarding clinician well-being with subsequent implementation of a plan for improvement.
Weighting:	High
New Improvement Activity	
Proposed Activity ID:	**IA_ERP_4**
Proposed Subcategory:	Emergency Response and Preparedness
Proposed Activity Title:	Implementation of a Personal Protective Equipment (PPE) Plan
Proposed Activity Description:	Implement a plan to acquire, store, maintain, and replenish supplies of personal protective equipment (PPE) for all clinicians or other staff who are in physical proximity to patients.

	In accordance with guidance from the Centers for Disease Control and Prevention (CDC) the PPE plan should address: • Conventional capacity: PPE controls that should be implemented in general infection prevention and control plans in healthcare settings, including training in proper PPE use. • Contingency capacity: actions that may be used temporarily during periods of expected PPE shortages. • Crisis capacity: strategies that may need to be considered during periods of known PPE shortages. The PPE plan should address all of the following types of PPE: • Standard precautions (e.g., hand hygiene, prevention of needle-stick or sharps injuries, safe waste management, cleaning and disinfection of the environment) • Eye protection • Gowns (including coveralls or aprons) • Gloves • Facemasks • Respirators (including N95 respirators)
Proposed Weighting:	Medium
Rationale:	The COVID-19 pandemic illustrated the importance of maintaining adequate PPE supplies for caregivers. Especially early in the pandemic, inadequate PPE supplies reduced access to care and exposed healthcare workers to unnecessary risk.[26] While clinicians may be following surge capacity procedures, they may not have a written plan for both preventing and preparing for surge capacity. In a survey conducted in mid-March of 2020, over 50 percent of physician practices cited a lack of supplies as an obstacle to caregiving.[27] Also, in a 2009 survey of American College of Emergency Physician Disaster Medicine Section members, fewer than 75 percent of respondents indicated that their emergency department had a plan for responding to pandemic influenza and other infectious disease threats.[28] This proposed improvement activity is based on the CDC guidelines for optimizing PPE supplies [29] and aligns with World Health Organization guidelines.[30] We believe that including this improvement activity in the inventory would encourage formalizing the process for creating a PPE plan, training staff, and ensuring adequate PPE inventory. Thus, it has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because both clinicians and their patients would be safer when responding to epidemics, reducing the transmission of viruses, and allowing clinicians to provide patients with appropriate care because supplies are available. We proposed that this activity should be weighted as medium, because it may be accomplished by conducting a training, providing resources, or incorporating new procedures into a MIPS eligible clinician's practice. The estimated level of effort for MIPS eligible clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	A commenter recommended that this improvement activity be modified to focus more on planning for access to PPE rather than on replenishing PPE, because accessing PPE has been challenging at times during the COVID-19 public health emergency. Another commenter suggested that CMS finalize the activity as a high-weighted activity because of the impact of lack of PPE during the COVID-19 public health emergency, and because preparation for current and future pandemics is essential for healthcare workers.
Response:	We agree that planning for access to PPE is essential. This activity addresses both access to and replenishment of PPE as it requires a written plan for the acquisition, storage, maintenance, and replenishment of PPE as well as for preventing and preparing for a surge in the need for PPE in contingency and crisis scenarios. We agree with the commenter who noted the impact of inadequate PPE during the COVID_19 public health emergency and its importance to health care workers. As explained in section III.I.3.h.(4)(d)(i)(C) of the CY 2019 PFS final rule (83 FR 59780 through 59781) high weighting is used for those activities of high intensity, requiring significant investment of time and resources. We do not believe creating a PPE plan requires significant levels of resources and therefore, we do not believe a high weighting is warranted.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_ERP_4**
Subcategory:	Emergency Response and Preparedness
Activity Title:	Implementation of a Personal Protective Equipment (PPE) Plan

Activity Description:	Implement a plan to acquire, store, maintain, and replenish supplies of personal protective equipment (PPE) for all clinicians or other staff who are in physical proximity to patients. In accordance with guidance from the Centers for Disease Control and Prevention (CDC) the PPE plan should address: • Conventional capacity: PPE controls that should be implemented in general infection prevention and control plans in healthcare settings, including training in proper PPE use. • Contingency capacity: actions that may be used temporarily during periods of expected PPE shortages. • Crisis capacity: strategies that may need to be considered during periods of known PPE shortages. The PPE plan should address all of the following types of PPE: • Standard precautions (e.g., hand hygiene, prevention of needle-stick or sharps injuries, safe waste management, cleaning and disinfection of the environment) • Eye protection • Gowns (including coveralls or aprons) • Gloves • Facemasks • Respirators (including N95 respirators)
Weighting:	Medium
New Improvement Activity	
Proposed Activity ID:	**IA_ERP_5**
Proposed Subcategory:	Emergency Response and Preparedness
Proposed Activity Title:	Implementation of a Laboratory Preparedness Plan
Proposed Activity Description:	Develop, implement, update, and maintain a preparedness plan for a laboratory intended to support continued or expanded patient care during COVID-19 or another public health emergency. The plan should address how the laboratory would maintain or expand patient access to health care services to improve beneficiary health outcomes and reduce healthcare disparities. For laboratories without a preparedness plan, MIPS eligible clinicians would meet with stakeholders, record minutes, and document a preparedness plan, as needed. The laboratory must then implement the steps identified in the plan and maintain them. For laboratories with existing preparedness plans, MIPS eligible clinicians should review, revise, or update the plan as necessary to meet the needs of the current PHE, implement new procedures, and maintain the plan. Maintenance of the plan in this activity could include additional hazard assessments, drills, training, and/or developing checklists to facilitate execution of the plan. Participation in debriefings to evaluate the effectiveness of plans are additional examples of engagement in this activity.
Proposed Weighting:	Medium
Rationale:	The COVID-19 pandemic demonstrated a need for many laboratories to develop and implement protocols to respond to the public health emergencies, as an increase in demand (due to a surge in COVID testing) and reduced staffing (due to needing to maintain distancing and other factors, such as childcare becoming unavailable) compromised laboratory functioning.[31] We believe that including this improvement activity in the inventory would encourage formalizing, updating, and maintaining preparedness plans to better equip laboratories to address another public health emergency, as well as other disasters such as floods, fires, or other emergencies. Such a plan will allow laboratory staff to respond and maintain operations during emergency situations. Thus, it has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because if needed laboratory services increase with the surge in demand, staff will be prepared to meet those needs. We proposed weighting this activity medium, because this activity may be accomplished by developing a plan and training staff on that plan. The estimated level of effort for MIPS eligible clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).

Comments:	Several commenters supported the addition of this improvement activity. One commenter urged CMS to finalize this improvement activity in order to expand the limited number of activities available to pathologists for reporting in this category.
Response:	We appreciate the support and would welcome the nomination of additional activities for pathologists and other non-patient facing clinicians.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_ERP_5**
Subcategory:	Emergency Response and Preparedness
Activity Title:	Implementation of a Laboratory Preparedness Plan
Activity Description:	Develop, implement, update, and maintain a preparedness plan for a laboratory intended to support continued or expanded patient care during COVID-19 or another public health emergency. The plan should address how the laboratory would maintain or expand patient access to health care services to improve beneficiary health outcomes and reduce healthcare disparities. For laboratories without a preparedness plan, MIPS eligible clinicians would meet with stakeholders, record minutes, and document a preparedness plan, as needed. The laboratory must then implement the steps identified in the plan and maintain them. For laboratories with existing preparedness plans, MIPS eligible clinicians should review, revise, or update the plan as necessary to meet the needs of the current PHE, implement new procedures, and maintain the plan. Maintenance of the plan in this activity could include additional hazard assessments, drills, training, and/or developing checklists to facilitate execution of the plan. Participation in debriefings to evaluate the effectiveness of plans are additional examples of engagement in this activity.
Weighting:	Medium
New Improvement Activity	
Proposed Activity ID:	IA_PSPA_33
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Application of CDC's Training for Healthcare Providers on Lyme Disease
Proposed Activity Description:	Apply the Centers for Disease Control and Prevention's (CDC) Training for Healthcare Providers on Lyme Disease using clinical decision support (CDS). CDS for Lyme disease should be built directly into the clinician workflow and support decision making for a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include but are not limited to: electronic health record (EHR) based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Proposed Weighting:	Medium
Rationale:	Lyme disease has a high burden of disease, with approximately 476,000 cases diagnosed and treated annually. Additionally, the places where Lyme disease is common is expanding.[32] We believe that including this improvement activity in the inventory would increase knowledge about Lyme disease. The CDC has developed a training course to support clinicians in identifying and treating Lyme disease, and this course will provide foundational knowledge to incorporate Lyme disease diagnosis and treatment into the workflow using CDS.[33] It has the potential to improve clinical practice and care delivery and is likely to result in improved outcomes; additional education to improve Lyme disease testing, ordering, and reporting systems are likely to improve patient care, reduce errors, and result in better Lyme disease-related outcomes. [34 35 36] We proposed weighting this activity medium because this activity may be accomplished by conducting a training and incorporating new procedures into a MIPS eligible clinician's practice. The estimated level of effort for MIPS eligible clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Final Action	We received no comments on this proposal; therefore, we are finalizing as proposed.
Finalized Improvement Activity	
Activity ID:	IA_PSPA_33
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Application of CDC's Training for Healthcare Providers on Lyme Disease
Activity Description:	Apply the Centers for Disease Control and Prevention's (CDC) Training for Healthcare Providers on Lyme Disease using clinical decision support (CDS). CDS for Lyme disease

	should be built directly into the clinician workflow and support decision making for a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include but are not limited to: electronic health record (EHR) based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Weighting:	Medium

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Table B: Changes to Previously Adopted Improvement Activities for the CY 2022 Performance Period/ 2024 MIPS Payment Year and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_AHE_1**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Engagement of new Medicaid patients and follow-up
Current Activity Description:	Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare. A timely manner is defined as within 10 business days for this activity.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). The proposed modified activity would continue to address the important objective of providing timely care to Medicaid patients, but also expand the target population to include all patients who are underserved and may face barriers to timely access to appropriate care. We also proposed modifying the description so that, instead of stating patients should receive follow-up in a "timely manner," defined as within 10 business days, clinicians would use their own time-to-treat data (i.e., data measuring the time between clinician identifying a need for an appointment and the patient having a scheduled appointment) to ensure that patients receive follow-up within standard guidelines and create, implement and monitor an approach for improvement in engagement in care. We wanted to broaden the description, because the amount of time that is clinically relevant for a follow up visit varies widely,[1] and therefore, setting a specific definition of "timely manner" may not be clinically appropriate for all patients. The proposed modification acknowledges this variation and encourages clinicians to use their own time-to-treat data and standard practice guidelines to enhance engagement. The proposed modified activity describes that this approach to improving engagement in care may include screening for treatment barriers, especially transportation barriers, and providing resources to patients who need assistance, including access to federally-mandated Medicaid transportation benefits. Lack of suitable transportation can pose a barrier to accessing needed care for many underserved patients—particularly for those who are elderly, disabled, or low-income.[2] As finalized in Federal regulation (42 CFR 431.53 and 440.170), Medicaid beneficiaries are eligible for the non-emergency medical transportation benefit, which assures transportation to and from non-emergency medical care for those without other options.[3] This activity is intended to encourage MIPS eligible clinicians to direct Medicaid beneficiaries and other underserved patients to access resources to reduce barriers to their timely access of needed care and ultimately help them achieve better health outcomes. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it creates more flexibility around the timeline for follow-up by using time-to-treat data, specifies that these data guide an approach for patient engagement, and addresses a broader range of underserved populations.
Proposed Revised Activity Title	Enhance Engagement of Medicaid and Other Underserved Populations
Proposed Revised Activity Description:	To improve responsiveness of care for Medicaid and other underserved patients: use time-to-treat data (i.e., data measuring the time between clinician identifying a need for an appointment and the patient having a scheduled appointment) to identify patterns by which care or engagement with Medicaid patients or other groups of underserved patients has not achieved standard practice guidelines; and with this information, create, implement, and monitor an approach for improvement. This approach may include screening for patient barriers to treatment, especially transportation barriers, and providing resources to improve engagement (e.g., state Medicaid non-emergency medical transportation benefit).
Comments:	Many commenters expressed support for the proposed modifications to this improvement activity. One commenter expressed concern that the modifications would make the activity harder to implement. The commenter believed that expanding the population would increase the burden for reporting and documenting by requiring that a MIPS eligible clinician ask patients sensitive questions about income and family. They also suggested that the modification's proposed expanded patient population may make it more difficult to filter records to identify targeted patients. For these reasons, they suggested CMS amend the definition of the applicable patient population defined in this activity. The commenter also expressed concern about changing the definition of timeliness, because the broader definitions for timeliness and population seem to require more complex analysis to identify trends in care and engagement.
Response:	We appreciate the commenters' support. We would like to clarify that expanding the population to all underserved populations would simply allow a MIPS eligible clinician to select and target an underserved community relevant to their practice. Targeting a patient population of their choice would enable them to determine the data they would need to collect and analysis they

	would need to perform to allow them to adequately meet the requirements of this activity, within the confines of their practice's resources and interests. One may focus on Medicaid beneficiaries, while another may select a different underserved community. Regarding the commenter's preference for the original threshold of 10 days for determining timeliness: as stated above, the amount of time that is clinically relevant for a follow up visit varies widely, and any given specific definition of "timely manner" may not be clinically appropriate for all patients. However, if a MIPS eligible clinician believes that the 10-day threshold for timeliness is clinically appropriate, they could still apply it to their time-to-treat data for a specific target population to identify timeliness issues in delivering care. Given the flexibility for a MIPS eligible clinician to define their population of interest and their time-to-treat threshold, we do not believe this modification increases burden or complexity of analysis to identify patients or trends in care and engagement.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_1**
Subcategory:	Achieving Health Equity
Activity Title:	Enhance Engagement of Medicaid and Other Underserved Populations
Activity Description:	To improve responsiveness of care for Medicaid and other underserved patients: use time-to-treat data (i.e., data measuring the time between clinician identifying a need for an appointment and the patient having a scheduled appointment) to identify patterns by which care or engagement with Medicaid patients or other groups of underserved patients has not achieved standard practice guidelines; and with this information, create, implement, and monitor an approach for improvement. This approach may include screening for patient barriers to treatment, especially transportation barriers, and providing resources to improve engagement (e.g., State Medicaid non-emergency medical transportation benefit).
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_AHE_5**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	MIPS Eligible Clinician Leadership in Clinical Trials or Community-Based Participatory Research (CBPR)
Current Activity Description:	MIPS eligible clinician leadership in clinical trials, research alliances or community-based participatory research (CBPR) that identify tools, research or processes that can focuses on minimizing disparities in healthcare access, care quality, affordability, or outcomes.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2018 Quality Payment Program final rule (82 FR 54175). The proposed modification would add as an explicit option that the research could focus on addressing health-related social needs as drivers of health. Risks for health-related social needs are more acute and widespread in underserved communities.[4] These risks are linked to worse health outcomes and addressing them can reduce costs.[5] The modification would also change verbiage in ways that clarify the activity, but do not affect the intent of the activity. The health-related social needs included in the proposed modification are aligned with our Accountable Health Communities (AHC) Model (https://innovation.cms.gov/innovation-models/ahcm), which looks at the impact of identifying and addressing patients' health-related social needs on their health outcomes. AHC has prioritized five areas of health-related social needs, namely: food insecurity, housing insecurity, transportation, utilities, and interpersonal safety.[6] These areas were selected as priority, because there is high-quality evidence linking it with poor health or increased health care utilization and cost, there are community providers who can help meet the need, and health care providers are not yet comprehensively screening for or addressing these needs.[7] We proposed to modify this improvement activity to identify the same five health-related social needs prioritized in the AHC Model as potential areas of research. Criteria for selecting new improvement activities, which we finalized in section IV.A.3.d.(3)(c)(i) of this final rule, align with those used for prioritizing health-related social needs. With this modification, this improvement activity would become more explicitly a part of our plan to help clinicians provide patient-centered care to patients who have complex and multi-faceted needs. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it explicitly includes research into health-related social needs, which are central to understanding and addressing disparities in achieving positive health outcomes. We believe that we would achieve the objectives of the Quality Payment Program—specifically, to improve beneficiary population health, to improve the care received by Medicare beneficiaries, and to lower costs to the Medicare program—by helping address health-related social needs.

Proposed Revised Activity Description:	Lead clinical trials, research alliances, or community-based participatory research (CBPR) that identify tools, research, or processes that focus on minimizing disparities in healthcare access, care quality, affordability, or outcomes. Research could include addressing health-related social needs like food insecurity, housing insecurity, transportation barriers, utility needs, and interpersonal safety.
Comments:	One commenter was supportive of improvement activity modifications that addressed using data to address disparities in health equity, for example, gathering and analyzing data by race and documenting disparities by different population groups. The commenter recommended that when implementing such modifications, CMS should ensure that such modifications do not alter the core intent of the activity.
Response:	We thank the commenter for this input and agree with this approach. When modifying several improvement activities to include collecting and analyzing population-level data, including health-related social needs, our intent is to highlight opportunities to strengthen core activities to close health equity gaps using a data-informed approach. This activity's modification includes an option, not a requirement, to address health-related social needs as part of research activities.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_5**
Subcategory:	Achieving Health Equity
Activity Title:	MIPS Eligible Clinician Leadership in Clinical Trials or Community-Based Participatory Research (CBPR)
Activity Description:	Lead clinical trials, research alliances, or community-based participatory research (CBPR) that identify tools, research, or processes that focus on minimizing disparities in healthcare access, care quality, affordability, or outcomes. Research could include addressing health-related social needs like food insecurity, housing insecurity, transportation barriers, utility needs, and interpersonal safety.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_BE_1**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of certified EHR to capture patient reported outcomes
Current Activity Description:	In support of improving patient access, performing additional activities that enable capture of patient reported outcomes (e.g., home blood pressure, blood glucose logs, food diaries, at-risk health factors such as tobacco or alcohol use, etc.) or patient activation measures through use of certified EHR technology, containing this data in a separate queue for clinician recognition and review.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to modify the activity by replacing examples of patient reported outcomes with current industry standards —functional status, symptoms and symptom burden, health behaviors, and patient experience. We also proposed to include a definition for patient activation[8] —measures of patient involvement in their care -- to improve clarity of the activity. Finally, we also proposed to simplify the wording in ways that clarify the activity but do not affect the purpose. These proposed modifications would improve the accuracy, applicability, and clarity of the activity. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it promotes clarity by providing more accurate and current industry standard patient reported outcomes.
Proposed Revised Activity Description:	To improve patient access, perform activities beyond routine care that enable capture of patient reported outcomes (for example, related to functional status, symptoms and symptom burden, health behaviors, or patient experience) or patient activation measures (that is, measures of patient involvement in their care) through use of certified electronic health record technology, and record these outcomes data for clinician review.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_1**
Subcategory:	Beneficiary Engagement
Activity Title:	Use of certified EHR to capture patient reported outcomes
Activity Description:	To improve patient access, perform activities beyond routine care that enable capture of patient reported outcomes (for example, related to functional status, symptoms and symptom burden, health behaviors, or patient experience) or patient activation measures (that is, measures of patient involvement in their care) through use of certified electronic health record technology, and record these outcomes data for clinician review.

Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_BE_6**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Collection of and follow-up on patient experience and satisfaction data on beneficiary engagement
Current Activity Description:	Collection of and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to combine multiple activities into this IA_BE_6 improvement activity to remove overlapping content and improve the applicability and ease of use. In addition to this activity, the previously adopted BE_13 (81 FR 77825) and PSPA_11 (81 FR 77825) improvement activities also require the collection of patient experience and satisfaction data with the objective of increasing patient-centeredness of care. The previously adopted activity descriptions are as follows: • IA_BE_13: Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms. • IA_PSPA_11: Participation in the Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS) or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets) We proposed to modify IA_BE_6 to include additional detail covering the unique content of IA_BE_13 and IA_PSPA_11. Specifically, we proposed to add surveys such as CAHPS, advisory councils, and other mechanisms in the modified version of BE_6 as options for tools used for collecting the patient experience data. We also proposed to update the title of the improvement activity to better reflect the full scope of the revised activity description. We also proposed to add language that will encourage MIPS eligible clinicians to consider the linguistic needs of their population, so that the satisfaction survey results could include the perspectives of patient groups who may not feel comfortable taking a survey in English.
Proposed Revised Title:	Regularly Assess Patient Experience of Care and Follow Up on Findings
Proposed Revised Activity Description:	Collect and follow up on patient experience and satisfaction data. This activity also requires follow-up on findings of assessments, including the development and implementation of improvement plans. To fulfill the requirements of this activity, MIPS eligible clinicians can use surveys (e.g., Consumer Assessment of Healthcare Providers and Systems Survey), advisory councils, or other mechanisms. MIPS eligible clinicians may consider implementing patient surveys in multiple languages, based on the needs of their patient population.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_6**
Subcategory:	Beneficiary Engagement
Activity Title:	Regularly Assess Patient Experience of Care and Follow Up on Findings
Activity Description:	Collect and follow up on patient experience and satisfaction data. This activity also requires follow-up on findings of assessments, including the development and implementation of improvement plans. To fulfill the requirements of this activity, MIPS eligible clinicians can use surveys (e.g., Consumer Assessment of Healthcare Providers and Systems Survey), advisory councils, or other mechanisms. MIPS eligible clinicians may consider implementing patient surveys in multiple languages, based on the needs of their patient population.
Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_BE_16**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Evidenced-based techniques to promote self-management into usual care
Current Activity Description:	Incorporate evidence-based techniques to promote self-management into usual care, using techniques such as goal setting with structured follow-up, Teach Back, action planning or motivational interviewing.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to combine this IA_BE_16 with the previously adopted IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 because of overlapping and duplicative content and to improve the applicability and ease of use of the inventory. The above previously

	adopted improvement activities included effective interventions for helping patients better engage in self-management. The previously adopted activity descriptions are as follows: • IA_BE_17: Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or "How's My Health"). (81 FR 77825) • IA_BE_18: Provide peer-led support for self-management. (81 FR 77825) • IA_BE_20: Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community. (81 FR 77825) • IA_BE_21: Provide self-management materials at an appropriate literacy level and in an appropriate language. (81 FR 77825) We proposed to change IA_BE_16 to include additional detail covering the unique content of IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21. Specifically, we proposed to add tools for self-management, peer-led support, provision of self-management materials, and retain the examples of evidence-based approaches patients may use to better engage in self-management included in the original IA_BE_16: goal setting with structured follow-up,[9] Teach-back methods,[10] action planning,[11] assessment of need for self-management (for example, the Patient Activation Measure[12]), and motivational interviewing[13] as options for tools and resources to provide patients as part of fulfilling the requirements for the activity. These tools and techniques could be particularly helpful for people with substance use disorders and individuals managing chronic physical conditions such as diabetes and heart disease[14]. We also proposed to add that evidence-based techniques for promoting self-management should be culturally and linguistically tailored.
Proposed Revised Activity Title:	Promote Self-management in Usual Care
Proposed Revised Activity Description:	To help patients self-manage their care, incorporate culturally and linguistically tailored evidence-based techniques for promoting self-management into usual care, and provide patients with tools and resources for self-management. Examples of evidence-based techniques to use in usual care include: goal setting with structured follow-up, Teach-back methods, action planning, assessment of need for self-management (for example, the Patient Activation Measure), and motivational interviewing. Examples of tools and resources to provide patients directly or through community organizations include: peer-led support for self-management, condition-specific chronic disease or substance use disorder self-management programs, and self-management materials.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_16**
Subcategory:	Beneficiary Engagement
Activity Title:	Promote Self-management in Usual Care
Activity Description:	To help patients self-manage their care, incorporate culturally and linguistically tailored evidence-based techniques for promoting self-management into usual care, and provide patients with tools and resources for self-management. Examples of evidence-based techniques to use in usual care include: goal setting with structured follow-up, Teach-back methods, action planning, assessment of need for self-management (for example, the Patient Activation Measure), and motivational interviewing. Examples of tools and resources to provide patients directly or through community organizations include: peer-led support for self-management, condition-specific chronic disease or substance use disorder self-management programs, and self-management materials.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_BE_25**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Drug Cost Transparency
Current Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the MIPS eligible clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).)
Current Weighting:	High

Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2020 PFS final rule (84 FR 63539). In the CY 2020 PFS final rule (84 FR 63515), we adopted IA_BE_25, titled "Drug Cost Transparency to include requirements for use of real-time benefit tools" beginning with the 2020 performance year and for subsequent years. It allows a real-time benefit tool (RTBT) to be one source of information for pricing of pharmaceuticals, which provides to the prescriber real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. The 2021 Consolidated Appropriations Act (H.R. 116-133, Pub. L. 116-260) subtitle B included section 119 "Increasing the use of real-time benefit tools to lower beneficiary costs" subsection (c) "Inclusion of Use of Real-Time Electronic Information in Shared Decision-Making Under MIPS" amended section 1848(q)(2)(B)(iii)(IV) of the Act by adding at the end the following new sentences: ``This subcategory shall include as an activity, for performance periods beginning on or after January 1, 2022, use of a real-time benefit tool as described in section 1860D-4(o). The Secretary may establish this activity as a standalone or as a component of another activity." In response to this amendment, in the proposed rule, we proposed to modify this improvement activity such that beginning with the CY 2022 performance period/2024 MIPS payment year and for subsequent years the activity will require use of RTBT. As previously finalized, use of RTBT was optional. We also proposed to update the description in ways that clarify the activity, but do not affect the intent of the activity. We believe that requiring RTBT will make this activity more likely to reduce the costs of care. As explained in the CY 2019 Modernizing Part D final rule (84 FR 23832), RTBTs that are integrated with at least one prescriber's e-prescribing and electronic medical record systems can make beneficiary-specific drug coverage and cost information visible to prescribers. Using RTBT thus allows the prescriber and patient, when appropriate, to choose among clinically acceptable alternatives while weighing costs. By making RTBT a requirement, this modification will also require prescribers to look for alternative drugs, in contrast to the existing activity where such comparisons are optional. We believe that furthering prescription price transparency is critical to lowering overall drug costs and patients' out-of-pocket costs and improving medication adherence. Additionally, it could help advance efforts to improve patient safety, quality of care, and efficiencies and cost savings in the delivery of care.
Proposed Revised Activity Description:	Provide counseling to patients and/or their caregivers regarding: costs of medications using a real time benefit tool (RTBT) which provides to the prescriber real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary.
Comments:	One commenter recommended that the use of a RTBT remain optional to meet the requirements for this activity given the variation in practices' access to RTBT.
Response:	The modification to this improvement activity was proposed to satisfy the requirement of the 2021 Consolidated Appropriations Act (H.R. 116-133, Pub. L. 116-260), which provides that the Improvement Activity performance category include a new or modified activity that requires use of RTBT. We chose to combine this requirement with an existing activity about RTBT because we viewed the CAA amendment as an opportunity to further advance patient counseling regarding drug cost. Requiring the use of RTBT would make this activity more likely to reduce the costs of care for patients. Moreover, MIPS eligible clinicians with delayed access to RTBT can choose appropriate improvement activities from over 100 activities in the inventory, until their access issues are resolved.
Final Action:	After consideration of the public comments we received, we are finalizing our CY 2022 performance period/2024 MIPS payment year proposal to modify IA_BE_25 without modification.
Finalized Improvement Activity	
Activity ID:	**IA_BE_25**
Subcategory:	Beneficiary Engagement
Activity Title:	Drug Cost Transparency
Activity Description:	Provide counseling to patients and/or their caregivers regarding: costs of medications using a real time benefit tool (RTBT) which provides to the prescriber real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary.
Current Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_CC_14**
Current Subcategory:	Care Coordination
Current Activity Title:	Practice improvements that engage community resources to support patient health goals
Current Activity Description:	Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following: • Maintain formal (referral) links to community-based chronic disease self-management

	support programs, exercise programs and other wellness resources with the potential for bidirectional flow of information; and provide a guide to available community resources. • Including through the use of tools that facilitate electronic communication between settings; • Screen patients for health-harming legal needs; • Screen and assess patients for social needs using tools that are preferably health IT enabled and that include to any extent standards-based, coded question/field for the capture of data as is feasible and available as part of such tool; and/or • Provide a guide to available community resources.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). The previously adopted improvement activity includes screening as one option to assess patients specifically for social and legal needs. We proposed to modify this improvement activity to instead require screening for a range of health-related social needs using evidence-based tools before and in addition to supporting connections to community resources. We believe that screening patients using evidence-based tools could help clinicians adopt a more systematic approach to addressing health related social needs among their patient population, including effective documentation and follow-up, and avoid missing patients who have such needs. Including screening in addition to supporting connections to community resources, represents a continuum of support that clinicians can provide to patients from within the health system. We also proposed to remove the promotion of systems for communication that have the "potential for bi-directional flow of information" and the option for using "tools that facilitate electronic communication between settings." In many communities, the resources and programs that might best provide patients who have health-related social needs with support may not have the baseline technological capacity to engage with clinician groups in ways that eclipse basic forms of communication like phone and email. We also proposed to add an option for using electronic health records to document screening results, trigger follow-up, and analyze data to better tailor approaches. For practices that already have processes for enabling connections to community resources established, this option would allow continued improvement and provision of more streamlined and systematized support to patients in need. The specific set of health-related social needs that clinicians might choose to prioritize remains part of the improvement activity, as does examples that were previously mentioned in the activity—for example, health-related legal needs. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it requires MIPS eligible clinicians to both screen for and address health related social needs, which are major contributors to health care access and health outcomes. In light of the above list of proposed changes in this modification, we also proposed to increase the weight for this activity from medium to high. Specifically, the modifications would require screening in addition to an activity that links patients to community resources. Previously, the activity required screening *or* linkages to community. Conducting screening then devoting clinical staff time to using that data to identify and disseminate appropriate community resource information to patients takes considerable time and resources. We proposed to increase the weight for this activity from medium to high to reflect the additional effort required, per high-weight criteria finalized in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Proposed New Weighting:	High
Proposed Revised Activity Description:	Select and screen for the health-related social needs (HRSN) that are relevant for your patient population using tools that have been tested with underserved populations. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded question/field for the capture of data. After screening, address HRSNs identified through at least one of the following: • Update a guide to available community resources and provide it to patients who are found to be at risk in one or more HRSN area; • Maintain formal (referral) links to key community resources and programs to strengthen the referral process, implementing closed-loop referrals where feasible; or • Record findings of screening and trigger follow-up within the electronic health record (EHR); then analyze EHR data on patients with one or more HRSN needed to identify and implement approaches to better serve their holistic needs through linkages with community resources.

	HRSNs prioritized by your practice might include health-harming legal needs, which require both health and legal support to resolve, areas such as food and housing insecurity, or needs such as exercise, nutrition, or chronic disease self-management.
Comments:	One commenter was supportive of improvement activity modifications that address using data to address disparities in health equity, e.g., gathering and analyzing data by race and documenting disparities by different population groups. The commenter recommended that when implementing such modifications, CMS ensures that such modifications do not alter the core intent of the activity. We also received feedback suggesting CMS modify the activity description to reflect that a MIPS eligible clinician should maintain relationships with community-based organizations to strengthen community service referrals to HRSN, especially for underserved populations. They suggested CMS could emphasize this point by placing this bullet first in the activity description. They believed these edits were needed to underscore the importance of leveraging the experience of and relationships with community-based organizations to connect patients to community services to address HRSN. They also suggested we modify the activity to specify that in addition to updating a guide to community resources, a MIPS eligible clinician could work with community partners to provide a community resource guide. They explain this addition would highlight the option for community organizations to share existing resource guides with patients found to be at risk for HRSN, via the MIPS eligible clinician.
Response:	We thank the commenter for this input and agree with this approach. When modifying several improvement activities to include collecting and analyzing population-level data including health-related social needs, our intent is to highlight opportunities to strengthen core activities to close health equity gaps using a data-informed approach. This activity's modification adds a requirement to screen patients for health-related social needs, which may rely on population-level data analysis. The intent of this modification is to help MIPS eligible clinicians adopt a more systematic approach to referring patients to community-based resources without altering the core intent of the activity. We also agree with the feedback regarding modifying the language of this activity to emphasize the importance of relationships between a MIPS eligible clinician and community-based organizations to strengthen community service referrals, and to include the option for community partners to share existing resource guides related to HRSN areas. We also agree to include these options for completing this activity in this order, involving a switch of the current second bullet to become the first.
Final Action:	After consideration of the public comments we received, we are modifying this activity by moving the current second bullet first and by editing the language to refer to a relationship between a MIPS eligible clinician and community-based organizations and to specify that they strengthen referrals to community services; and to include the option for community partners to share existing resource guides.
Finalized Improvement Activity	
Activity ID:	**IA_CC_14**
Subcategory:	Care Coordination
Activity Title:	Practice improvements that engage community resources to support patient health goals
Activity Description:	Select and screen for the health-related social needs (HRSN) that are relevant for your patient population using tools that have been tested with underserved populations. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded question/field for the capture of data. After screening, address HRSNs identified through at least one of the following: • Maintain formal relationships with community- based organizations to strengthen the community service referral process, implementing closed-loop referrals where feasible; or • Update a guide to available community resources, or work with community partners to provide a community resource guide and provide it to patients who are found to be at risk in one or more HRSN area; or • Record findings of screening and trigger follow-up within the electronic health record (EHR); then analyze EHR data on patients with one or more HRSN needed to identify and implement approaches to better serve their holistic needs through linkages with community resources. HRSNs prioritized by your practice might include health-harming legal needs, which require both health and legal support to resolve, areas such as food and housing insecurity, or needs such as exercise, nutrition, or chronic disease self-management.
Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_CC_15**
Current Subcategory:	Care Coordination
Current Activity Title:	PSH Care Coordination
Current Activity Description:	Participation in a Perioperative Surgical Home (PSH) that provides a patient-centered, physician-led, interdisciplinary, and team-based system of coordinated patient care, which coordinates care from pre-procedure assessment through the acute care episode, recovery, and post-acute care.

	This activity allows for reporting of strategies and processes related to care coordination of patients receiving surgical or procedural care within a PSH. The MIPS eligible clinician must perform one or more of the following care coordination activities: • Coordinate with care managers/navigators in preoperative clinic to plan and implementation comprehensive post discharge plan of care; • Deploy perioperative clinic and care processes to reduce post-operative visits to emergency rooms; • Implement evidence-informed practices and standardize care across the entire spectrum of surgical patients; or • Implement processes to ensure effective communications and education of patients' post-discharge instructions.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2018 Quality Payment Program final rule (82 FR 54175). We proposed to increase the weight for this activity from medium to high, because it came to our attention that the level of effort to complete this activity was better aligned to our high-weight criteria, which specifies that high-weight activities reflect high intensity activities, requiring significant investment of time and resources. This activity requires team-based, interdisciplinary care coordinated across multiple care settings and requires efforts to both plan for and implement the selected care coordination actions. We note that the activity description will remain the same.
Proposed New Weighting:	High
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_15**
Subcategory:	Care Coordination
Activity Title:	PSH Care Coordination
Activity Description:	Participation in a Perioperative Surgical Home (PSH) that provides a patient-centered, physician-led, interdisciplinary, and team-based system of coordinated patient care, which coordinates care from pre-procedure assessment through the acute care episode, recovery, and post-acute care. This activity allows for reporting of strategies and processes related to care coordination of patients receiving surgical or procedural care within a PSH. The MIPS eligible clinician must perform one or more of the following care coordination activities: • Coordinate with care managers/navigators in preoperative clinic to plan and implementation comprehensive post discharge plan of care; • Deploy perioperative clinic and care processes to reduce post-operative visits to emergency rooms; • Implement evidence-informed practices and standardize care across the entire spectrum of surgical patients; or • Implement processes to ensure effective communications and education of patients' post-discharge instructions.
Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_EPA_1**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
Current Activity Description:	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to remove references to a "consistent" MIPS eligible clinician, group or care team, because the requirement for a consistent clinician was unclear and unnecessary to achieve the activity's objectives. We also proposed to limit the scope of the activity to "urgent care" only rather than both "urgent

	and emergent care," because emergent care would only require the activity's interventions when also urgent. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because the improved clarity will promote expanded access to MIPS eligible clinicians in urgent care settings. We believe that these modifications help clarify the nature and intent of this activity, and thus would help clinicians selecting it to improve access to care for their patients.
Proposed Revised Activity Description:	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent care (e.g., MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_EPA_1**
Subcategory:	Expanded Practice Access
Activity Title:	Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
Activity Description:	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent care (e.g., MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_EPA_2**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Use of telehealth services that expand practice access
Current Activity Description:	Use of telehealth services and analysis of data for quality improvement, such as participation in remote specialty care consults or teleaudiology pilots that assess ability to still deliver quality care to patients.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 QPP final rule (81 FR 77825). We proposed to shift the focus of the activity to developing standardized approaches for telehealth in their daily practice and away from the analysis of data to evaluate effectiveness. This proposed shift retains the objective of the original activity, namely, of improving health outcomes for patients utilizing telehealth services. We believe this proposed shift makes the activity more relevant, because while telehealth has become a routine part of health care during the COVID-19 pandemic and is perceived as effective by clinicians and patients, clinicians may not have implemented it in a standardized manner or as widely as possible due to the rapid adaptation needed during the pandemic.[15] We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it promotes creation and implementation of standardized telehealth services, which can improve access and quality of care by offering another mode by which patients can interact with their care team.
Proposed Revised Activity Description:	Create and implement a standardized process for providing telehealth services to expand access to care.
Comments:	Commenters expressed support for the proposed modifications to this improvement activity.
Response:	We appreciate the commenters' support.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_EPA_2**

Subcategory:	Expanded Practice Access
Activity Title:	Use of telehealth services that expand practice access
Activity Description:	Create and implement a standardized process for providing telehealth services to expand access to care.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PM_6**
Current Subcategory:	Population Management
Current Activity Title:	Use of toolsets or other resources to close health care disparities across communities
Current Activity Description:	Take steps to improve healthcare disparities, such as Population Health Toolkit or other resources identified by CMS, the Learning and Action Network, Quality Innovation Network, or National Coordinating Center. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs work under the direction of CMS to assist MIPS eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to add language that is more explicit about the improvement activity's focus on using population health data analysis to assess the prevalence of inequities in a practice and community. Specifically, we proposed to modify the activity description to specify that population health data analysis tools should be used to identify health inequities; MIPS eligible clinicians should then assess the options for effective interventions to address those inequities.[16] We also proposed to add a requirement that MIPS eligible clinicians create, refine, and implement an action plan to address inequities based on the data analysis conducted. We also proposed to remove references to the Learning and Action Network, Quality Innovation Network, and National Coordinating Center as organizations that may identify tools or resources, because they may not be appropriate resources to support clinicians in assessing and addressing health disparities. Population health data analytic tools may be identified in a number of ways, and we seek to keep the activity broad in this manner. We also proposed to replace the term "disparities" with "inequities" in both the title and description of the activity, which acknowledges structural problems like racism are inequities (that is, state of being unfair) rather than using the term disparities, which is defined as being different or not at parity but does not clearly state the unjustness of the result. We also proposed to modify the title to recognize that inequities in both health (that is, status and outcomes) and health care (that is, access, quality, and safety) may be addressed. With the proposed modifications, MIPS eligible clinicians attesting to this improvement activity would need to first analyze inequities in their patient populations, and then use that data to identify and then address issues or gaps. We believe that participation in the modified version of this improvement activity will be more likely to result in improved outcomes, because it is more focused on a data-driven approach to population health analysis and requires practices to use this data to inform a formal action planning process to address them.
Proposed Revised Activity Title:	Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
Proposed Revised Activity Description:	Address inequities in health outcomes by using population health data analysis tools to identify health inequities in the community and practice and assess options for effective and relevant interventions such as Population Health Toolkit or other resources identified by the clinician, practice, or by CMS. Based on this information, create, refine, and implement an action plan to address and close inequities in health outcomes and/or health care access, quality, and safety.
Comments:	Commenters expressed support for the proposed modifications to this improvement activity. One commenter was supportive of improvement activity modifications that addressed using data to address disparities in health equity, e.g., gathering and analyzing data by race and documenting disparities by different population groups. The commenter recommended that when implementing such modifications, CMS ensures that such modifications do not alter the core intent of the activity.
Response:	We appreciate the commenters' support and agree with this approach to implementing such modifications. When modifying several improvement activities to include collecting and analyzing population-level data, our intent is to highlight opportunities to strengthen core activities to close health equity gaps using a data-informed approach. This activity's modification specifies that population health data analysis tools should be used to identify health inequities. This strengthens, but does not alter, the intent of the activity, which was already focused on using toolsets or other resources to address such inequities. We refer stakeholders to the Executive

	Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government for more information about health equity.[17]
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PM_6**
Subcategory:	Population Management
Activity Title:	Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
Activity Description:	Address inequities in health outcomes by using population health data analysis tools to identify health inequities in the community and practice and assess options for effective and relevant interventions such as Population Health Toolkit or other resources identified by the clinician, practice, or by CMS. Based on this information, create, refine, and implement an action plan to address and close inequities in health outcomes and/or health care access, quality, and safety.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PM_11**
Current Subcategory:	Population Management
Current Activity Title:	Regular review practices in place on targeted patient population needs
Current Activity Description:	Implementation of regular reviews of targeted patient population needs, such as structured clinical case reviews, which includes access to reports that show unique characteristics of MIPS eligible clinician's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to make explicit the acknowledgement that structural issues, like racism, are a root cause of many disparities in health outcomes across populations. Specifically, we proposed to modify the improvement activity to encourage MIPS eligible clinicians to explore structural issues like racism explicitly and openly during their reviews of targeted patient population needs. We proposed to remove reference to "vulnerable patients" and replace it with "underserved patients" to better clarify that there is nothing inherently vulnerable about a person. Instead, their poorer health outcomes are due to systemic failures within and beyond the health system—failures which leave the health needs of underserved communities unmet. We believe these additions would allow MIPS eligible clinicians to gain perspective and ideas beneficial to their patients by specifically identifying underserved patients, related structural inequities such as those due to racism, and tailor treatment needs and identify community resources to address those problems. We also proposed to modify the description language in ways that clarify the activity, but do not change the intent. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it requires MIPS eligible clinicians to implement regular reviews of patient population needs to identify and address the needs of underserved populations and connect those patients to resources in the community.
Proposed Revised Activity Description:	Implement regular reviews of targeted patient population needs, such as structured clinical case reviews, which include access to reports that show unique characteristics of MIPS eligible clinician's patient population, identification of underserved patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources. The review should consider how structural inequities, such as racism, are influencing patterns of care and consider changes to acknowledge and address them. Reviews should stratify patient data by demographic characteristics and health related social needs to appropriately identify differences among unique populations and assess the drivers of gaps and disparities and identify interventions appropriate for the needs of the sub-populations.
Comments:	Commenters expressed support for the proposed modifications to this improvement activity.
Response:	We appreciate the commenters' support.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PM_11**
Subcategory:	Population Management
Activity Title:	Regular review practices in place on targeted patient population needs
Activity Description:	Implement regular reviews of targeted patient population needs, such as structured clinical case

	reviews, which include access to reports that show unique characteristics of MIPS eligible clinician's patient population, identification of underserved patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources. The review should consider how structural inequities, such as racism, are influencing patterns of care and consider changes to acknowledge and address them. Reviews should stratify patient data by demographic characteristics and health related social needs to appropriately identify differences among unique populations and assess the drivers of gaps and disparities and identify interventions appropriate for the needs of the sub-populations.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_6**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Consultation of the Prescription Drug Monitoring program
Current Activity Description:	Clinicians would attest to reviewing the patients' history of controlled substance prescription using State prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. For the transition year, clinicians would attest to 60 percent review of applicable patient's history. For the Quality Payment Program Year 2 and future years, clinicians would attest to 75 percent review of applicable patient's history performance.
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to increase the percentage of applicable patients for whom clinicians must review prescription history within the PDMP from 75 percent to 100 percent and remove language referencing prior year requirements, which are now obsolete. States are increasingly mandating that providers review the PDMP for all applicable patients.[18] We also proposed to include an exception for patients receiving palliative and hospice care, as they are exempt from CDC prescribing guidelines.[19] The CDC has identified increasing use of PDMP as the most promising State-level strategy for improving clinical care and outcomes for at-risk patients.[20] We support the continued efforts of MIPS eligible clinicians to increase usage of PDMP in their practice. We also proposed to modify the description language in ways that clarify the activity but do not affect its intent. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it supports use of prescription drug monitoring programs to reduce overprescribing of controlled substance prescriptions lasting longer than three days,[21] which can lead to substance use disorder.
Proposed Revised Activity Description:	Review the history of controlled substance prescriptions for 100 percent* of patients using State prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. *Apply exceptions for patients receiving palliative and hospice care.
Comments:	One commenter stated they do not support the changes made to IA_PSPA_6 to increase the percentage of applicable patients for whom clinicians must review prescription history within the PDMP from 75 percent to 100 percent. They requested that CMS issue detailed guidance on which patient populations are exempt from these PDMP checks to ensure clinicians can provide individualized care and meet varied patient needs. They suggested that CMS take an alternative approach to this improvement activity—one that focuses on reducing deaths from non-medical use of drugs, which accounts for more drug-related deaths than prescriptions. Furthermore, they recommended a new/alternative activity that is intended to reduce deaths from non-medical use of drugs.
Response:	The proposed modification to this improvement activity aligns with the CDC's guidance that increasing use of PDMP is the most promising State-level strategy for improving clinical care and outcomes for at-risk patients.[20] The PDMP is a basic tool to ensure clinicians are well-informed when prescribing opioids. We recognize that this improvement activity will not alone resolve the opioid epidemic. However, MIPS eligible clinicians implementing it can still reduce the overprescribing of controlled substance prescriptions. We invite stakeholders to submit new or alternate activities on this subject through the annual Call for Improvement Activities. With respect to the exceptions to this activity, the improvement activity includes exceptions for patients receiving palliative and hospice care, per the CDC prescribing guidelines. We refer interested parties to the CDC's prescribing guidelines,[18] which state clear definitions for palliative care and hospice care. Checking the PDMP would not preclude the prescription of opioids after careful individual

	evaluation. While we understand that 100 percent seem to be a high, we believe that 75 percent is too low. Due the importance of reviewing the history of controlled substance prescriptions using PDMP data we believe that a 90 percent is attainable and does not require perfection in instances where a review is impossible.
Final Action:	After consideration of the public comments we received, we are finalizing this activity with an increase in the percentage of applicable patients for whom MIPS eligible clinicians must review prescription history within the PDMP from 75 percent to 90 percent, instead of the proposed increase to 100 percent. We also added language to direct clinicians to the CDC prescribing guidelines for determining exceptions to this activity's required prescription history review percentage.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_6**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Consultation of the Prescription Drug Monitoring program
Activity Description:	Review the history of controlled substance prescriptions for 90 percent* of patients using State prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. *Apply exceptions for patients receiving palliative and hospice care per CDC prescribing guidelines.
Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_18**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Measurement and improvement at the practice and panel level
Current Activity Description:	Measure and improve quality at the practice and panel level, such as the American Board of Orthopaedic Surgery (ABOS) Physician Scorecards, that could include one or more of the following: • Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel); and/or • Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We proposed to modify this activity to include the opportunities for MIPS eligible clinicians to fulfill this improvement activity by applying the quality, utilization, patient satisfaction, and other measures or quality improvement actions to address inequities in quality and outcomes for underserved populations, including racial, ethnic, and gender minorities. We also proposed to improve the activity language in ways that clarify the activity, but do not affect its intent, including simplifying the first activity option by removing the language "that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel)," since it is stated at the beginning of the description that these activities can take place at the practice and panel levels. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because MIPS eligible clinicians who review these relevant data sources for particular underserved populations and create benchmarks and goals for improvement are likely to provide better quality and more equitable care.
Proposed Revised Activity Description:	Measure and improve quality at the practice and panel level, such as the American Board of Orthopaedic Surgery (ABOS) Physician Scorecards that could include one or more of the following: • Regularly review measures of quality, utilization, patient satisfaction and other measures; and/or • Use relevant data sources to create benchmarks and goals for performance at the practice or panel levels. MIPS eligible clinicians can apply the measurement and quality improvement to address inequities in quality and outcomes for underserved populations, including racial, ethnic, and/or gender minorities.
Comments:	One commenter was supportive of improvement activity modifications that addressed using data to address disparities in health equity, e.g., gathering and analyzing data by race and documenting disparities by different population groups. The commenter recommended that when implementing such modifications, we ensure that such modifications do not alter the core intent of the activity.
Response:	We thank this commenter for this input and agree with this approach. When modifying several improvement activities to include collecting and analyzing population-level data, our intent is to highlight opportunities to strengthen core activities to close health equity gaps using a data-informed approach. This activity's modification includes an option, not a requirement, to use data to create benchmarks or performance goals to address inequities and improve outcomes.

Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_18**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Measurement and improvement at the practice and panel level
Activity Description:	Measure and improve quality at the practice and panel level, such as the American Board of Orthopaedic Surgery (ABOS) Physician Scorecards that could include one or more of the following: • Regularly review measures of quality, utilization, patient satisfaction and other measures; and/or • Use relevant data sources to create benchmarks and goals for performance at the practice or panel levels. MIPS eligible clinicians can apply the measurement and quality improvement to address inequities in quality and outcomes for underserved populations, including racial, ethnic, and/or gender minorities.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_ERP_3**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Current Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data should be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.
Current Weighting:	High
Proposed Action and Rationale:	We previously adopted this improvement activity to the inventory for the 2020 and 2021 MIPS performance periods only in response to the PHE for COVID-19 and planned to reassess its need for the CY 2022 performance period/2024 MIPS payment year and future years. We proposed to continue this improvement activity for the CY 2022 performance period/2024 MIPS payment year and future years. Despite increasing dissemination of COVID-19 vaccines, we anticipate that COVID-19 infections may continue to be prevalent in communities with low vaccine adoption and/or among groups (i.e., children) who do not yet have access to vaccines. Additionally, new variants of COVID may introduce additional challenges to the eradication and treatment of the illness. Due to these concerns, clinicians may likely continue to encounter COVID-19 patients, and therefore we anticipate the need for COVID-19 clinical trials and data collection/sharing through registries to continue through CY 2022 and future years. Each year we will reassess whether there remains a

	need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We want MIPS eligible clinicians to be able to attest to this improvement activity if it is still pertinent. If this improvement activity becomes no longer needed, we would remove the activity through rulemaking. While COVID-19 continues to be a PHE and a great concern for clinicians, patients, and communities, we believe that continued participation in this improvement activity would result in improved outcomes by improving the collection of data MIPS eligible clinicians use for the care of their patients as they monitor and manage COVID-19. We note that the activity description will remain the same.
Comments:	One commenter expressed support for the proposed modifications to this improvement activity and suggested we continue to extend the improvement activity as long as appropriate.
Response:	We appreciate the commenter's support.
Final Action:	After consideration of the public comment we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_ERP_3**
Subcategory:	Emergency Response and Preparedness
Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data should be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.
Weighting:	High

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TABLE C: Improvement Activities for Removal for the CY 2022 Performance Period/ 2024 MIPS Payment Year and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_ BE_13**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms
Current Activity Description:	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_13 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_6. We proposed to consolidate the unique language from IA_BE_13 into IA_BE_6 per the proposed changes in Table B. The proposed revised IA_PM_6 adds additional detail from IA_BE_13 (e.g., use of advisory councils). IA_BE_6 has a stronger relationship to improvement in clinical practice because it also requires the development of an improvement plan based on the results of the patient experience data gathered and assessed. We note that this proposed removal was made in conjunction with our proposal to change IA_BE_6 in Table B, as well as our proposal to remove IA_PSPA_11 in Table C.
Comments:	One commenter disagreed with our proposal to remove this activity, as they use surveys and activities in meaningful ways for their practice.
Response:	We direct this commenter to revised activity BE_6 in Table B, above, which now incorporates the unique components of BE_13. As such, this commenter may continue to use surveys and related patient experience assessment activities and attest to BE_6 to receive improvement activity credit for this work.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_11**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in CAHPS or other supplemental questionnaire
Current Activity Description:	Participation in the Consumer Assessment of Healthcare Providers and Systems Survey or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).
Current Weighting:	High
Removal Rationale:	We proposed to remove this activity under removal factor 1, improvement activity is "duplicative." We believe IA_PSPA_11 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_6. We proposed to consolidate the unique language from IA_PSPA_11 into IA_BE_6 per the proposed change in Table B. The proposed revised IA_BE_6 adds additional detail from IA_PSPA_11 (e.g., CAHPS). We note that this proposed removal was made in conjunction with our proposal to change IA_BE_6 in Table B, as well as our proposal to remove IA_BE_13 in Table C.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BE_17**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of tools to assist patient self-management
Current Activity Description:	Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or How's My Health).
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_17 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. We proposed to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_17 (e.g., Patient Activation Measure). Proposed modified IA_BE_16 has a stronger relationship to improvement in clinical practice, because it emphasizes the incorporation of new tools and techniques into routine care processes. We note that this proposed removal was made in conjunction with our proposal to change IA_BE_16 in Table B, as well as our proposals to remove IA_BE_18, IA_BE_20, and IA_BE_21 in Table C.

Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BE_18**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Provide peer-led support for self-management.
Current Activity Description:	Provide peer-led support for self-management.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_18 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. We proposed to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_18 (e.g., peer-led support for self-management). Proposed modified IA_BE_16 has a stronger relationship to improvement in clinical practice because it emphasizes the incorporation of new tools and techniques into routine care processes. We note that this proposed removal was made in conjunction with our proposal to modify IA_BE_16 in Table B, as well as our proposals to remove IA_BE_17, IA_BE_20, and IA_BE_21 in Table C.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BE_20**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Implementation of condition-specific chronic disease self-management support programs
Current Activity Description:	Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_20 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. We proposed to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_20 (e.g., condition-specific chronic disease self-management support programs). Proposed modified IA_BE_16 has a stronger relationship to improvement in clinical practice because it emphasizes the incorporation of new tools and techniques into routine care processes. We note that this proposed removal was made in conjunction with our proposal to change IA_BE_16 in Table B, as well as our proposals to remove IA_BE_17, IA_BE_18, and IA_BE_21 in Table C.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BE_21**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Improved practices that disseminate appropriate self-management materials
Current Activity Description:	Provide self-management materials at an appropriate literacy level and in an appropriate language.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_21 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. We proposed to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_21 (e.g., provision of appropriate self-management materials). Proposed modified IA_BE_16 has a stronger relationship to improvement in clinical practice because it emphasizes the incorporation of new tools and techniques into routine care processes. We note that this proposed removal was made in conjunction with our proposal to change IA_BE_16 in Table B, as well as our proposals to remove IA_BE_17, IA_BE_18, and IA_BE_20 in Table C.
Final Action:	We received no comments on this proposal; therefore, we are finalizing as proposed.

APPENDIX 3: MVP INVENTORY

MVP Development Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), we finalized a set of criteria to be used in the development of MVPs. In addition, in section IV.A.3.b of this final rule, we are finalizing additional MVP policies, including MVP reporting requirements and selection of measures and activities within an MVP.

This appendix includes seven MVPs that we are finalizing for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.[287] Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category that are relevant to the clinical theme of the MVP. In addition, as described in the CY 2021 PFS final rule (85 FR 84841) and section IV.A.3.b.(4)(b)(i)(C) of this final rule, all MVPs include a foundational layer, which is comprised of population health measures and Promoting Interoperability performance category measures. We refer readers to CY 2021 PFS final rule (85 FR 84849) and section IV.A.3.b.(4)(b)(i) of this final rule for key considerations and overall development approach for the MVPs included in this appendix. For additional details regarding the finalized annual maintenance process for MVPs, we refer readers to section IV.A.3.b.(4)(b)(ii) of this final rule.

MVP Development Performance Category Sources

The MVP tables below contain a set of MIPS quality measures, which may include QCDR measures, improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures considered in developing the MVPs are located in Appendix 1: MIPS Quality Measures of this final rule.
- Existing QCDR measures considered in developing the MVPs were based on the most recent publication of the 2021 QCDR Measure Specification file. The QCDR measures are listed in the 2021 QCDR Measure Specification file located in the QPP Resource Library.[288] An updated list of 2022 QCDR measures will be available in December 2021. We refer readers to section IV.A.3.b.(4)(b)(i) of this final rule for additional details regarding QCDR measures and selection of measures within an MVP.
- Improvement activities considered in developing the MVPs are located in the 2021 Improvement Activities Inventory and the 2021 MIPS Data Validation Criteria located in the QPP Resource Library.[289]
- Existing cost measures considered in developing the MVPs are located in the CY 2020 PFS final rule (84 FR 62979).
- For further details on the new episode-based cost measures, refer to section IV.A.3.d.(2)(b) of this final rule.
- For further details on the population health measures included in the foundational layer, refer to section IV.A.3.b.(4)(b)(i)(C)(aa) of this final rule.
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located in the QPP Resource Library.[290] In addition, see section IV.A.3.d.(4)(c) of this final rule for any modifications to the existing Promoting Interoperability measures.

Please note that new quality and Promoting Interoperability measures for inclusion in MIPS beginning with the CY 2022 performance period/2024 MIPS payment year are identified with a caret symbol (^) within the MVP tables in this appendix. (See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.) In addition, existing quality measures and improvement activities with revisions are identified with an asterisk (*) before the quality measure or improvement activity ID # within the MVP tables in this appendix. See Appendix 1: MIPS Quality Measures and Appendix 2: Improvement Activities for further details regarding the substantive changes and revisions in this final rule.

Quality measures that are considered high priority are noted with an exclamation point (!) and outcome measures are noted with a double exclamation point (!!). Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

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[287] See section IV.A.3.b.(2)(d) of this final rule for additional details regarding the MVP implementation timeline.
[288] See https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1231/2021%20QCDR%20Measure%20Specifications.xlsx for QCDR measures.
[289] See the 2021 Improvement Activities Inventory: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1189/2021%20Improvement%20Activities%20List.zip 2021 MIPS Data Validation Criteria: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1316/2021%20MIPS%20Data%20Validation%20Criteria.zip for improvement activity details.
[290] See the 2021 MIPS Promoting Interoperability Measure Specifications: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1260/2021%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip for Promoting Interoperability measure details.

To determine whether a QCDR measure may be finalized within an MVP, we requested that we receive QCDR measure testing data for review by the end of the self-nomination period (that is, no later than September 1 of the year prior to the applicable performance period). If a QCDR was unable to submit testing data to demonstrate that their QCDR measure was fully tested by the end of the self-nomination period (September 1st) or otherwise did not meet our requirements, we were unable to finalize the inclusion of the QCDR measure within an MVP. In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within the relevant MVPs. We refer readers to section IV.A.3.b.(4)(b)(i) of this final rule for additional details regarding QCDR measures and selection of measures within the MVP.

In addition, consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," each MVP includes improvement activities designed to advance health equity and address and eliminate barriers to care in underserved communities.[291] Improvement activities that include a health equity component are noted with a tilde (~) before the improvement activity ID # within the MVP table. Improvement activity medium/high weight designations are identified in parentheses after each improvement activity. IA_PCMH is noted with a percent (%) before the improvement activity ID # within the MVP tables below to indicate that attestation to this improvement activity will provide full credit for the improvement activities performance category within the MVP.

[291] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

Advancing Rheumatology Patient Care MVP
Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), we proposed and solicited comments on the Advancing Rheumatology Patient Care MVP for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.

We received public comments on the Advancing Rheumatology Patient Care MVP. The following is a summary of the comments we received and our responses:

Comment: Some commenters expressed support for the seven proposed MVPs.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern that their vendors do not support any of the measures through the eCQM format under this MVP, which would require them to join multiple registries/QCDRs to submit the various quality measures. The commenter stated that this would be cost prohibitive because many of their clinicians are in rural areas and may only cover one weekend a month.

Response: MVPs include a more focused selection of quality measures and would allow clinicians to use their discretion to determine which quality measures and collection types to submit to meet the MVP reporting requirements. We disagree with the commenter's statement that participants would be required to join multiple registries or QCDRs due to lack of available eCQMs and note that all of the above MIPS quality measures are available for the MIPS CQM Specifications collection type and may be submitted either directly by the MIPS eligible clinician as noted in the 2021 MIPS Quality Quick Start Guide[292] or by using a third-party intermediary. As stated in section IV.A.3.h.(2)(b)(i) of this final rule, beginning with the 2023 performance period/2025 MIPS payment year, QCDRs, qualified registries, and health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. We believe that the commenter's circumstances are a temporary result of the transition to MVPs and will be addressed prior to implementation. We will also require QCDRs, qualified registries, health IT vendors, and CMS-approved survey vendors to support subgroup reporting beginning with the 2023 performance period/2025 MIPS payment year, as outlined in section IV.A.3.h.(2)(b)(ii) of this final rule. For these reasons, MVP participants will not have to work with multiple third-party intermediaries to report an MVP.

Comment: One commenter did not support Q111: Pneumococcal Vaccination Status for Older Adults in this MVP. They stated the implementation could promote treatment overuse if patients seek medical care from multiple clinicians and/or have poor medical record continuity. Additionally, they suggested the developer update the numerator specifications to align with current clinical recommendations on pneumococcal vaccination.

Response: We disagree with the commenter. This MIPS quality measure has been included to ensure that pneumococcal vaccinations are comprehensively assessed and used. Vaccinations play an important role in the management of patients with rheumatological conditions who are at an increased risk for infections because of their underlying condition, comorbidities, and use of immunosuppressive therapies. We would like to note that the intent of the measure can be met by reporting that the pneumococcal vaccine was previously administered and does not require a patient to receive a vaccine during each performance period. Additionally, care coordination remains a priority and we believe previously administered vaccines should be documented within a patient's medical record to facilitate communication amongst the clinicians providing care. We encourage the commenter to reach out to the measure steward to collaborate on measure revisions for potential inclusion in future rulemaking; however, please review Table D.11 in Appendix 1: MIPS Quality Measures of this final rule for any updates we are finalizing for the 2022 performance period.

Comment: One commenter did not support Q130: Documentation of Current Medications in the Medical Record in this MVP and stated there is a lack of high-quality evidence to support its inclusion in accountability programs, it is burdensome for clinicians to document complete medication lists at every patient visit and encouraging documentation at every visit could result in underuse of more valuable clinical services. In addition, they noted there is no evidence cited that links attesting to medication reconciliation to quality outcomes and in particular medication safety.

Response: We disagree with the commenter. This MIPS quality measure has been included as a broadly applicable measure to promote care coordination to collect complete and reliable medication records, while promoting patient and medication safety. We note this measure requires documentation of all known prescriptions utilizing all immediate resources. Various studies have shown that patients with a chronic disease have a low adherence to medications, understanding and addressing issues with adherence as expediently as possible may drastically improve the effectiveness of drug therapy for patients with rheumatological conditions. Additionally, one study looked at the incidence of drug-related problems (DRPs) in rheumatoid arthritis patients and found at least one DRP in 78.5 percent of the population, with the second and third most common DRPs being drug interactions

[292] https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1294/2021%20MIPS%20Quality%20Quick%20Start%20Guide.pdf

and drug-choice problems, respectively.[293] Therefore, we believe that it is of critical importance to ensure the current medication list is reviewed at each visit to mitigate potential DRPs or address them quickly.

Comment: One commenter did not support Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management in this MVP. They stated that the developers did not provide adequate information to meaningfully evaluate the validity of the measure. In their opinion, the numerator and the denominator are poorly specified, and the measure specifications do not include appropriate exclusions for patients prescribed prednisone therapy for a symptomatic flare. Additionally, the current American College of Rheumatology (ACR) clinical guidelines demonstrate the importance of assessing glucocorticoid use, but only in patients who have specifically been prescribed glucocorticoid therapy.

Response: We disagree with the commenter. Glucocorticoids are a common treatment for rheumatological conditions; however, use of these medications is concomitant with significant morbidity and mortality. This measure requires providers to assess all rheumatoid arthritis (RA) patients, regardless of current medications, for glucocorticoid use to allow for ongoing monitoring of glucocorticoid use and to minimize potential health complications to the patient. The numerator options within the measure cover the concerns raised as there is delineation between patients who are not currently taking or are on low dose glucocorticoid therapy as well as those patients who have used glucocorticoids for less than 6 months. A glucocorticoid management plan is only required for patients receiving prolonged, high doses of prednisone (or equivalent). This approach ensures a complete patient population is being monitored for numerator compliance, accounting for patients being treated for symptomatic flares and not prolonged usage. Assessing for and monitoring glucocorticoid use in RA patients is extremely important and should be an ongoing discussion between the clinician and patient to ensure positive outcomes. We encourage the commenter to reach out to the measure steward to collaborate on measure revisions for potential inclusion in future rulemaking.

Comment: Some commenters expressed concern that either IA_BE_ 24: Financial Navigation Program or IA_BE_25: Drug Cost Transparency were not included in this MVP, despite stating that most of these patients require assistance given the associated costs with the medications used to manage their rheumatologic disease. The commenter also expressed concern that the improvement activities included limits practices to a too narrow set of activities.

Response: We agree with the commenters that either IA_BE_ 24: Financial Navigation Program or IA_BE_25: Drug Cost Transparency should be considered for this MVP because of the significant costs associated with managing rheumatologic disease. We will consider the inclusion of these activities through future MVP maintenance and rulemaking processes.

Comment: A few commenters opposed the TPCC cost measure in MIPS and MVPs. In their opinion, the measure is difficult to influence outside of a total cost of care APM, where there is shared interest and accountability in improving performance by the larger health care system. Since there is no such shared accountability in MIPS, it seems likely primary care physicians will be penalized for decisions made by other members of a patient's care team.

Response: We disagree with the commenters. We continue to believe that the measure is appropriate for use in MIPS and MVPs, as the measure underwent a comprehensive re-evaluation process and has now been endorsed by the NQF in 2020 with testing at the TIN and TIN-NPI level. The measure is intended to capture costs of care broadly; the measure complements episode-based measures which have a more targeted focus. As a broadly applicable measure, clinicians are encouraged to coordinate with other providers for treating a patient to improve overall cost performance. By holding multiple clinicians accountable, this promotes shared responsibility for a patient's care across primary care and specialties who tend to provide ongoing care. In this way, the measure promotes shared accountability amongst clinicians in MIPS. This shared accountability can reflect the role of both primary care clinicians and specialists in managing and treating a patient's ongoing care. That is, many types of clinicians can be attributed to the TPCC measure which aligns incentives to provide cost-effective, high-quality care to mitigate the concern that primary care clinicians could be penalized based on other clinicians' decisions. Additionally, the TPCC measure includes a specialty adjustment to account for the different scope of care provided by primary care clinicians and specialists, and to ensure fair comparisons.

After consideration of public comments, we are finalizing the *Advancing Rheumatology Patient Care MVP* as proposed in Table A below for the CY 2023 performance period/2025 MIPS payment year and future years.

[293] Ther Clin Risk Manag. 2019; 15: 505–524.Published online 2019 Mar 21. doi: 10.2147/TCRM.S194921

TABLE A: Advancing Rheumatology Patient Care MVP
Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

The table below serves to represent the measures and activities that are finalized within the Advancing Rheumatology Patient Care MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[a]; existing quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within this MVP and the pound sign (#) was removed. Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

Quality	Improvement Activities	Cost
(*) Q111: Pneumococcal Vaccination Status for Older Adults (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q176:** Tuberculosis Screening Prior to First Course Biologic Therapy (MIPS CQMs Specifications) **Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (MIPS CQMs Specifications) **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (MIPS CQMs Specifications) **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (MIPS CQMs Specifications) **ACR12:** Disease Activity Measurements for Patients with PsA (QCDR) **(!!) ACR14:** Gout Serum Urate Target (QCDR) **(!) ACR15:** Safe Hydroxychloroquine Dosing (QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(*)(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_BMH_4:** Depression screening (Medium) **(*)(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(*)IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(*)IA_PSPA_6:** Consultation of the Prescription Drug Monitoring Program (High) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	**Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Administrative Claims) **(^)(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

[a] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39885 through 39887), we proposed and solicited comments on the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.

We received public comments on the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. The following is a summary of the comments we received and our responses:

Comment: Some commenters expressed support for the seven proposed MVPs.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern that the measures included in this MVP are not widely applicable to stroke neurologists. They stated that measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) is outside the scope of the neurologist, three others are cross-cutting or would often fall to a primary care provider (Q047: Advance Care Plan, Q236: Controlling High Blood Pressure, Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)) and one is topped out (Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy), leaving neurologists with three measures to potentially report. They noted concern that this MVP will not be attractive to neurologists (especially those in small practices) given the measures offered and dearth of outpatient stroke measures. The commenter noted this MVP will include a condition-specific cost measure, and has concerns about its applicability and attribution to outpatient neurologists, as it currently assesses management of inpatient care for stroke patients. The commenter noted CMS should work with specialty societies and provide funding to them to develop clinically relevant, condition-specific cost measures for inclusion in future MVPs.

Response: We thank the commenter for their feedback. While we understand that this MVP may not be applicable to all neurologists, the goal of this MVP is to support prevention of strokes and promote positive outcomes for patients suffering from strokes, as a medical condition specific MVP. As stated in the introduction of the CY 2022 PFS proposed rule (86 FR 39885 through 39887), cerebral infarction is the 9th most expensive condition treated in United States hospitals making it a high priority condition as it is more common in the aged 65 and older patient population and is the leading cause of serious long-term disability.[294] This MVP was intentionally developed to include other clinician types that may support the prevention and/or treatment of strokes and patient positive outcomes, such as a stroke care team which may consist of neurologists, neurosurgeons, and vascular surgeons, among other clinician types. As such, this MVP could be utilized within an existing stroke care team and additionally may foster a team-based care approach promoting coordination of patient care, while also being applicable to individual clinician types whose scope of care aligns with the MVP topic. Measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) may not be applicable to neurologists although we believe this measure is beneficial to patients at low risk for morbidity, in achieving the benefit of long-term risk of stroke reduction and supports a team-based approach to patient care. Measure Q047: Advance Care Plan captures the patient voice, which is part of the guiding principles for MVP development and is an important clinical topic to ensure that the treatment plan considered by the clinician is in alignment with the patient's wishes, are being documented and respected. We believe that the addition of advance care planning is valuable especially for those patients that are at a higher risk of potential life altering medical events. Measures Q236: Controlling High Blood Pressure and Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) are important aspects for stroke prevention and support the enhancement of communication and care coordination for patients by clinicians. While Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy is currently topped out, it is a critical clinical action for stroke prevention and was included to allow for clinician choice. However, through the maintenance process, the quality measures contained within the MVP may be revised through future public notice and comment. We encourage the commenter to reach out to measure developers/stewards to develop new outpatient measures for submission to the Call for Measures or through the QCDR self-nomination process for possible future implementation (see section IV.A.3.b.(4)(b)(i)(B)(cc) of this final rule for specifics on QCDR measure requirements within an MVP). Additionally, inclusion of this stroke specific MVP would not preclude the potential future inclusion of a broader neurology MVP, one that is applicable and attributable to outpatient neurologists. We encourage the commenter to reach out to CMS and other stakeholders to collaborate on the development of measures and to support the creation of a meaningful MVP for outpatient neurology.

Comment: One commenter requested emergency medicine clinicians who treat patients within the emergency department as an additional clinician type for whom this MVP would also be applicable. They stated this change would appropriately reflect the fact that emergency medicine clinicians play a key role in driving better patient outcomes in acute stroke care due to the highly time-dependent nature of clinical outcomes in this disease, which correlate with reduced times to treatment initiation. In addition, the commenter suggested breaking out the

[294] https://www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.jsp.

risk reduction measures that are currently included in the MVP into a separate, standalone stroke prevention MVP that would be applicable for primary care clinicians and cardiologists. In addition, they recommended that in order to ensure comprehensive measurement of "Door to Treatment Time" for all stroke patients that there should be a new quality measure added to this MVP for "Door to Needle Time for Intravenous Thrombolytic Therapy", which would be applicable for patients who are treated with thrombolytic instead of endovascular therapy.

Response: We agree with the commenter that emergency medicine clinicians play an important role in treating acute stroke patients. Although only neurology and vascular surgery clinician types were specifically indicated, all clinician types are encouraged to submit this MVP if it is applicable and meaningful to their treatable patient population. The submission of MVPs and choice of MVP is at the clinician's discretion. We thank the commenter for their feedback and will consider the development of an MVP that separately addresses stroke risk reduction; however, MVPs allow choice in quality measure selection and therefore would allow clinicians to choose those measures that best align with their scope of care. By keeping all of these clinical actions together, we are able to obtain an overall picture of stroke related clinical care from prevention to positive outcomes. The MVP does include the measure Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy, which requires initiation of IV alteplase within three hours of last known well time, with the denominator criteria including that the patient must arrive in the emergency department within two hours of last known well time. We encourage the commenter to reach out to measure developers/stewards to develop new measures addressing thrombolytic therapy for submission to the Call for Measures or through the QCDR self-nomination process for possible future implementation (see section IV.A.3.b.(4)(b)(i)(B)(cc) of this final rule for specifics on QCDR measure requirements within an MVP).

Comment: One commenter stated most vascular surgeons will not select to participate in this MVP due to low volume of stroke care and the lack of four quality measures for them to report.

Response: When developing this MVP, we attempted to include quality measures that are both meaningful to the clinical topic being addressed and broad enough to allow inclusion of all clinicians that may participate, whether individually or within a team, in stroke prevention and positive outcomes for patients that experience a stroke. The measure and activities found within the MVP may allow for vascular surgeons to participate if their scope of care aligned with this MVP clinical topic; however, through the maintenance process, the quality measures contained within the MVP may be revised through future public notice and comment. We encourage the commenter to reach out to measure developers/stewards to develop new measures applicable to vascular surgeons for submission to the Call for Measures or through the QCDR self-nomination process for possible future implementation (see section IV.A.3.b.(4)(b)(i)(B)(cc) of this final rule for specifics on QCDR measure requirements within an MVP).

Comment: One commenter did not support Q047: Advance Care Plan in this MVP. They object to the requirement for clinicians to annually document an advance care plan for all patients aged 65 years and older because they stated it is burdensome and lacks empirical support. Furthermore, it may be inappropriate for clinicians to perform this intervention during an initial office visit. They suggested the developers revise the specifications to limit the denominator population to established patient visits only.

Response: We disagree with the commenter. During development of this MVP, we reached out for feedback from stakeholders regarding the measures and activities being considered for inclusion, who expressed their support for including this measure as it is both appropriate and applicable to the MIPS eligible neurology clinician type. Additionally, this measure captures the patient voice, which is part of the guiding principles for MVP development. The measure does not require that an advance care plan be developed and documented each year, only that there is documentation of a discussion regarding an advance care plan annually or that a surrogate decision maker is documented in the medical record. This is an important clinical topic to ensure that the treatment plan considered by the clinician is in alignment with the patient's wishes, are being documented within the medical record and are being respected. We believe that the addition of advance care planning is valuable especially for those patients that are at a higher risk of potential life altering medical events. We believe that there are benefits to ensuring an advance care plan is in place as demonstrated by a 2014 systemic review showing an increase in compliance with patient preferences, quality of life for the patient, increased use of hospice and palliative care services, and a decrease in subsequence hospitalization among other outlined benefits.[295] We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. MVPs allow choice in quality measure selection, if a clinician does not find that this measure is meaningful to their scope of care, they may choose not to submit it as one of their four quality measures.

Comment: One commenter did not support Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy in this MVP. They stated that the measure specification requires further clarification and is not clinically specific regarding the indications for treatment. They shared evidence suggesting that in some cases the harms of thrombolytic therapy may outweigh the benefit, especially if the full exclusion criteria published by the National Institute of Neurological Disorders and Stroke and others are not followed. The commenter stated this should be made explicit in the measure exclusion criteria. In addition, their understanding is that there are specific

[295] https://www.uptodate.com/contents/advance-care-planning-and-advance-directives?topicRef=86295&source=see_link

qualifications hospitals must meet in order to provide tPa and the absence of such conditions should also be noted as an exclusion criterion.

Response: We disagree with the commenter. We acknowledge that not every patient is eligible for recombinant tissue plasminogen activator (alteplase or r-tPa); however, the safety, efficacy, and benefit of this treatment when administered within the first three hours after onset of stroke is evidence-based and supported through empirical data (Class 1, Level of Evidence A)(AHA/ASA).[296] [297] Given the MVP clinical topic being addressed, this measure is directly applicable and important in ensuring early treatment of acute ischemic strokes and does contain a denominator exception allowing documented reasons for the clinician not initiating IV alteplase. MVPs allow choice in quality measure selection, if a clinician does not find that this measure is meaningful to their scope of care, they may choose not to submit it as one of their four quality measures. We encourage the commenter to reach out to the measure steward to collaborate on measure revisions for potential inclusion in future rulemaking.

Comment: One commenter did not support the Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) in this MVP. They stated that the measure disregards patient preferences, that the specifications do not consider factors beyond the clinicians' control (for example, patient adherence, patient access), and stated it does not align with the Eighth Joint National Committee (JNC-8) recommendations for hypertension management. Another commenter did not support Q236: Controlling High Blood Pressure for application at the proposed levels of attribution: Individual Clinician, Group/Practice, Health Plan, and Integrated Delivery System, because there is uncertain validity. The commenter noted concerns with the strict blood pressure control across the whole patient population, especially for older patients. Based on AAFP/ACP guidelines, the commenter stated that less than 140 is ideal for every hypertensive patient across all age groups. Moreover, they noted that by assessing the most recent blood pressure from the measurement period, the measure deviates from actual practice.

Response: We disagree with the commenter. We acknowledge that the JNC-8 recommends pharmacological treatment for the general population should be initiated at 140/90 mm Hg or higher for adults younger than 60 years of age and 150/90 mm Hg or high for adults 60 year of age and older; however, Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) is not addressing the general population as it requires either a diagnosis of coronary artery disease (CAD) or a CAD risk-equivalent condition or an acute coronary event for denominator eligibility. According to an ACC/AHA statement regarding the treatment of hypertension in patients with CAD, they recommend a goal blood pressure for patient with CAD of <140/90.[298] This measure is directly applicable to the MVP topic as heart disorders, such as coronary artery disease, increase your risk for stroke, therefore it is extremely important to ensure optimal control within this patient population to mitigate clinical risk factors by keeping blood pressure within target, staying tobacco free, use of daily aspirin or antiplatelet, and statin. We encourage the commenter to reach out to the measure steward to collaborate on measure revisions for potential inclusion in future rulemaking.

Comment: One commenter stated that the proposed improvement activities are relevant to this MVP.

Response: We thank the commenter for supporting the improvement activities included in this MVP.

Comment: One commenter expressed concerns with the condition-specific cost measure for this MVP regarding its applicability and attribution to outpatient neurologists, as it currently assesses management of inpatient care for stroke patients. They noted that CMS should work with specialty societies and provide funding to them to develop clinically relevant, condition-specific cost measures for inclusion in future MVPs**.**

Response: We thank the commenter for their feedback. The commenter is correct in that the cost measure does not apply to outpatient neurologists; rather, it focuses on the inpatient care for patients with stroke which includes hospitalists and internal medicine clinicians, as well as neurologists. This measure intent was selected as a priority and conceptualized as an inpatient measure as stroke is amongst the top 10 costliest conditions treated in US hospitals.[299] For developing further clinically relevant, condition-specific cost measures, such as conditions treated by outpatient neurologists, we appreciate the comment and encourage stakeholders to participate in future cycles of episode-based cost measure development.

After consideration of public comments, we are finalizing the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP* as proposed in Table B below for the CY 2023 performance period/2025 MIPS payment year and future years.

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[296] https://www.ninds.nih.gov/About-NINDS/Impact/NINDS-Contributions-Approved-Therapies/Tissue-Plasminogen-Activator-Acute

[297] 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association; Originally published 24 Jan2018 https://doi.org/10.1161/STR.0000000000000158Stroke. 2018;49:e46–e99

[298] AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2006 Update Originally published16 May 2006https://doi.org/10.1161/CIRCULATIONAHA.106.174516Circulation. 2006;113:2363–2372

[299] https://www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.jsp.

TABLE B: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP
Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

The table below serves to represent the measures and activities that are finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[b]; existing quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within this MVP and the pound sign (#) was removed. Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (MIPS CQMs Specifications) **(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (MIPS CQMs Specifications) **(*)(!!) Q409:** Clinical Outcome Post Endovascular Stroke Treatment (MIPS CQMs Specifications) **(*)(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (eCQM Specifications, MIPS CQMs Specifications) **(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (MIPS CQMs Specifications)	**(*)(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_17:** Patient Navigator Program (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	**Intracranial Hemorrhage or Cerebral Infarction**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information**

(^)(!!) Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

[b] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.

Advancing Care for Heart Disease MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39888 through 39891), we proposed and solicited comments on the Advancing Care for Heart Disease MVP for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.

We received public comments on the Advancing Care for Heart Disease MVP. The following is a summary of the comments we received and our responses:

Comment: A couple commenters expressed support for the seven proposed MVPs.

Response: We thank the commenters for their support.

Comment: One commenter noted that they believe the MVP falls short of capturing heart disease as a condition, and in general is not inclusive for all of heart disease/cardiology or a broad-based heart program. The commenter also noted that the MVP included measures related to heart failure, ischemic heart disease, and several broadly applicable measures relevant to heart disease. However, some pertinent measures that would be applicable to the MVP were not included, such as those related to rhythm disorders, complications, and pharmacotherapy (for example, anticoagulation for atrial fibrillation).

Response: We thank the commenter for their feedback and will consider expanding this MVP or consider the development of an MVP that addresses the additional cardiac concepts such as rhythm disorders, complications, and pharmacotherapy. Our goal is to implement MVPs that are meaningful, provide data and feedback to MIPS eligible clinicians, and enhance information provided to patients. We assessed for inclusion of these clinical topics for this MVP but believed we did not have at least four quality measures to represent this specific specialty of clinicians. We encourage the commenter to submit potential new measures that covers these concepts (rhythm disorders, complications, and pharmacotherapy) during the annual Call for Measures or through the QCDR self-nomination process for possible future implementation (see section IV.A.3.b.(4)(b)(i)(B)(cc) of this final rule for specifics on QCDR measure requirements within an MVP).

Comment: One commenter recommended the inclusion of Q006: CAD Antiplatelet Therapy measure as it is a guideline-directed therapy for the population included in this MVP.

Response: At this time, we disagree with the inclusion of Q006: CAD Antiplatelet Therapy within this MVP. We do not plan to include this quality measure in this MVP as we believe it would be duplicative to Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) since this measure includes a component that specifically addresses use of aspirin or other antiplatelet. Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) includes specific CAD diagnosis coding, reflective of the patient population applicable to this MVP, which ensures that clinicians who choose to report this MVP have meaningful measures that reflect and support positive patient outcomes. We believe Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) is a more robust measure in that it is a composite and outcome measure and will be able to provide clinicians with meaningful performance data to drive quality care.

Comment: One commenter recommended the removal or significant revision of Q007: CAD: Beta Blocker therapy - prior MI or LVEF<40% from this MVP due to the dramatic changes in treatment and diagnosis of myocardial infarction.

Response: We disagree with the commenter. There are two patient populations within this measure: (1) patients with a diagnosis of CAD or history of cardiac surgery who have a current or prior LVEF < 40 percent and (2) patients with a diagnosis of CAD or history of cardiac surgery who have a prior myocardial infarct within the past 3 years. For the population of patients that may have endured a myocardial infarct, we acknowledge that there has been further research regarding the length of time beta blocker therapy may be continued after a patient experiences myocardial infarction. However, as noted by the National Institutes of Health, "at the present time, the data on duration of therapy with beta blockers after an MI is inconclusive. In patients with preserved left ventricular ejection fraction and without any evidence of arrhythmias and ischemia, beta blockers can most likely be stopped after one year."[300] Based on this information, we believe the measure continues to be in alignment with current clinical guidelines and meaningful to MIPS eligible clinicians who treat this patient population and continues to allow these clinicians to determine the best therapy for their patients. Measure performance is not reliant on the length of time in which the beta blocker must be prescribed and allows for medical, patient, or system reasons for the pharmacological therapy to be discontinued or not prescribed. We will await potential revisions for the measure from the measure steward.

Comment: One commenter did not support Q047: Advance Care Plan in this MVP. They objected to the requirement for clinicians to annually document an advance care plan for all patients aged 65 years and older because they stated it would be burdensome and would lack empirical support. Furthermore, it may be inappropriate for clinicians to perform this intervention during an initial office visit. They suggested the developers revise the specifications to limit the denominator population to established patient visits only.

[300] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4438466/

Response: We disagree with the commenter. This measure captures the patient voice, which is part of the guiding principles for MVP development. The measure does not require that an advance care plan be developed and documented each year, only that there is documentation of a discussion regarding an advance care plan annually or that a surrogate decision maker is documented in the medical record. This is an important clinical topic to ensure that the treatment plan considered by the clinician is in alignment with the patient's wishes, are being documented within the medical record, and respected. We believe that the addition of advance care planning is valuable especially for those patients that are at a higher risk of potential life altering medical events. We believe that there are benefits to ensuring an advance care plan is in place as demonstrated by a 2014 systemic review showing an increase in compliance with patient preferences, quality of life for the patient, increased use of hospice and palliative care services, and a decrease in subsequence hospitalization among other outlined benefits.[301] We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. MVPs allow choice in quality measure selection, if a clinician does not find that this measure is meaningful to their scope of care, they may choose not to submit it as one of their four quality measures.

Comment: One commenter did not support Q128: Preventive Care and Screening: BMI Screening and Follow-Up in this MVP. They stated it is a burdensome "check box" measure that lacks sufficient evidence to support implementation of obesity interventions for patients with a BMI measurement between 25-30 kg/m². In addition, they noted they believe the specified obesity interventions do not necessarily lead to meaningful improvements in quality outcomes. Their recommendation is that measure developers update the measure specifications to align with current United States Preventive Services Task Force (USPSTF) recommendations on obesity screening and include waist circumference as a screening tool. In addition, without evidence regarding appropriate screening intervals they advocate for annual versus biennial screening.

Response: We disagree with the commenter. We believe that this process measure is important as it encourages patients to implement lifestyle modifications, with the support of their clinician, to reduce their BMI. Currently, data from the U.S. Preventive Services Task Force suggests that "obesity is associated with health problems such as increased risk for coronary heart disease, type 2 diabetes, various types of cancer, gallstones, and disability. Obesity is also associated with an increased risk for death, particularly among adults younger than 65 years."[302] The quality measure allows a clinician to use his or her expertise and best judgement in selecting intervention(s) for their patients in this category until more adequate evidence emerges from research for this clinical topic. The intent of this measure is to screen for BMI values that are above or below "normal" parameters. The measure intent is to screen all patients aged 18 years and older for BMIs outside of the normal range by requiring documentation of the patient's BMI during the current encounter or within the previous twelve months. Therefore, it implies that a patient should be screened annually. As such, the measure specification also states, "This measure is to be submitted a minimum of once per performance period for patients seen during the performance period." This performance period is a 12-month period, from January 1 - December 31. Annually, we convene a measure expert work group (EWG) to review evidence and reassess the appropriateness of the measure. We believe that this measure currently represents the 2018 United States Preventive Services Task Force (USPSTF) recommendations on obesity screening. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter did not support Q238: Use of High-Risk Medications in the Elderly measure in this MVP. They noted that while it is clinically important to monitor high-risk medications in elderly adults, implementation may result in underuse of clinically appropriate pharmacotherapy in adults aged > 65 years. Furthermore, they indicated developers cite the controversial American Geriatrics Society Beers Criteria to form the basis of the measure, which is based on expert opinion as opposed to high-quality evidence. In addition, the commenter noted that there are several issues with the measure specification and that while the measure is appropriate for health plan-level assessment, individual clinicians may encounter interoperability barriers to patient information access.

Response: We agree with the commenter that it is important to monitor high-risk medications in elderly adults although we disagree that implementation may result in underuse of clinically appropriate pharmacology in adults aged > 65 years. Within Table D.30 in Appendix 1: MIPS Quality Measures of this final rule, we proposed and are finalizing to restructure all of the collection types to introduce new performance rates based upon the American Geriatric Society (AGS) Beers Criteria and expert panel recommendations, with performance rate one being utilized for benchmarking purposes as it is more comprehensive in assessment and aligns across the collection types. The AGS Beers Criteria is based on the review of over 1400 clinical trials and research studies by a panel of 13 experts. Based on the number of clinical trials under review to provide to determine the recommendations, we believe there is clinical evidence to support the measure. These revisions allow for the inclusion of antipsychotics and benzodiazepines to ensure alignment with most recent recommendations. Due to these updates in the measures, we believe that this measure aligns with the AGS Beers Criteria in that it "aims to guide older people and health

[301] https://www.uptodate.com/contents/advance-care-planning-and-advance-directives?topicRef=86295&source=see_link
[302] https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/obesity-in-adults-interventions#tab

professionals away from potentially harmful medications while also helping health systems recognize such decisions when assessing care quality." Therefore, this quality measure "should never solely dictate how medications are prescribed, nor should it serve as a justification for restricting health coverage."[303]

Comment: One commenter expressed concerns with the inclusion of Q238: Use of High-Risk Medications in the Elderly in this MVP. They shared that many cardiac medications are not considered high-risk except for digoxin as it is often prescribed indefinitely. They voiced their concern that clinicians may wrongfully not perform well on this measure if a medication such as digoxin is prescribed long-term.

Response: We disagree with the commenter. This quality measure includes other high-risk medications including Methyldopa and Disopyramide along with Digoxin. The intent of this inverse quality measure is that there are at least two orders for the same high-risk medication on different days during the measurement period. Therefore, we believe that MIPS eligible clinicians should still be able to meet the intent of the measure even if the medication is prescribed long-term. Specifically, the quality measure negatively impacts performance if there are two or more prescriptions on different days, where the sum of days' supply exceeds 90 days or, specifically for Digoxin, the prescription does not exceed the average daily dose criteria.

Comment: One commenter stated that patients are typically referred for cardiac rehabilitation from an inpatient setting, therefore some clinicians may not receive credit for Q243: Cardiac Rehab Patient Referral from an Outpatient Setting.

Response: We disagree with the commenter. When developing this MVP, we attempted to include quality measures that are both meaningful to the clinical topic being addressed and broad enough to allow inclusion of all clinicians that may participate in the cares for this population of patients. In the instance a patient is referred to cardiac rehabilitation from the inpatient setting, if the patient is seen in the outpatient setting, the clinician may receive credit based on the documented previous referral. Alternatively, the patient would not be eligible for the measure until the patient is seen in the outpatient setting. We encourage the commenter to reach out to CMS and other stakeholders to collaborate on the development of measures and support this MVP being meaningful to patients and the clinicians that support them.

Comment: One commenter recommended the addition of Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease to the MVP. They stated that the statin therapy has one of the greatest impacts on decreasing mortality and morbidity in patients with atherosclerotic cardiovascular disease. Additionally, they noted that the measure represents an opportunity for improvement with substantial clinical benefit.

Response: At this time, we disagree with the inclusion of Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease within this MVP. We do not plan to include this quality measure in this MVP as we believe it would be duplicative to Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) since this measure includes a component that specifically addresses use of statin within the CAD patient population. This ensures that clinicians who choose to report this MVP have meaningful measures that reflect and support positive patient outcomes. We believe Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) is a more robust measure in that it is a composite and outcome measure and will be able to provide clinicians with meaningful performance data to drive quality care.

Comment: One commenter did not support the Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) in this MVP. They noted that the measure disregards patient preferences, that the specifications do not consider factors beyond the clinicians' control (for example, patient adherence, patient access), and noted it does not align with the Eighth Joint National Committee (JNC-8) recommendations for hypertension management.

Response: We disagree with the commenter. We acknowledge that the JNC-8 recommends pharmacological treatment for the general population should be initiated at 140/90 mm Hg or higher for adults younger than 60 years of age and 150/90 mm Hg or high for adults 60 year of age and older, however, measure 441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) is not addressing the general population as it requires either a diagnosis of coronary artery disease (CAD) or a CAD risk-equivalent condition or an acute coronary event for denominator eligibility. According to an ACC/AHA statement regarding the treatment of hypertension in patients with CAD, they recommend a goal blood pressure for patient with CAD of <140/90.[304] We also acknowledge that the measure does not account for denominator exceptions such as patient adherence or patient access, but it does account for medical reasons for not performance the components of this intermediate outcome quality measure. We believe that the quality actions presented within this intermediate outcome measure represent and support the reduction of risk factors for patients that are diagnosed with CAD or a CAD risk-equivalent condition. Therefore, we believe this measure is beneficial to supporting positive clinical outcomes in patients diagnosed with CAD or a CAD risk-equivalent condition. According to the American Heart Association, "preventive measures instituted early are thought to have greater lifetime benefits. Healthy lifestyles will delay the

[303] https://www.americangeriatrics.org/media-center/news/older-people-medications-are-common-updated-ags-beers-criteriar-aims-make-sure
[304] AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2006 Update Originally published16 May 2006https://doi.org/10.1161/CIRCULATIONAHA.106.174516Circulation. 2006;113:2363–2372

progression of CAD, and there is hope that CAD can be regressed before it causes CHD".[305] We encourage the commenter to reach out to the measure steward to collaborate on measure revisions for potential inclusion in future rulemaking.

Comment: One commenter recommended including NQF 0076: Optimal Vascular Care since it is NQF-endorsed in this MVP instead of Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control).

Response: We disagree with the commenter. We note that NQF 0076: Optimal Vascular Care is not currently a measure within the MIPS quality measure inventory. Quality measures not currently in the MIPS inventory will be required to follow the existing pre-rulemaking processes in order to be considered for inclusion within an MVP.

Comment: One commenter recommended the addition of IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients as this activity is designed to directly address patients assigned to care teams for the purpose of population health management and encourages the adoption of practices and protocols that are essential in high-quality care for chronic diseases. An important action noted in this activity includes an individualized plan of care as appropriate to age and health status, including gender, age, and condition-specific preventive care services (for example, managing cardiovascular risk in patients with diabetes). The absence of this activity as an option is a noteworthy omission given the intent of this MVP. If the addition of this activity requires the removal of another activity the commenter recommended that IA_EPA_4: Additional improvement in access as a result of QIN/QIO TA be removed as the activity has minimal specificity for this MVP.

Response: We disagree with the commenter that this MVP lacks activities that address an individualized plan of care. This MVP includes IA BE_15: Engagement of patients, family and caregivers in developing a plan of care and IA_CC_9: Implementation of practices/processes for developing regular individual care plans, which both address plan of care elements. We agree that IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients could be a viable option in general for this MVP and will consider the inclusion of this activity through future MVP maintenance and rulemaking processes.

Comment: A few commenters expressed opposition to the TPCC cost measure in MIPS and MVPs. In their opinion the measure is difficult to influence outside of a total cost of care APM, where there is shared interest and accountability in improving performance by the larger health care system. Since there is no such shared accountability in MIPS, it seems likely primary care physicians will be penalized for decisions made by other members of a patient's care team.

Response: We disagree with the commenters. We continue to believe that the measure is appropriate for use in MIPS and MVPs, as the measure underwent a comprehensive re-evaluation process and has now been endorsed by the NQF in 2020 with testing at the TIN and TIN-NPI level. The measure is intended to capture costs of care broadly; the measure complements episode-based measures which have a more targeted focus. As a broadly applicable measure, clinicians are encouraged to coordinate with other providers for treating a patient to improve overall cost performance. By holding multiple clinicians accountable, this promotes shared responsibility for a patient's care across primary care and specialties who tend to provide ongoing care. In this way, the measure promotes shared accountability amongst clinicians in MIPS. This shared accountability can reflect the role of both primary care clinicians and specialists in managing and treating a patient's ongoing care. That is, many types of clinicians can be attributed the TPCC measure which aligns incentives to provide cost-effective, high-quality care to mitigate the concern that primary care clinicians could be penalized based on other clinicians' decisions. Additionally, the TPCC measure includes a specialty adjustment to account for the different scope of care provided by primary care clinicians and specialists, and to ensure fair comparisons.

Comment: One commenter expressed concern with the inclusion of the Q479: Hospital Wide 30-Day Hospital-Wide All Cause Readmission Rate population health measure in this MVP. They noted that they do not believe the measure should be attributed to individual physicians or smaller specialty groups that have smaller case numbers and limited ability to influence readmission rates.

Response: We disagree with the commenter. This measure is a re-specification of Q458: the All-Cause Readmission measure currently within the MIPS program, which attributes outcomes solely to the primary care physician that provides the plurality of care during the measurement period. However, the primary care physician may not be the clinician with opportunity to impact readmissions. The intent of this measure is to improve upon the attribution of the current ACR measure and incentivize collaboration of care across inpatient and outpatient settings by considering shared attribution to up to three eligible clinician groups that provide care for patients inside and outside of the hospital and are therefore in position to influence patient risk of readmission.

Comment: One commenter recommended that if CMS finalizes and adopts the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure administrative claims measure, that this administrative claim measure be included in this MVP.

Response: We agree with the commenter. This measure would result in providing comparative performance data, which would be valuable to patients and caregivers in evaluating clinician performance and

[305] https://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease/coronary-artery-disease

making choices about their care. However, as described in Table A.4 in Appendix 1: MIPS Quality Measures of this final rule, we have received opposition to this administrative measure from commenters. Therefore, we are not finalizing this measure. We will continue to monitor this measure's progress and evaluate it for future inclusion within this MVP.

After consideration of public comments, we are finalizing the *Advancing Care for Heart Disease MVP* as proposed in Table C below for the CY 2023 performance period/2025 MIPS payment year and future years.

TABLE C: Advancing Care for Heart Disease MVP
Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

The table below serves to represent the measures and activities that are finalized within the Advancing Care for Heart Disease MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[c]; existing quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within this MVP and the pound sign (#) was removed. Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

Quality	Improvement Activities	Cost
(*) Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (eCQM Specifications, MIPS CQMs Specifications) **(*) Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (eCQM Specifications, MIPS CQMs Specifications) **(*) Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (eCQM Specifications, MIPS CQMs Specifications) **(!) Q047:** Advance Care Plan (Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q128**: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (eCQM Specifications, MIPS CQMs Specifications) **(!) Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (MIPS CQMs Specifications) **(!!) Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (MIPS CQMs Specifications)	**IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **(*)(~) IA_CC_14:** Practice improvements that engage community resources to support patient health goals (High) **IA_EPA_4:** Additional improvements in access as a result of QIN/QIO TA (Medium) **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_30:** PCI Bleeding Campaign (High)	**Elective Outpatient Percutaneous Coronary Intervention (PCI)** **ST Elevation Myocardial Infarction (STEMI) with PCI** **Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing**	

(^)(!!) Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

[c] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.

Optimizing Chronic Disease Management MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39892 through 39895), we proposed and solicited comments on the Optimizing Chronic Disease Management MVP for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.

We received public comments on the Optimizing Chronic Disease Management MVP. The following is a summary of the comments we received and our responses:

Comment: Some commenters expressed support for the seven proposed MVPs.

Response: We thank the commenters for their support.

Comment: One commenter noted that despite its prevalence, direct measures of chronic kidney disease (CKD) care are absent from this MVP. This is likely because there are limited measures in the current MIPS set that specifically address CKD aside from the cross-cutting population health measures.

Response: We thank the commenter for their feedback. The intent of this MVP is to include quality measure concepts that may be applicable to a broad type of MIPS eligible clinicians. We agree that the current MIPS quality measure does not include measures that specifically address CKD; therefore, we encourage stakeholders to submit potential new measures that will align with the Meaningful Measures Initiative during the annual Call for Measures. Additionally, this MVP was intentionally developed to include other clinician types that may support the prevention and/or treatment of chronic conditions, such as an interdisciplinary care team which may consist of family practitioners, internist, cardiologist, nephrologist, and/or endocrinologists among other clinician types. As such, this MVP could be utilized within an existing interdisciplinary care team and additionally may foster a team-based care approach promoting coordination of patient care, while also being applicable to individual clinician types whose scope of care aligns with the MVP topic.

Comment: One commenter requested clarification and further information as to CMS' rationale for including measures of coronary artery disease in the Chronic Disease Management MVP as they may also be applicable in the Heart Disease MVP. They noted that this MVP has the potential to capture such a broad range of clinicians that some settings may choose to report this set for all clinicians and not implement specific MVPs that would be more clinically relevant to specialty care.

Response: We thank the commenter for their feedback. CAD measures were included within this MVP and the Advancing Care for Heart Disease MVP due to the prevalence of CAD within the patient population. The CDC indicates that 'coronary heart disease is the most common type of heart disease, killing 365,914 people in 2017". [306] Therefore, we believe that this clinical condition is an important clinical topic to address in patients with chronic conditions. We understand that some MVPs may have overlap in clinical concepts that are represented in the MVPs. We encourage clinicians to explore all finalized MVPs in order to choose the MVP that is most appropriate and best represents engagement with their patients, while also representing performance data that is meaningful to their clinical practice and driving quality care.

Comment: One commenter recommended that one or more of the measures with the eCQM Specifications collection type that are in the proposed Heart Disease MVP be added to the Chronic Disease Management MVP.

Response: We disagree with the commenters suggestion to include eCQM Specification collection type measures found within the proposed Advance Heart Disease MVP based upon collection type. The intent of the Optimizing Chronic Disease Management MVP is to provide treatment and management of chronic diseases such as diabetes, coronary artery disease, asthma, and major adult depression. We believe the inclusion of the eCQMs within the Heart Disease MVP would skew the intent of this MVP on the treatment and management of patients with chronic conditions to potentially promoting a focus specifically to the heart clinical chronic conditions.

Comment: One commenter expressed concern that if two different specialties are reporting different measures and activities within the MVP that the MVP is too broad and should be split into two separate MVPs, one appropriate for cardiologists and one appropriate for family physicians. They noted that this would better meet the intention of MVPs by allowing an appropriate comparison. Furthermore, the commenter noted that having too broad of a selection of measures is more likely to encourage providers to choose measures for which they will get the best quality score rather than the measures that are most appropriate for their clinical setting.

Response: We believe the quality actions and resultant performance rates that may be captured within this MVP would be applicable to the clinicians that choose to report the Optimizing Chronic Disease Management MVP. MVPs allow choice in quality measure selection and therefore would allow clinicians to choose those measures that best align with their scope of care. For this reason, we believe that this MVP would be able to support quality measure performance comparison across clinicians, and potentially different specialties that provide similar care.

Comment: One commenter recommended the addition of Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) as a high priority quality measure option for this MVP. In addition, the HbA1c control measure aligns with measures in the MIPS APM Performance Pathway and insurer-level programs.

[306] https://www.cdc.gov/heartdisease/facts.htm.

Response: We thank the commenter for their feedback and will consider adding this quality measure to the MVP in the future. We agree that this measure would align with measures in the MIPS APM Performance Pathways and other insurer-level programs and will consider the inclusion of this measure through future MVP maintenance and rulemaking.

Comment: Some commenters did not support Q047: Advance Care Plan in this MVP. They objected to the requirement for clinicians to annually document an advance care plan for all patients aged 65 years and older because they feel it is burdensome and lacks empirical support. Furthermore, the commenters noted it may be inappropriate for clinicians to perform this intervention during an initial office visit. They suggested the developers revise the specifications to limit the denominator population to established patient visits only.

Response: We disagree with the commenters. This measure captures the patient voice, which is part of the guiding principles for MVP development. The measure does not require that an advance care plan be developed and documented each year, only that there is documentation of a discussion regarding an advance care plan annually or that a surrogate decision maker is documented in the medical record. This is an important clinical topic to ensure that the treatment plan considered by the clinician is in alignment with the patient's wishes, are being documented within the medical record and are being respected. We believe that the addition of advance care planning is valuable especially for those patients that are at a higher risk of potential life altering medical events. We believe that there are benefits to ensuring an advance care plan is in place as demonstrated by a 2014 systemic review showing an increase in compliance with patient preferences, quality of life for the patient, increased use of hospice and palliative care services, and a decrease in subsequence hospitalization among other outlined benefits.[307] We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. MVPs allow choice in quality measure selection, if a clinician does not find that this measure is meaningful to their scope of care, they may choose not to submit it as one of their four quality measures.

Comment: One commenter did not support Q236: Controlling High Blood Pressure in this MVP. They did not support application at the proposed levels of attribution: Individual Clinician and Group/Practice because they noted there is uncertain validity. The commenter expressed concerns with the strict blood pressure control across the whole patient population, especially for older patients. Based on AAFP/ACP guidelines, the commenter did not believe that less than 140 is ideal for every hypertensive patient across all age groups. Moreover, they noted that by assessing the most recent blood pressure from the measurement period, the measure deviates from actual practice.

Response: We disagree with the commenter. CMS strives to ensure alignment between the different reporting programs and the measures implemented within each program. MIPS measures are required to be tested prior to implementation into the program and MIPS has implemented a version that is functional within the MIPS requirements. Therefore, we believe this measure are valid for reporting within MIPS. We acknowledge that the JNC-8 recommends pharmacological treatment for the general population should be initiated at 140/90 mm Hg or higher for adults younger than 60 years of age and 150/90 mm Hg or high for adults 60 year of age and older; however, Q236: Controlling High Blood Pressure is not addressing the general population as it requires a diagnosis of essential hypertension condition for denominator eligibility. According to an ACC/AHA statement regarding the treatment of hypertension in patients with CAD, they recommend a goal blood pressure for patient with CAD of <140/90.[308]

Comment: One commenter did not support the Q398: Optimal Asthma Control measure in this MVP. The commenter stated that they do not believe the measure developer cited any evidence to form the basis of the measure. Additionally, they noted the measure is difficult to navigate and unnecessarily burdensome for clinicians to report on the six components of asthma control included in the numerator. Furthermore, the measure is not risk-adjusted for disease severity and socioeconomic status and could potentially penalize clinicians who care for sicker patients. Clinicians who treat severely affected populations may incur financial penalties which could worsen health disparities by penalizing safety-net hospitals and institutions with lower socioeconomic status patients. Lastly, although the Asthma Control Test (ACT) is considered best practice it is a proprietary assessment tool.

Response: We disagree with the commenter. The intent of this outcome measure is to determine the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age-appropriate patient reported outcome tools and not at risk for exacerbation. We believe that this composite measure is a well-constructed measure, as it allows clinicians to obtain performance data based on the stratification of age of the patient population, based on well-controlled asthma without elevated risk of exacerbation, and the results of the age-appropriate assessment tool used for patients for which they provide treatment. Therefore, if the clinician supports adult patients, they would only be required to report the three applicable components. We believe this stratification of the denominator allows the clinician to focus on the patients they treat, reducing burden of reporting for this robust composite measure. Additionally, this measure's denominator focuses on outpatient encounters for established patients. We believe this will mitigate the risk of penalizing safety-net hospitals and institutions with lower socioeconomic status patients since the patient will be known to the clinician reporting the measure. The

[307] https://www.uptodate.com/contents/advance-care-planning-and-advance-directives?topicRef=86295&source=see_link

[308] AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2006 Update Originally published16 May 2006https://doi.org/10.1161/CIRCULATIONAHA.106.174516Circulation. 2006;113:2363–2372

quality measure also identifies the assessment tools that would be considered best practice and allows for clinician choice of tool. The denominator criteria of the measure ensures that patients have a diagnosis of asthma with any contact during the current or prior performance period or had asthma present on an active problem list any time during the performance period, ensuring that the clinician submits measure data on patients specific to their practice. Additionally, the measure does allow patients to be excluded from the denominator in instances where the patient presents with a diagnosis for chronic obstructive pulmonary disease, emphysema, cystic fibrosis, or acute respiratory failure, in addition to other exclusions, to constrict the denominator eligible patient population being assessed. MVPs allow choice in quality measure selection, if a clinician does not find that this measure is meaningful to their scope of care, they may choose not to submit it as one of their four quality measures. We encourage the commenter to reach out to the measure steward to collaborate on measure revisions for potential inclusion in future rulemaking.

Comment: A few commenters supported the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) as part of the Optimizing Chronic Disease Management MVP. In addition, one commenter noted that well-designed quality measures, preferably outcomes measures, can help provide a counter-balance to cost measures and ensure that patients are receiving the right types of treatment to achieve desired health outcomes, particularly if those quality measures relate to cost or efficiency measures. Cost measures that are not accompanied by strong quality measures create a risk of incentives for stinting on care that best meets varying patient needs. They noted the inclusion of the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) will be an important quality measure in this MVP as a counterbalance to the cost measures.

Response: We agree that outcome measures ensure that patients are receiving the best health outcomes and strive to include outcome measures within MVPs. This preference of outcome measures aligns with the agency's prioritization of outcome and patient reported outcome measures. We also agree that selecting complimentary quality measures, improvement activities, cost measures, and foundational layer measure is very important in supporting clinicians and patients with meaningful data to drive quality care outcomes.

Comment: Some commenters did not support the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) in this MVP. They expressed concerns that the measure was poorly specified and does not have data to show that it will lead to improvements in care or clinical outcomes. Additionally, the measure includes all patients who have completed the survey without any exclusions or risk adjustment, and hence this would result in a non-representative sample. Also, while the measure intends to establish a benchmark for good, comprehensive primary care, they noted the evidence that this measure will lead to improved outcomes and is actionable at the level of the individual clinician or group, has not been presented. There are no articles cited to support the actions that can be done to improve the scores on individual items. The vast majority of these interventions are at the system level. While the developer presents quite a bit of information regarding the validity and reliability of the PCPCM instrument, the commenter had a number of concerns regarding the face validity of the instrument. The commenter also expressed concerns on how the measure would work in a clinical practice when there are multiple issues to focus on during a patient visit, and therefore, is not certain the measure would apply to internal medicine.

Response: We disagree with the commenters. Fielding of the PCPCM PROM for reliability and validation was conducted both digitally and at point of care. The measure steward utilized three methods for reliability testing, and a multistep process for validity testing, which resulted in a fully tested measure. Based on the information submitted by the measure steward for this measure, the reliability and validity of the instrument are sufficient.[309] Validity of the PCPCM PRO-PM was created through a multi-step approach to identify stakeholder-defined characteristics of high-quality care, compare these with best-practices as represented in the literature, fit these areas to purpose through conversation with national experts of measure development and high-quality primary care, and then test for meaningfulness and validity among patients and clinicians. This process involves extensive use of face validity and concurrent validity to test the PCPCM PROM and resulting PCPCM Performance Measure. For reliability, the variation of PCPCM performance measure scores as found during the measure steward's validation process, illustrated a difference of moderate (0.5) to large effect size (0.8) among clinicians in our validation tests, is evidence of a performance gap and opportunities for improvement. In a recently submitted manuscript regarding the score validity and reliability of the PCPCM PROM, among 6 practices, there were significant differences ($p=0.004$) in PCPCM PROM scores with a moderate effect size (at least .5 standard deviation). According to the measure steward, the American Board of Family Medicine, the Person-Centered Primary Care Measure PRO-PM (PCPCM PRO-PM) fulfills the call from the Institute of Medicine and from CMS to create a stakeholder informed, meaningful measure that is an assessment of quality, low burden for implementation and collection, and provides adequate ability to compare performance across clinicians and practices while providing greater transparency and actionable information.

[309] Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.

Comment: One commenter shared their enthusiasm for the Optimizing Chronic Disease Management MVP. Additionally, they noted that if the Kidney Health Evaluation measure is adopted by CMS, then CMS should consider the measure for use in this MVP by the CY 2023 Performance Period.

Response: We will monitor the progress of the Kidney Health Evaluation measure as it progresses for possible inclusion of MIPS for a future program year. If this measure becomes available as a MIPS measure, we will assess it for possible inclusion in this MVP through future MVP maintenance and rulemaking processes.

Comment: One commenter supported the improvement activities included in this MVP.

Response: We thank the commenter for their support.

Comment: One commenter recommended the addition of IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients as this activity is designed to directly address patients assigned to care teams for the purpose of population health management and encourages the adoption of practices and protocols that are essential in high-quality care for chronic diseases. An important action noted in this activity includes an individualized plan of care as appropriate to age and health status, including gender, age, and condition-specific preventive care services (for example, managing cardiovascular risk in patients with diabetes). The absence of this activity as an option is a noteworthy omission given the intent of this MVP. If the addition of this activity requires the removal of another activity the commenter recommended that IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes be removed as the activity has minimal specificity for this MVP.

Response: We disagree with the commenter that this MVP lacks activities that address an individualized plan of care. This MVP includes IA CC_12: Care coordination agreements that promote improvements in patient tracking across settings, and IA_PCMH: Implementation of Patient-Centered Medical Home model, which both address plan of care elements. We agree that IA_PM_13: Chronic Care and Preventative Care Management for Empaneled Patients could be a viable option in general for this MVP and will consider the inclusion of this activity through future MVP maintenance and rulemaking processes.

Comment: A few commenters opposed the TPCC cost measure in MIPS and MVPs. In their opinion, the measure is difficult to influence outside of a total cost of care APM, where there is shared interest and accountability in improving performance by the larger health care system. Since there is no such shared accountability in MIPS, it seems likely primary care physicians will be penalized for decisions made by other members of a patient's care team.

Response: We disagree with the commenters. We continue to believe that the measure is appropriate for use in MIPS and MVPs, as the measure underwent a comprehensive re-evaluation process and has now been endorsed by the NQF in 2020 with testing at the TIN and TIN-NPI level. The measure is intended to capture costs of care broadly; the measure complements episode-based measures which have a more targeted focus. As a broadly applicable measure, clinicians are encouraged to coordinate with other providers for treating a patient to improve overall cost performance. By holding multiple clinicians accountable, this promotes shared responsibility for a patient's care across primary care and specialties who tend to provide ongoing care. In this way, the measure promotes shared accountability amongst clinicians in MIPS. This shared accountability can reflect the role of both primary care clinicians and specialists in managing and treating a patient's ongoing care. That is, many types of clinicians can be attributed the TPCC measure which aligns incentives to provide cost-effective, high-quality care to mitigate the concern that primary care clinicians could be penalized based on other clinicians' decisions. Additionally, the TPCC measure includes a specialty adjustment to account for the different scope of care provided by primary care clinicians and specialists, and to ensure fair comparisons.

Comment: Some commenters recommended that if CMS finalizes and adopts the Diabetes and Asthma/COPD episode-based cost measures they should both be included in this MVP to evaluate a clinician's or clinician group's risk-adjusted cost to Medicare for patients receiving medical care to manage and treat these chronic conditions.

Response: We are finalizing these two episode-based measures, as described in section IV.A.3.d.(2)(b) of this final rule. These measures cover two highly prevalent chronic conditions; assessing costs for the management of those chronic disease processes could align well with the quality measures and improvement activities in this MVP. To give stakeholders time to become familiar with these measures, we will consider adding the Diabetes and Asthma/COPD cost measures to this MVP in a future year. Consideration to adding these measures to the MVP would occur through the MVP maintenance process and future rulemaking processes.

Comment: One commenter recommended that if CMS finalizes and adopts the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure administrative claims measure, that this administrative claims measure be included in this MVP.

Response: We agree with the commenter. This measure would result in providing comparative performance data, which would be valuable to patients and caregivers in evaluating clinician performance and making choices about their care. However, we have received opposition to this administrative measure from commenters in Table A.4 in Appendix 1: MIPS Quality Measures of this final rule. Therefore, we are not finalizing this measure. We will continue to monitor this measure's progress and evaluate it for future inclusion within this MVP through the MVP maintenance process and future rulemaking.

After consideration of public comments, we are finalizing the *Optimizing Chronic Disease Management MVP* as proposed with modifications in Table D below for the CY 2023 performance period/2025 MIPS payment year and future years. We refer readers to Appendix 2: Improvement Activities Inventory, where we discuss the finalization of updates to the improvement activities IA_BE_20: Implementation of condition-specific chronic disease self-management support programs and IA_BE_21: Improved Practices that Disseminate Appropriate Self-Management Materials have been combined into the improvement activity IA_BE_16: Promote Self-management in Usual Care. Therefore, in this MVP, we have removed IA_BE_20: Implementation of condition-specific chronic disease self-management support programs and IA_BE_21: Improved Practices that Disseminate Appropriate Self-Management Materials from this MVP; and added IA_BE_16: Promote Self-management in Usual Care to this MVP to reflect this change.

TABLE D: Optimizing Chronic Disease Management MVP
Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

The table below serves to represent the measures and activities that are finalized within the Optimizing Chronic Disease Management MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[d]; existing quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within this MVP and the pound sign (#) was removed. Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

Quality	Improvement Activities	Cost
Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy (MIPS CQMs Specifications) **(!) Q047**: Advance Care Plan (Medicare Part B Claims, MIPS CQMs Specifications) **Q107:** Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (eCQM Specifications) **Q118**: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (MIPS CQMs Specifications) **(*) Q119**: Diabetes: Medical Attention for Nephropathy (eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236**: Controlling High Blood Pressure (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!!) Q398:** Optimal Asthma Control (MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (eCQM Specifications, MIPS CQMs Specifications) **(^)(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (MIPS CQMs Specifications)	**(~) IA_AHE_3**: Promote use of Patient-Reported Outcome Tools (High) **IA_BE_4**: Engagement of patients through implementation of improvements in patient portal (Medium) **(*) IA_BE_16**: Promote Self-management in Usual Care (Medium) **IA_BE_22**: Improved practices that engage patients pre-visit (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium) **IA_CC_13**: Practice improvements for bilateral exchange of patient information (Medium) **(*)(~) IA_CC_14:** Practice improvements that engage community resources to support patient health goals (High) **(*)(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium)	**Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Administrative Claims) **(^)(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

[d] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39896 through 39899), we proposed and solicited comments on the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.

We received public comments on the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. The following is a summary of the comments we received and our responses:

Comment: Some commenters expressed support for the seven proposed MVPs.

Response: We thank the commenters for their support.

Comment: One commenter supported the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. They noted this MVP will help improve quality of care, reduce costs, and transition emergency physicians to alternative payment models (APMs) as it aligns with the Acute Unscheduled Care Model (AUCM).

Response: We thank the commenter for their support.

Comment: One commenter stated there are ongoing coverage gaps in the episode-based cost measures and that many of the proposed MVPs rely on the Medicare Spending Per Beneficiary (MSPB) measure. They noted that the MSPB measure was originally developed for hospital-level accountability but has limited actionable information for clinicians when used under MIPS. They also noted that this measure can result in holding specialists accountable for care that is often beyond their direct control and have ability to impact care coordination in a clinician-focused accountability program. As such, they request CMS to only use the global or population-based measures only for confidential feedback and continue to develop more episode-based measures.

Response: We disagree with the commenter. The MSPB Clinician measure was previously used in the Value-Based Payment Modifier program and has now undergone comprehensive re-evaluation to ensure that it is well-suited to assessing clinicians on cost in MIPS. It is intended to apply broadly to inpatient care alongside more focused, episode-based measures. That is, the measure intends to apply to a broad range of costs of care. To address stakeholder concerns about clinicians being held accountable for care that is outside their control, the measure was re-evaluated to implement a set of service exclusions. For example, the measure excludes the cost of all hospice services occurring at any time during the episode window. There are also a set of service exclusions specific to each Major Diagnostic Category (MDC) to remove the cost of some unrelated services. For example, a downstream hospital admission for acute major eye infections is excluded from an episode that was triggered in the MDC for diseases and disorders of the respiratory system; this is because clinical input identified these services as unrelated. As such, a clinician who had treated the patient's initial respiratory hospitalization would not be held responsible for the cost of that subsequent hospitalization for eye infection. The revised attribution methodology involves separate attribution methods for medical and surgical episodes to identify the clinicians who are providing inpatient care. For medical episodes, the measure requires that the TIN bill at least 30 percent of inpatient E&Ms to focus on clinician groups that play a substantial role in inpatient care. For surgical episodes, the measure attribution is based on the clinician billing the procedure code. This attribution methodology appropriately identifies the clinicians who are providing care and reflects the team-based nature of hospital care. Internal medicine clinicians have the largest share of episodes (46 percent), followed by hospitalists (19 percent). We believe that it is appropriate to continue to use MSPB Clinician in MIPS and for MVPs where it is related to the focus of the care being assessed. CMS is also continuing to develop episode-based measures and has finalized five new measures for implementation in MIPS in section IV.A.3.d.(2)(b) of this final rule. We will continue to explore opportunities to incorporate more episode-based measures in MVPs when clinically appropriate.

After consideration of public comments, we are finalizing the *Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP* as proposed with modifications in Table E below for the CY 2023 performance period/2025 MIPS payment year and future years. In the CY 2022 PFS proposed rule (86 FR 39896 through 39899), we proposed the inclusion of several QCDR measures in this MVP. We did not receive data indicating that the QCDR measure ECPR55: Avoidance of Long-Acting (LA) or Extended-Release (ER) Opiate Prescriptions and Opiate Prescriptions for Greater Than 3 Days Duration for Acute Pain is fully tested at the clinician level, therefore we are not finalizing the inclusion of this QCDR measure in this MVP.

TABLE E: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

The table below serves to represent the measures and activities that are finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[e]; existing quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within this MVP and the pound sign (#) was removed. Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

Quality	Improvement Activities	Cost
(*) Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (MIPS CQMs Specifications) **(*) Q254:** Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain (MIPS CQMs Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group survey (CAHPS Survey Vendor) **(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (MIPS CQMs Specifications) **(*) Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (MIPS CQMs Specifications) **(!) ACEP21:** Coagulation studies in patients presenting with chest pain with no coagulopathy or bleeding (QCDR) **(!!) ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (QCDR) **(!) ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (QCDR) **(!) ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (QCDR)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **(*) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*)(~) IA_CC_14:** Practice improvements that engage community resources to support patient health goals (High) **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(*) IA_PSPA_6:** Consultation of the Prescription Drug Monitoring Program (High) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_15:** Implementation of Antimicrobial Stewardship Program (ASP) (Medium) **IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium) **IA_PSPA_20:** Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)**	

(^)(!!) Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

° See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.

Improving Care for Lower Extremity Joint Repair MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39900 through 39903), we proposed and solicited comments on the Improving Care for Lower Extremity Joint Repair MVP for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.

We received public comments on the Improving Care for Lower Extremity Joint Repair MVP. The following is a summary of the comments we received and our responses:

Comment: Some commenters expressed support for the seven proposed MVPs.

Response: We thank the commenters for their support.

Comment: Some commenters supported the Improving Care for Lower Extremity Joint Repair MVP.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern that this MVP does not incorporate post-fracture follow-up and care coordination. They noted that they believe as constructed the MVP fails to consider the care gap patients suffer in post-acute follow-up to address the chronic underlying bone loss that increases risk of future fractures and associated morbidity, mortality, and costs. The commenter was also concerned that the MVP would widen, rather than reduce, the care gap in osteoporosis. Finally, they recommended including measures that reflect appropriate use of screening DXA in male and female populations at risk for an osteoporotic fracture, as well as appropriate diagnosis and pharmaceutical management in individuals who have experienced one or more osteoporotic fractures.

Response: We agree with the commenter and will finalize inclusion of measure Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older within this MVP. During the development, the intention was to focus on those patients who have undergone a total joint arthroplasty; however, we agree that ensuring care coordination for the treatment of osteoporosis is important for this patient population to driving improved quality care for patient undergoing lower extremity joint repair. Additionally, this measure contains procedural coding for lower extremity fracture repair which would be applicable to those clinicians completing total knee and hip arthroplasty.

Comment: One commenter recommended the Q375: Functional Status Assessment After Total Knee Replacement eCQM be added to this MVP.

Response: We thank the commenter for their feedback to include Q375: Functional Status Assessment for Total Knee Replacement within this MVP. We acknowledge that this eCQM would apply to orthopedic surgeons who perform total joint replacements; however, Q470: Functional Status After Primary Total Knee Replacement is included in this MVP and captures the quality action assessed for in Q375 for the same patient population, making it duplicative and allows multiple measures to be met through a single quality action. While Q375: Functional Status Assessment for Total Knee Replacement requires completion of a functional assessment following total knee replacement, Q470: Functional Status After Primary Total Knee Replacement requires functional status target achievement following total knee replacement making it the more robust measure focused on quality outcomes.

After consideration of public comments, we are finalizing the *Improving Care for Lower Extremity Joint Repair MVP* as proposed with modifications in Table F below for the CY 2023 performance period/2025 MIPS payment year and future years.

TABLE F: Improving Care for Lower Extremity Joint Repair MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

The table below serves to represent the measures and activities that are finalized within the Improving Care for Lower Extremity Joint Repair MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[f]; existing quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within this MVP and the pound sign (#) was removed. Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

Quality	Improvement Activities	Cost
(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(*) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (MIPS CQMs Specifications) **(*)(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (MIPS CQMs Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (eCQM Specifications) **(*)(!!) Q470:** Functional Status After Primary Total Knee Replacement (MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (Administrative Claims)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(*) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_12** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **(*) IA_CC_15:** PSH Care Coordination (High) **(*) IA_PSPA_6:** Consultation of the Prescription Drug Monitoring Program (High) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **(*) IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium) **IA_PSPA_27:** Invasive Procedure or Surgery Anticoagulation Medication Management (Medium)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Administrative Claims) **(^)(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

[f] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.

Patient Safety and Support of Positive Experiences with Anesthesia MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

In the CY 2022 PFS proposed rule (86 FR 39904 through 39907), we proposed and solicited comments on the Patient Safety and Support of Positive Experiences with Anesthesia MVP for implementation beginning with the CY 2023 performance period/2025 MIPS payment year.

We received public comments on the Patient Safety and Support of Positive Experiences with Anesthesia MVP. The following is a summary of the comments we received and our responses:

Comment: Some commenters expressed support for the seven proposed MVPs.

Response: We thank the commenters for their support.

Comment: One commenter supported the finalization of the Patient Safety and Support of Positive Experiences with Anesthesia MVP as proposed.

Response: We thank the commenter for their support.

Comment: One commenter noted they believe CMS should also include "CRNAs" or "anesthesia providers" to recognize the contributions and value of all anesthesia providers where they use the term "anesthesiologist," in the anesthesia MVP.

Response: We thank the commenter for their feedback. As noted in the introduction for this MVP, this MVP will be most applicable to clinicians who provide anesthesia services to patients within the surgical setting or who are considered anesthesiologists or other qualified anesthesia professionals. We appreciate the feedback and intended the MVP to be inclusive of all anesthesia providers and will be more cognizant of language in the future.

Comment: One commenter noted they believe there are ongoing coverage gaps in the episode-based cost measures and that many of the proposed MVPs rely on the Medicare Spending Per Beneficiary (MSPB) measure. They noted that the MSPB measure was originally developed for hospital-level accountability but has limited actionable information for clinicians when used under MIPS. They also noted that this measure can result in holding specialists accountable for care that is often beyond their direct control and have ability to impact care coordination in a clinician-focused accountability program. As such, they requested CMS to only use the global or population-based measures only for confidential feedback and continue to develop more episode-based measures.

Response: We disagree with the commenter. The MSPB Clinician measure was previously used in the Value-Based Payment Modifier program and has now undergone comprehensive re-evaluation to ensure that it is well-suited to assessing clinicians on cost in MIPS. It is intended to apply broadly to inpatient care alongside more focused, episode-based measures. That is, the measure intends to apply to a broad range of costs of care. To address stakeholder concerns about clinicians being held accountable for care that is outside their control, the measure was re-evaluated to implement a set of service exclusions. For example, the measure excludes the cost of all hospice services occurring at any time during the episode window. There are also a set of service exclusions specific to each Major Diagnostic Category (MDC) to remove the cost of some unrelated services. For example, a downstream hospital admission for acute major eye infections is excluded from an episode that was triggered in the MDC for diseases and disorders of the respiratory system; this is because clinical input identified these services as unrelated. As such, a clinician who had treated the patient's initial respiratory hospitalization would not be held responsible for the cost of that subsequent hospitalization for eye infection. The revised attribution methodology involves separate attribution methods for medical and surgical episodes to identify the clinicians who are providing inpatient care. For medical episodes, the measure requires that the TIN bill at least 30 percent of inpatient E&Ms to focus on clinician groups that play a substantial role in inpatient care. For surgical episodes, the measure attribution is based on the clinician billing the procedure code. This attribution methodology appropriately identifies the clinicians who are providing care and reflects the team-based nature of hospital care. Internal medicine clinicians have the largest share of episodes (46 percent), followed by hospitalists (19 percent). We believe that it is appropriate to continue to use MSPB Clinician in MIPS and for MVPs where it is related to the focus of the care being assessed. We are also continuing to develop episode-based measures and has finalized five new measures for implementation in MIPS in section IV.A.3.d.(2)(b) of this final rule. We will continue to explore opportunities to incorporate more episode-based measures in MVPs when clinically appropriate.

After consideration of public comments, we are finalizing the *Patient Safety and Support of Positive Experiences with Anesthesia MVP* as proposed with modifications in Table G below for the CY 2023 performance period/2025 MIPS payment year and future years. In the CY 2022 PFS proposed rule (86 FR 39904 through 39907), we proposed the inclusion of several QCDR measures in this MVP. We did not receive data to demonstrate that the QCDR measure AQI70: Prevention of Arterial Line-related Bloodstream Infections is fully tested at the clinician level. Therefore, we are not finalizing its inclusion in this MVP.

TABLE G: Patient Safety and Support of Positive Experiences with Anesthesia MVP Beginning with the CY 2023 Performance Period/2025 MIPS Payment Year

The table below serves to represent the measures and activities that are finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP.

Notes: If applicable, new MIPS quality and Promoting Interoperability measures are identified below with a caret symbol (^)[g]; existing quality measures and improvement activities with revisions are identified below with an asterisk (*); and quality measures that are considered high priority are identified with an exclamation point (!) and outcome measures are identified with a double exclamation point (!!). In the CY 2022 PFS proposed rule (86 FR 39881 through 39884), QCDR measures proposed in this MVP table that were pending testing data were noted with a pound sign (#). In this final rule, in instances where evidence of testing data at the clinician level was received and demonstrates the QCDR measure is fully tested at the clinician level, we are finalizing the QCDR measures within this MVP and the pound sign (#) was removed. Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

Quality	Improvement Activities	Cost
(!!) Q404: Anesthesiology Smoking Abstinence (MIPS CQMs Specifications) **(!!) Q424:** Perioperative Temperature Management (MIPS CQMs Specifications) **(*)(!) Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (MIPS CQMs Specifications) **(*)(!) Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (MIPS CQMs Specifications) **(!) Q477:** Multimodal Pain Management (MIPS CQMs Specifications) **(!!) AQI48:** Patient-Reported Experience with Anesthesia (QCDR) **(!) AQI69:** Intraoperative Antibiotic Redosing (QCDR)	**(*) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_15:** PSH Care Coordination (High) **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) **(*)(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Records (High) **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium) **IA_PSPA_20:** Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	

(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Groups (Administrative Claims) **(^)(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

[8] See Appendix 1, MIPS Quality Measures: Table Group A for further information regarding new MIPS measures and section IV.A.3.d.(4)(d)(ii) of this final rule regarding new Promoting Interoperability measures.

[FR Doc. 2021–23972 Filed 11–2–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410

[CMS–1751–IFC]

RIN 0938–AU95

Medicare Program; Opioid Treatment Programs: CY 2022 Methadone Payment Exception

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) freezes the payment to Opioid Treatment Programs for methadone in CY 2022 at the CY 2021 rate because it would not be appropriate to implement a decrease to the rate when substance use and overdoses have been exacerbated by the Coronavirus Disease 2019 (COVID–19) pandemic.

DATES: *Effective date:* These regulations are effective on January 1, 2022.

Comment date: To be assured consideration, comments on CMS–1751–IFC must be received at one of the addresses provided below, no later than 5 p.m. January 3, 2022.

ADDRESSES: Please refer to file code CMS–1751–IFC when commenting on issues in the interim final rule with comment period.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1751–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1751–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Lindsey Baldwin, (410) 786–1694, and Michele Franklin, (410) 786–9226.

SUPPLEMENTARY INFORMATION:

I. Background

A. Methadone

The Food and Drug Administration (FDA) has approved three medications for the treatment of opioid use disorder (OUD): Methadone, buprenorphine, and naltrexone. These are referred to as medications for opioid use disorder (MOUD). The combination of MOUD with counseling and behavioral therapies to provide a ''whole-patient'' approach to OUD care is referred to as medication-assisted treatment (MAT). Opioid treatment programs (OTPs) are clinically driven and tailored to meet each patient's needs.[1] MOUD are also used to prevent or reduce opioid overdose. These medications are safe to use for months, years, or even a lifetime.[2]

As discussed in the CY 2020 PFS final rule (84 FR 62630), when used to treat those with a confirmed diagnosis of OUD, methadone cannot be dispensed by a pharmacy like certain other MOUD treatments (that is buprenorphine, buprenorphine-naloxone combination

[1] *https://www.samhsa.gov/medication-assisted-treatment.*

[2] *https://www.samhsa.gov/medication-assisted-treatment.*

products, or naltrexone products) and therefore is not covered under Medicare Part D. Methadone is a schedule II controlled substance that is highly regulated because it has a potential for misuse and serious adverse effects if taken by opioid-naïve individuals. Methadone is also used as an analgesic to treat chronic pain. When used for the treatment of OUD, methadone is taken daily and is available in tablet, tablet for suspension, and solution forms and can only be dispensed and administered by an OTP as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. In the CY 2020 PFS final rule, we noted that approximately 74 percent of patients receiving services from OTPs receive methadone for OUD treatment, with the vast majority of the remaining patients receiving buprenorphine (84 FR 62631).[3] In monitoring utilization of OTP services furnished under the new Medicare benefit, we have observed the percentage of Medicare beneficiaries receiving methadone to be closer to 95 percent.

According to SAMHSA's website, MAT has been shown to improve patient survival and increase retention in treatment.[4] Several studies indicate that retention in MAT is associated with lower mortality rates. One study stated that ''Retention in MAT of over one year was associated with a lower mortality rate than that with retention of less than one year. Improved coverage and adherence to MAT and post-treatment follow-up are crucial to reduce the mortality.'' [5]

B. Effects of the COVID–19 pandemic on the Opioid Crisis

The United States is now facing a fourth wave of the overdose crisis as a result of rising polysubstance use, such as the co-use of opioids and psychostimulants (for example, methamphetamine, cocaine). Recent CDC estimates of overdose deaths now exceed 96,000 for the 12-month period to March 2021,[6] with overdose death rates surging among Black and Latino Americans.[7] While overdose deaths were already increasing in the months preceding the COVID–19 pandemic, the latest numbers suggest an acceleration of overdose deaths during the pandemic. Public comments received in response to the CY 2022 PFS proposed rule described the recent increases in overdose deaths. One commenter stated that drug overdose deaths have reached historic highs in this country. According to the commenter, these spikes in substance use and overdose deaths reflect a combination of increasingly deadly illicit drug supplies, as well as treatment disruptions, social isolation, and other hardships imposed by the COVID–19 pandemic, but they also reflect the longstanding inadequacy of our medical infrastructure when it comes to preventing and treating substance use disorders (SUD) (for example, alcohol, tobacco, cannabis, opioids). Even before the COVID–19 pandemic began, more than 21 million Americans aged 12 or over in 2019 needed treatment for a SUD in the past year, but only about 4.2 million of them received any treatment or ancillary services for it.[8]

C. Opioid Use Disorders (OUDs) in the Medicare Population

Nearly one million adults aged 65 and older live with a SUD, as reported in 2018 data.[9] According to a Data Highlight published by CMS' Office of Minority Health, Medicare beneficiaries represent a growing proportion of individuals with OUD. Overall, 2.8 percent of Medicare Fee-for-Service (FFS) beneficiaries had an opioid use disorder (OUD) in 2018 out of a total of 38,665,082 Medicare FFS beneficiaries.[10] The problems associated with OUD in the Medicare population are compounded by chronic pain-associated conditions more common in later life, as well as the increased prevalence of multiple comorbidities and polypharmacy risks that exist among older adults.[11] A public comment received in response to the CY 2022 PFS proposed rule referred to increases in overdose deaths in individuals over age 65, stating that data from the CDC indicates that drug overdose deaths are increasing across all age groups, including those over age 65. Additionally, a recent Office of Inspector General (OIG) analysis of Medicare data reported that opioid overdoses have resulted in more than 200,000 deaths among Medicare beneficiaries nationwide since 2015. From 2016 to 2019, Medicare Part D saw a steady decline in opioid use, along with an increased use of drugs for treatment of OUD. OIG also noted that COVID–19 poses specific dangers for people using opioids, as respiratory diseases like COVID–19 can increase the risk of fatal overdose among those taking opioids and those with OUD are more likely to contract COVID–19 and suffer complications. With the onset of COVID–19 and the new dangers it poses for beneficiaries taking opioids, the OIG report states that it is imperative that the HHS closely monitor opioid use during this unprecedented time. During the first 8 months of 2020, about 5,000 Medicare Part D beneficiaries per month had an opioid overdose.[12]

II. Methadone Pricing

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy in § 410.67(d)(2)(i) under which the payment for the drug component of episodes of care will be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. Under the policy finalized at § 410.67(d)(2)(i)(B), for oral medications, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart J and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate. The payment amount for methadone furnished by OTPs during an episode of care in CY 2021 is $37.38,[13] which is 100 percent of ASP, as determined based on voluntarily submitted ASP data for the methadone.

Quarterly ASP pricing files are typically posted on the CMS website

[3] *https://www.cdc.gov/drugoverdose/deaths/index.html.*

[4] *https://www.samhsa.gov/medication-assisted-treatment.*

[5] Ma, J., Bao, YP., Wang, RJ. *et al.* Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. *Mol Psychiatry* 24, 1868–1883 (2019). *https://doi.org/10.1038/s41380-018-0094-5.*

[6] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[7] Drake, J., Charles, C., Bourgeois, J.W., Daniel, E.S., & Kwende, M. (January 2020). Exploring the impact of the opioid epidemic in Black and Hispanic communities in the United States. Drug Science, Policy and Law. doi:10.1177/2050324520940428.

[8] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–07–01–001, NSDUH Series H–55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/.*

[9] *https://www.drugabuse.gov/publications/substance-use-in-older-adults-drugfacts.*

[10] *https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2018-medicare-enrollment-section.*

[11] *https://www.cms.gov/files/document/oud-disparities-prevalence-2018-medicare-ffs-dh-002.pdf.*

[12] Opioid Use in Medicare Part D During the Onset of the COVID–19 Pandemic. U.S. Department of Health and Human Services Office of Inspector General. Data Snapshot, OEI–02–20–00400. Published February 2021.

[13] *https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.*

prior to the beginning of the quarter in which Medicare payments will be effective, which allows drug manufacturers that are required to submit their sales data to review and identify any issues. Due to the timing of CY PFS rulemaking and because ASP drug pricing file data is updated on a quarterly basis, the most recent ASP drug pricing file data available for this CY 2022 PFS final rule is the October 2021 update. For payment limits effective October 1, 2021, CMS posted the ASP drug pricing file on September 9, 2021.

In early September 2021, while gathering available manufacturer-reported ASP data for the annual update to the OTP drug pricing for CY 2022, we found that the volume-weighted ASP for oral methadone had decreased by just over 50 percent compared to last year's rate, from $37.38 to $17.64.[14] This reduction is due to inclusion of newly reported ASP data for methadone tablets, whereas previously the manufacturer-reported ASP data reflected only sales of the methadone oral concentrate. The ASP is volume-weighted; however, ASP reporting is not required for oral methadone and only a small subset of methadone manufacturers voluntarily submit ASP data. Of the nearly 50 available NDCs for oral methadone preparations with available pricing in the Red Book® compendia, voluntarily submitted ASP data is available for only three of these NDCs. Pricing for oral methadone is distinct from most other drug pricing based on ASP because oral methadone is not separately payable as a drug or biological under Medicare Part B, and manufacturers are not subject to ASP reporting requirements under section 1927(b)(3)(A)(iii) of the Act for those NDCs. Additionally, we do not currently have utilization data on the different forms of methadone that can be dispensed or administered at the OTPs. That is, at this time we do not have data showing whether OTPs utilize oral methadone concentrate or tablets more often, or if the two formulations are utilized equally. When we researched OTP practice patterns as we were preparing to implement this new benefit, we received anecdotal reports that several OTPs used the oral concentrate exclusively.

For these reasons, we have questions as to whether the current ASP data, which reflects voluntarily reported data from only a very small subset of methadone manufacturers, is representative of utilization of the two forms of oral methadone by the Medicare beneficiaries receiving OUD treatment services in OTPs.

Given recent reports regarding the effects of the public health emergency (PHE) for COVID–19 on individuals with SUD, including OUD, and the questions we have related to whether the ASP data we have for methadone is reflective of OTP utilization due to the distinct nature of methadone pricing, as described above, we believe it is in the public's best interest not to implement a significant decrease in the payment rate for methadone furnished by OTPs as part of OUD treatment services without first having an opportunity to review the issue, seek input from the OTP stakeholder community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs. We note that section 1834(w)(2) of the Act allows for flexibility to consider the scope of services furnished, the characteristics of the individuals receiving services, and such other factors as the Secretary determines appropriate, in determining the rates paid to OTPs under Medicare.

Therefore, in this interim final rule with comment period (IFC), we are establishing a limited exception to the current methodology for determining the payment amount for the drug component of an episode of care in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the payment amount that was determined for CY 2021. We are also revising the regulation at § 410.67(d)(2)(i)(B), which governs the determination of the payment amount for oral medications, to reflect this exception and to make a conforming change to the reference to 42 CFR part 414, subpart J.

Under this exception, the payment amount for the drug component of the methadone bundle described by HCPCS code G2067 (*Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*)) and the methadone add-on code described by HCPCS code G2078 (*Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*) will be maintained at the CY 2021 rate of $37.38 for the duration of CY 2022. We will apply the annual update to the non-drug component of HCPCS G2067 for CY 2022 as required under § 410.67(d)(4)(iii). We believe that maintaining the payment amount for methadone at the CY 2021 rate during CY 2022 will allow time for CMS to study the issue further and, if appropriate, to develop an alternative payment methodology for methadone that could be proposed through notice-and-comment rulemaking for CY 2023.

We seek comment on the exception to the payment methodology for the drug component of an episode of care that we are adopting in this IFC in order to maintain the payment rate for methadone at the CY 2021 payment amount during CY 2022. Additionally, we are seeking comment on OTP utilization patterns for methadone, particularly, the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting, including any applicable data on this topic. As the OTP benefit is still new under Medicare, we have not had the opportunity to fully understand how changes in the payment rates may affect OTP operations and beneficiary access to treatment. However, it is our intent to continue to refine our payment policies in order to best meet the needs of Medicare beneficiaries. We will consider the comments received in determining how best to determine the payment rate for methadone in CY 2023, including whether we should propose changes in future rulemaking to the structure of OTP coding and payment in order to account for differences in pricing and utilization for the different formulations of methadone.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and consider public comment on the proposed rule before the provisions of the rule are finalized and take effect, either as proposed or as amended, in accordance with the Administrative Procedure Act (APA) (Pub. L. 79–404), 5 U.S.C. 553 and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of proposed rulemaking in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved.

[14] The TRICARE rate for the drug portion of its weekly bundled payment for methadone treatment is $24.04 for 2022, which would also be a decrease from the CY 2021 payment rate under Medicare and cannot be used to set the Medicare payment rate for methadone in CY 2022 under § 410.67(d)(2)(i)(B) because ASP data is available for methadone.

Section 553(c) of the APA further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under Title XVIII of the Act. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

According to the National Quality Forum (NQF) September 2021 Report, *Addressing Opioid-Related Outcomes Among Individuals With Co-occurring Behavioral Health Conditions,* ''the ongoing opioid and SUDs crisis has been amplified by COVID–19 pandemic. The convergence of these two public health emergencies has led to an acceleration in overdose deaths. As information continues to emerge related to the long-term impacts of the pandemic, it has become increasingly clear that individuals with SUDs have been disproportionately affected by the disruption to daily life. Not only are individuals with a recent diagnosis of SUDs—particularly OUD and tobacco use disorder—at a significantly increased risk for COVID–19, but individuals with SUDs and COVID–19 had significantly worse outcomes than other COVID–19 individuals (for example, death and hospitalization). The mental health ramifications of social distancing and isolation also have far reaching impacts, especially for individuals with SUDs. In particular, younger adults and racial/ethnic minorities experienced disproportionally worse mental health outcomes during the pandemic, including increased substance use and suicidal ideation.'' [15]

Additionally, the NQF September 2021 Report states, ''OUD is often associated with a high risk for morbidity, mortality, and other adverse health and social conditions. Adverse events include, but are not limited to, overdose, infection, injury, hospitalization, and suicide. Individuals with OUD and/or other SUDs may face challenges across multiple facets of their lives, such as unemployment or underemployment, fractured family structures, and involvement with the criminal justice system.'' It goes on to say that ''with over 255 individuals dying each day from a drug overdose—and with just over 70 percent of all drug overdose deaths involving an opioid—it is essential for stakeholders to take action to address overdose and mortality related to the ongoing SUD crisis.[10] [16]

We believe that it would be contrary to the public interest to allow the payment rate for methadone furnished by OTPs to decrease to $17.64, a decrease of over 50 percent from the current payment rate of $37.38, on January 1, 2022, as required under the current regulation. As described in section I. of this IFC, the PHE for COVID–19 has had a significant impact on individuals with SUD, including OUD. We believe it is essential to ensure that Medicare beneficiaries retain access to treatment for OUD at OTPs at a time when overdose deaths are increasing. As we previously discussed, this is the second year we have updated the payment rates for OTPs. This benefit was established by the SUPPORT Act as part of the strategy to fight the opioid crisis. This benefit is still building the trust and confidence of OTPs to enroll in Medicare and furnish OUD treatment services and we have heard stakeholder feedback regarding the shortage of available behavioral health specialists for treatment of SUDs. According to a report by the National Academies of Sciences, Engineering, and Medicine Committee on Medication-Assisted Treatment for Opioid Use Disorder, ''the barriers preventing broader access to life-saving medications for OUD include stigma, inadequate professional education and training related to the evidence base for using medication, and challenges in connecting individuals with medication-based treatment due to delivery system fragmentation, regulatory and legal barriers, barriers related to public and private health insurance coverage, and reimbursement and payment policies that do not incentivize the provision of high-value care for OUD'' [17]. From 2010 through 2019, we have seen that the Medicare population has a growing need for OUD treatment. Specifically, analyzing Medicare data regarding chronic condition counts, we found that in 2010 there were approximately 311,000 beneficiaries with OUD and this number has grown to approximately 983,000 beneficiaries as of 2019.[18] We anticipate that this data will continue to trend upward and that the number of Medicare beneficiaries with OUD will increase as well as the need for access to these lifesaving services. We are still studying the payment system implemented in CY 2020 and the implications of the payment methodologies put into place. We had not contemplated that there could be such a significant fluctuation in payment at this point especially for one of the most commonly used medications for OUD treatment.

In addition, as discussed in section II. of this IFC, we have questions with respect to whether the ASP data we have for methadone is reflective of OTP utilization due to the distinct nature of methadone pricing and anecdotal reports that the more expensive methadone oral concentrate is more commonly used by OTPs. We note that public comments received in response to the CY 2020 PFS proposed rule described that OTPs incur costs associated with rigorous storage and inventory tracking systems required by the DEA and suggested a cautious approach to pricing the drugs to ensure the success of these programs (84 FR 62656). Regarding the annual update to the rates, commenters also indicated that if the OTP rates were not adequately updated, this would create access to care issues as federal and state mandated OTP costs grow faster than Medicare reimbursements (84 FR 62668). Additionally, in the CY 2017 PFS final rule, we referred to the shortage of available psychiatric and other mental health professionals in many parts of the country, and stated we believe it is important to identify and make accurate payment for models of care that facilitate access to psychiatric and other behavioral health specialty care (81 FR 80233). As a result, we believe it is in the public's best interest not to decrease the payment rate for methadone furnished by OTPs as part of OUD treatment services and risk restricting access to OUD treatment services without first having an opportunity to review the issue, seek

[15] *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=93434.*

[16] Ahmad F, Rossen L, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. Centers for Disease Control and Prevention. *https://www.cdc.gov/nchs/nvss/vsrr/drugoverdose-data.htm.* Published August 5, 2021. Last accessed August 2021.

[17] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Medication-Assisted Treatment for Opioid Use Disorder; Mancher M, Leshner AI, editors. Washington (DC): National Academies Press (US); 2019 Mar 30. *https://www.ncbi.nlm.nih.gov/books/NBK541389/.*

[18] *https://www2.ccwdata.org/web/guest/medicare-tables-reports.*

input from the OTP stakeholder community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs.

As explained in section II. of this IFC, we identified the reduction in the payment rate for methadone in September as part of determining the annual update to the drug component of the OTP payment rates under § 410.67(d)(2)(i) in conjunction with the development of the CY 2022 PFS final rule. Because we did not propose any change to the payment methodology for methadone in the CY 2022 PFS proposed rule, it was not possible for us to address the payment decrease in the CY 2022 PFS final rule. In addition, we have determined that it would be impracticable to undertake a new notice-and-comment rulemaking process in order to freeze the payment rate for methadone before the payment rate decrease required under the current regulations takes effect on January 1, 2022.

If we were to proceed with notice-and-comment rulemaking procedures to propose a change to the payment methodology for methadone, we estimate the process would take at least 6 months to complete, which would require that the decreased rate take effect on January 1, 2022, and remain in effect for several months before we would be able to issue a final rule to modify the payment rate. For the reasons explained previously, we believe that allowing the payment decrease to take effect could cause harm to the Medicare beneficiaries who rely on OTP services during a time where stable and predictable access to OUD treatment services is needed the most. We believe that implementing a sudden and significant decrease in the rate for methadone could affect the ability of OTPs to continue to offer services to Medicare beneficiaries, thereby impeding access to treatment for OUD, at a time when overdose deaths are at an all-time high. As noted in section I. of this IFC, estimates of total drug overdose deaths now exceed 96,000 for the 12-month period to March 2021. Therefore, we believe that maintaining the payment amount for methadone at the CY 2021 rate while we seek information about OTP utilization patterns and explore other alternatives for addressing our payment methodology is of life-saving importance. Thus, in light of the timing constraints and the potential consequences of allowing the payment reduction to take effect, we have determined that it would be impracticable and contrary to the public interest to undertake notice-and-comment rulemaking before freezing the payment rate for methadone during CY 2022.

Therefore, we find good cause to waive notice-and-comment procedures and to issue this IFC. We are providing a 60-day public comment period as specified in the **DATES** section of this document. The agency will carefully consider any comments received before taking any future action with respect to this policy.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

This IFC is necessary to make policy changes under Medicare fee-for-service. Specifically, this IFC freezes payment to Opioid Treatment Programs for methadone in CY 2022 at the CY 2021 rate because it would not be appropriate to implement a decrease to the payment rate when substance use and overdoses have been exacerbated by the COVID–19 pandemic.

We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this IFC. The relevant sections of this IFC contain a description of significant alternatives, if applicable.

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy under which the payment to opioid treatment programs (OTPs) for the drug component of episodes of care will be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. However, in gathering available manufacturer-reported ASP data for the annual update to the OTP drug pricing for CY 2022, we found that the volume-weighted ASP for oral methadone had decreased by just over 50 percent compared to last year's rate because it now includes newly reported ASP data for methadone tablets, whereas previously only manufacturer-reported data for methadone oral concentrate had been included. The ASP is volume-weighted; however, because ASP reporting is not required for oral methadone, we have questions as to whether this data is representative of utilization of the two types of oral methadone in OTPs. Given the recent reports on the effects of the PHE for COVID–19 on individuals with substance use disorders, including opioid use disorder, and the questions we have related to whether the ASP data we have for methadone is reflective of OTP utilization, we believe it is in the public's best interest not to implement a significant decrease in the payment rate for methadone furnished by OTPs without first having an opportunity to review the issue, seek input from the OTP stakeholder community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets in the OTP setting, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs. Therefore, in this IFC we are modifying our payment methodology in order to maintain the price for the drug component of the methadone bundle described by HCPCS code G2067 (*Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*) and the methadone add-on code described by HCPCS code G2078 (*Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*) at the CY 2021 rate of $37.38 on an interim final basis for the duration of CY 2022.

Based on an analysis of the 2020 and 2021 utilization of the OTP benefit, we estimate that the Part B cost impact of maintaining the CY 2021 price for the drug component of the methadone bundle and the methadone add-on code for take-home supplies of methadone on an interim final basis for the duration of CY 2022 rather than implementing the

decrease in the available manufacturer-reported ASP data will be approximately $25 million. Additionally, we believe that not implementing the decrease based on the available manufacturer-reported ASP data is in the public's best interest given the recent reports on the effects of the PHE for COVID–19 on individuals with OUD, especially as it pertains to overdose deaths. We note that we are also seeking public comment on patterns of utilization of oral methadone by OTPs in order to inform future rulemaking on this topic.

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this IFC will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this IFC will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2021.

List of Subjects in 42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Amend § 410.67 by revising paragraph (d)(2)(i)(B) to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(B) *For oral medications.* (*1*) Except as provided under paragraph (d)(2)(i)(B)(*2*) of this section, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart J of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate and for buprenorphine will be calculated using the National Average Drug Acquisition Cost.

(*2*) For CY 2022, the payment amount for methadone is the payment amount determined under paragraph (d)(i)(B)(*1*) of this section for methadone in CY 2021.

* * * * *

Dated: October 29, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–23973 Filed 11–2–21; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Part 63
National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks, Surface Coating of Metal Cans, Boat Manufacturing, and Clay Ceramics Manufacturing; Technical Correction; National Emission Standards for Hazardous Air Pollutants: Refractory Products Manufacturing Residual Risk and Technology Review; National Emission Standards for Hazardous Air Pollutants: Carbon Black Production and Cyanide Chemicals Manufacturing Residual Risk and Technology Reviews, and Carbon Black Production Area Source Technology Review; National Emission Standards for Hazardous Air Pollutants: Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources Technology Review; Final Rules and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2019–0314, EPA–HQ–OAR–2017–0684, EPA–HQ–OAR–2016–0447, EPA–HQ–OAR–2013–0290; FRL–8472–01–OAR]

RIN 2060–AT49, 2060–AT51, 2060–AT12, and 2060–AT25

National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks, Surface Coating of Metal Cans, Boat Manufacturing, and Clay Ceramics Manufacturing; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: In this action, the U.S. Environmental Protection Agency (EPA) is making technical corrections to four regulations under the National Emission Standards for Hazardous Air Pollutants (NESHAP) program. Specifically, the rules to be amended by this action include the following: The NESHAP for Surface Coating of Automobiles and Light-Duty Trucks, promulgated on July 8, 2020; the NESHAP for Surface Coating of Metal Cans, promulgated on February 25, 2020; the NESHAP for Boat Manufacturing, promulgated on March 20, 2020; and the NESHAP for Clay Ceramics Manufacturing, promulgated on November 1, 2019. Following signature of each of these final rules, the EPA discovered inadvertent minor errors and is correcting these errors in this action.

DATES: This final rule is effective on November 19, 2021. The incorporation by reference (IBR) of certain publications listed in the rule is approved by the Director of the Federal Register as of November 19, 2021. The incorporation by reference of certain other publications listed in the rule was approved by the Director of the Federal Register as of June 25, 2004 and July 8, 2020.

ADDRESSES: The EPA has established a docket for each rule included in this action under the following: Docket ID No. EPA–HQ–OAR–2019–0314 (NESHAP for Surface Coating of Automobiles and Light-Duty Trucks), Docket ID No. EPA–HQ–OAR–2017–0684 (NESHAP for Surface Coating of Metal Cans), Docket ID No. EPA–HQ–OAR–2016–0447 (NESHAP for Boat Manufacturing), and Docket ID No. EPA–HQ–OAR–2013–0290 (NESHAP for Clay Ceramic Manufacturing). All documents in each docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov/.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Brian Storey, Sector Policies and Programs Division (D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1103; fax number: (919) 541–4991; and email address: *storey.brian@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of This Action

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that for this action, there is good cause for making these technical corrections final without a prior proposal and the opportunity for comment because the Agency is correcting minor errors that do not substantially change the Agency action taken in each of the four final rules discussed. These technical corrections will ensure that the regulatory text agrees with the description of the rule that the EPA provided in the final rule preamble for each of the four rules discussed in this action. Thus, notice and comment public procedures are unnecessary. The Agency finds that this constitutes a good cause under 5 U.S.C. 553(b)(3)(B). See also the final sentence of section 307(d)(1) of the Clean Air Act (CAA), 42 U.S.C. 307(d)(1), indicating that the good cause provisions in subsection 553(b) of the APA continue to apply to this type of rulemaking under section 307(d) of the CAA. Refer to sections I.A through I.D of this preamble for a more detailed discussion of the goof cause rationale for each rule.

A. Summary of Technical Corrections to the NESHAP for Surface Coating of Automobiles and Light-Duty Trucks and Incorporation by Reference

In the July 8, 2020, final rule (85 FR 41100) the EPA included reference to the document, *Protocol for Determining the Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Topcoat,* published December 1988 (EPA–450/3–88–018). This document was found to be out-of-date. In this action, the EPA is amending the rule to refer to the document, *Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat,* published September 2008 (EPA–453/R–08–002). This protocol determines the daily VOC emission rate (pounds of VOC per gallon of coating solids deposited) for a complete auto and light duty truck topcoat operation. The EPA has made, and will continue to make, the EPA document generally available electronically through *https://www.regulations.gov/* and at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information). A copy of the red line version of the corrected rule language is available in Docket ID No. EPA–HQ–OAR–2019–0314. The intent of the rule remains unchanged by correcting the reference. The protocols provided by the revised September 2008 document (EPA–453/R–08–002) are consistent with the protocols of the December 1988 document (EPA–450/3–88–018); therefore, the EPA finds good cause to make the correction in this direct final action.

B. Summary of Technical Corrections to the NESHAP for Surface Coating of Metal Cans

The publication of the February 25, 2020, final rule (85 FR 10828) inadvertently deleted Equation 1 of the rule from the text of the Code of Federal Regulations. This equation was not intended to be deleted. In this action, the EPA is restoring the deleted equation and the associated definitions to § 63.3541(h). A red line version of the corrected rule language is available in Docket ID No. EPA–HQ–OAR–2017–0684. Equation 1 is used to calculate organic HAP emission reductions from controlled coating operations not using

liquid-liquid material balances. Equation 1 was not part of the 2020 final rule amendments and was already in the rule prior to the amendments. Section 63.3541(h) of the rule references Equation 1, and without the equation, the reference is incomplete; therefore, the EPA finds good cause to make the correction in this direct final action.

C. Summary of Technical Corrections to the NESHAP for Boat Manufacturing

Table 8 of the March 20, 2020, final rule (85 FR 15960) included specific references to the general provisions of 40 CFR part 63, subpart A. After promulgation, the EPA found that Table 8 indicates that 40 CFR 63.6(f) applies to the rule, but, in fact, section 63.6(f)(1) includes start-up, shutdown, and malfunction (SSM) language that has been vacated by the D.C. Circuit and the EPA stated in the preamble the Agency intended to remove from the Boat Manufacturing NESHAP (85 FR at 15963 and 15967–68). In this action, the EPA is revising Table 8 to indicate § 63.6(f)(1) does not apply. A red line version of the corrected rule language is available in Docket ID No. EPA–HQ–OAR–2016–0447. The correction to the reference in Table 8 only corrects the reference to subpart A and does not change the requirement to comply with emission limits of the rule at all times, as addressed in the proposed and final rule preamble. These corrections will ensure that the regulatory text agrees with the description of the rule that was provided in the final rule preamble; therefore, the EPA finds good cause to make the correction in this direct final action.

D. Summary of Technical Corrections to the NESHAP for Clay Ceramic Manufacturing

Following signature of the November 1, 2019, final rule (84 FR 58601), the EPA discovered inadvertent errors in Table 2 of the rule. In several instances, the rows of the table were misaligned when published. Table 2 of the rule provides operating limits for regulated emission sources and their various control technology configurations and includes three columns. As a result of the error in publication, several of the control technologies identified in the rightmost column (column 3) were misaligned with the sources identified in the leftmost column (column 1), so that they no longer were appropriate or relevant. In this action, the EPA is correcting the table to ensure the control technology information is relevant to the appropriate source. In addition, the EPA's Electronic Reporting Tool (ERT) URL included a typographical error rendering the weblink, as written in the rule text, inoperable. This action corrects the URL of the weblink to ensure accessibility of the tool. A red line version of the corrected rule language is available in Docket ID No. EPA–HQ–OAR–2013–0290. The corrections to Table 8 and to the URL do not affect the standards of the rule, and only ensure the information provided is accurate and relevant; therefore, the EPA finds good cause to make the correction in this direct final action.

II. Summary of Cost, Environmental, and Economic Impacts

This action will have no cost, environmental, energy, or economic impacts beyond those impacts presented in the July 8, 2020, NESHAP for Surface Coating of Automobiles and Light-Duty Trucks final rule (85 FR 41100), the February 25, 2020, NESHAP for Surface Coating of Metal Cans final rule (85 FR 10828), the March 20, 2020, NESHAP for Boat Manufacturing final rule (85 FR 15960), and the October 26, 2015 NESHAP for Clay Ceramics Manufacturing final rule (84 FR 58601). The technical corrections are cost neutral.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practices and procedures, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Joseph Goffman,

Office of Air and Radiation, Acting Assistant Administrator.

For the reasons set out in the preamble, 40 CFR part 63 is corrected as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

Subpart A—General Provisions

■ 2. Section 63.14 is amended by revising paragraph (n)(1) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(n) * * *

(1) EPA–453/R–08–002, Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat, published September 2008, IBR approved for §§ 63.3130(c), 63.3161(d) and (g), 63.3165(e), and appendix A to subpart IIII.

* * * * *

Subpart IIII—National Emission Standards for Hazardous Air Pollutants: Surface Coating of Automobiles and Light-Duty Trucks

■ 3. Section 63.3130 is amended by revising paragraphs (c)(4) and (5) to read as follows:

§ 63.3130 What records must I keep?

* * * * *

(c) * * *

(4) A record of the calculation of the organic HAP emission rate for electrodeposition primer, primer-surfacer, topcoat, final repair, glass bonding primer, and glass bonding adhesive plus all coatings and thinners, except for deadener materials and for adhesive and sealer materials that are not components of glass bonding systems, used in coating operations added to the affected source pursuant to § 63.3082(c) for each month if subject to the emission limit of § 63.3090(a) or § 63.3091(a). This record must include all raw data, algorithms, and intermediate calculations. If the guidelines presented in the ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14), are used, you must keep records of all data input to this protocol. If these data are maintained as electronic files, the electronic files, as well as any paper copies must be maintained. These data must be provided to the permitting authority on request on paper, and in (if calculations are done electronically) electronic form.

(5) A record of the calculation of the organic HAP emission rate for primer-surfacer, topcoat, final repair, glass bonding primer, and glass bonding adhesive plus all coatings and thinners, except for deadener materials and for adhesive and sealer materials that are not components of glass bonding systems, used in coating operations added to the affected source pursuant to § 63.3082(c) for each month if subject to the emission limit of § 63.3090(b) or § 63.3091(b), and a record of the weight fraction of each organic HAP in each material added to the electrodeposition primer system if subject to the limitations of § 63.3092(a). This record

must include all raw data, algorithms, and intermediate calculations. If the guidelines presented in the ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14), are used, you must keep records of all data input to this protocol. If these data are maintained as electronic files, the electronic files, as well as any paper copies must be maintained. These data must be provided to the permitting authority on request on paper, and in (if calculations are done electronically) electronic form.

* * * * *

■ 4. Section 63.3161 is amended by revising paragraphs (d) and (g) to read as follows:

§ 63.3161 How do I demonstrate initial compliance?

* * * * *

(d) *Compliance with emission limits.* You must follow the procedures in paragraphs (e) through (o) of this section to demonstrate compliance with the applicable emission limit in § 63.3090(a) or § 63.3091(a). You may also use the guidelines presented in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14) in making this demonstration.

* * * * *

(g) *Determine the transfer efficiency for each coating.* You must determine the transfer efficiency for each primer-surfacer and topcoat coating, and for all coatings, except for deadener and for adhesive and sealer that are not components of glass bonding systems, used in coating operations added to the affected source pursuant to § 63.3082(c) using ASTM Method D5066–91 (Reapproved 2017), ''Standard Test Method for Determination of the Transfer Efficiency UnderProduction Conditions for Spray Application of Automotive Paints-Weight Basis'' (incorporated by reference, *see* § 63.14), or the guidelines presented in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14). You may conduct transfer efficiency testing on representative coatings and for representative spray booths as described in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14). You may assume 100 percent transfer efficiency for electrodeposition primer coatings, glass bonding primers, and glass bonding adhesives. For final repair coatings, you may assume 40 percent transfer efficiency for air atomized spray and 55 percent transfer efficiency for electrostatic spray and high volume, low pressure spray. For blackout, chip resistant edge primer, interior color, inline repair, lower body anti-chip coatings, or underbody anti-chip coatings, you may assume 40 percent transfer efficiency for air atomized spray, 55 percent transfer efficiency for electrostatic spray and high volume-low pressure spray, and 80 percent transfer efficiency for airless spray.

* * * * *

■ 5. Section 63.3165 is amended by:
■ a. Revising paragraph (e) introductory text, and
■ b. In Equation 6 of paragraph (e)(2), Equation 7 of paragraph (e)(3), and Equation 8 of paragraph (e)(4) remove the text 'Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Topcoat Operations, EPA–450/3–88–018'', and add, in its place, the text ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat, EPA–453/R–08–002''.

The revision reads as follows:

§ 63.3165 How do I determine the emission capture system efficiency?

* * * * *

(e) *Panel testing to determine the capture efficiency of flash-off or bake oven emissions.* You may conduct panel testing to determine the capture efficiency of flash-off or bake oven emissions using ASTM Method D5087–02, ''Standard Test Method for Determining Amount of Volatile Organic Compound (VOC) Released from Solventborne Automotive Coatings and Available for Removal in a VOC Control Device (Abatement)'' (incorporated by reference, *see* § 63.14), ASTM Method D6266–00a (2017), ''Test Method for Determining the Amount of Volatile Organic Compound (VOC) Released from Waterborne Automotive Coatings and Available for Removal in a VOC Control Device (Abatement)'' (incorporated by reference, *see* § 63.14), or the guidelines presented in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14). You may conduct panel testing on representative coatings as described in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14).

* * * * *

■ 6. Amend Appendix A to subpart IIII of part 63 by:
■ a. Revising paragraphs 2.1 and 2.2 of section 2.0, and
■ b. In section 4.0:
■ i. Revising paragraph 4.1; and
■ ii. In section 4.2 Equation A–4, remove the text ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Topcoat Operations, EPA–450/3–88–018'', and add, in its place, the text ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat,EPA–453/R–08–002''.

The revisions read as follows:

Appendix A to Subpart IIII of Part 63—Determination of Capture Efficiency of Automobile and Light-Duty Truck Spray Booth Emissions From Solvent-Borne Coatings Using Panel Testing

* * * * *

2.1 You may conduct panel testing to determine the capture efficiency of spray booth emissions. You must follow the instructions and calculations in this appendix A, and use the panel testing procedures in ASTM Method D5087–02, ''Standard Test Method for Determining Amount of Volatile Organic Compound (VOC) Released from Solvent-borne Automotive Coatings and Available for Removal in a VOC Control Device (Abatement)'' (incorporated by reference, *see* § 63.14), or the guidelines presented in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14). You must weigh panels at the points described in section 2.5 of this appendix A and perform calculations as described in sections 3 and 4 of this appendix A. You may conduct panel tests on the production paint line in your facility or in a laboratory simulation of the production paint line in your facility.

2.2 You may conduct panel testing on representative coatings as described in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14). If you panel test representative coatings, then you may calculate either a unique percent

capture efficiency value for each coating grouped with that representative coating, or a composite percent capture efficiency value for the group of coatings. If you panel test each coating, then you must convert the panel test result for each coating to a unique percent capture efficiency value for that coating.

* * * * *

4.1 If you panel test representative coatings, then you may convert the panel test result for each representative coating from section 3.3 of this appendix A either to a unique percent capture efficiency value for each coating grouped with that representative coating by using coating specific values for the mass fraction coating solids and mass fraction VOC in section 4.2 of this appendix A, or to a composite percent capture efficiency value for the group of coatings by using the average values for the group of coatings for mass fraction coating solids and mass fraction VOC in section 4.2 of this appendix A. If you panel test each coating, then you must convert the panel test result for each coating to a unique percent capture efficiency value by using coating specific values for the mass fraction coating solids and mass fraction VOC in section 4.2 of this appendix A. The mass fraction of VOC in the coating and the mass fraction of solids in the coating must be determined by Method 24 (appendix A–7 to 40 CFR part 60) or by following the guidelines for combining analytical VOC content and formulation solvent content presented in ''Protocol for Determining the Daily Volatile Organic Compound Emission Rate of Automobile and Light-Duty Truck Primer-Surfacer and Topcoat'' EPA–453/R–08–002 (incorporated by reference, *see* § 63.14).

* * * * *

Subpart KKKK—National Emission Standards for Hazardous Air Pollutants: Surface Coating of Metal Cans

■ 7. Section 63.3541 is amended by revising paragraph (h) to read as follows:

§ 63.3541 How do I demonstrate initial compliance?

* * * * *

(h) *Calculate the organic HAP emission reduction for each controlled coating operation not using liquid-liquid material balances.* For each controlled coating operation using an emission capture system and add-on control device, other than a solvent recovery system for which you conduct liquid-liquid material balances, calculate the organic HAP emission reduction, using Equation 1 of this section. The calculation applies the emission capture system efficiency and add-on control device efficiency to the mass of organic HAP contained in the coatings and thinners that are used in the coating operation served by the emission capture system and add-on control device during each month. For any period of time a deviation specified in § 63.3542(c) or (d) occurs in the controlled coating operation, you must assume zero efficiency for the emission capture system and add-on control device, unless you have other data indicating the actual efficiency of the emission capture system and add-on control device, and the use of these data has been approved by the Administrator. Equation 1 of this section treats the materials used during such a deviation as if they were used on an uncontrolled coating operation for the time period of the deviation.

$$H_c = (A_c + B_c - H_{unc})\left(\frac{CE}{100} \times \frac{DRE}{100}\right) \qquad \text{(Eq. 1)}$$

Where:

H_c = Mass of organic HAP emission reduction for the controlled coating operation during the month, kg.

A_c = Total mass of organic HAP in the coatings used in the controlled coating operation during the month, kg, as calculated in Equation 1A of this section.

B_c = Total mass of organic HAP in the thinners used in the controlled coating operation during the month, kg, as calculated in Equation 1B of this section.

H_{unc} = Total mass of organic HAP in the coatings and thinners used during all deviations specified in § 63.3542(c) and (d) that occurred during the month in the controlled coating operation, kg, as calculated in Equation 1C of this section.

CE = Capture efficiency of the emission capture system vented to the add-on control device, percent. Use the test methods and procedures specified in §§ 63.3543 and 63.3544 to measure and record capture efficiency.

DRE = Organic HAP destruction or removal efficiency of the add-on control device, percent. Use the test methods and procedures in §§ 63.3543 and 63.3545 to measure and record the organic HAP destruction or removal efficiency.

* * * * *

Subpart VVVV—National Emission Standards for Hazardous Air Pollutants for Boat Manufacturing

■ 8. Table 8 to subpart VVVV of part 63 is revised to read as follows:

Table 8 to Subpart VVVV of Part 63—Applicability of General Provisions (40 CFR Part 63, Subpart A) to Subpart VVVV

As specified in § 63.5773, you must comply with the applicable requirements of the General Provisions according to the following table:

Citation	Requirement	Applies to subpart VVVV	Explanation
§ 63.1(a)	General Applicability	Yes.	
§ 63.1(b)	Initial Applicability Determination	Yes.	
§ 63.1(c)(1)	Applicability After Standard Established	Yes.	
§ 63.1(c)(2)		Yes	Area sources are not regulated by subpart VVVV.
§ 63.1(c)(3)		No	[Reserved].
§ 63.1(c)(4)–(5)		Yes.	
§ 63.1(d)		No	[Reserved].
§ 63.1(e)	Applicability of Permit Program	Yes.	
§ 63.2	Definitions	Yes	Additional definitions are found in § 63.5779.
§ 63.3	Units and Abbreviations	Yes.	
§ 63.4(a)	Prohibited Activities	Yes.	
§ 63.4(b)–(c)	Circumvention/Severability	Yes.	
§ 63.5(a)	Construction/Reconstruction	Yes.	
§ 63.5(b)	Requirements for Existing, Newly Constructed, and Reconstructed Sources.	Yes.	

Citation	Requirement	Applies to subpart VVVV	Explanation
§ 63.5(c)		No	[Reserved].
§ 63.5(d)	Application for Approval of Construction/Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction/Reconstruction	Yes.	
§ 63.5(f)	Approval of Construction/Reconstruction Based on prior State Review.	Yes.	
§ 63.6(a)	Compliance with Standards and Maintenance Requirements—Applicability.	Yes.	
§ 63.6(b)	Compliance Dates for New and Reconstructed Sources.	Yes	§ 63.695 specifies compliance dates, including the compliance date for new area sources that become major sources after the effective date of the rule.
§ 63.6(c)	Compliance Dates for Existing Sources	Yes	§ 63.5695 specifies compliance dates, including the compliance date for existing area sources that become major sources after the effective date of the rule.
§ 63.6(d)		No	[Reserved].
§ 63.6(e)(1)–(2)	Operation and Maintenance Requirements	No	Operating requirements for open molding operations with add-on controls are specified in § 63.5725.
§ 63.6(e)(3)	Startup, Shut Down, and Malfunction Plans	No	Only sources with add-on controls must complete startup, shutdown, and malfunction plans.
§ 63.6(f)(1)		No.	
§ 63.6(f)(2)–(3)	Compliance with Nonopacity Emission Standards.	Yes.	
§ 63.6(g)	Use of an Alternative Nonopacity Emission Standard.	Yes.	
§ 63.6(h)	Compliance with Opacity/Visible Emissions Standards.	No	Subpart VVVV does not specify opacity or visible emission standards.
§ 63.6(i)	Extension of Compliance with Emission Standards.	Yes.	
§ 63.6(j)	Exemption from Compliance with Emission Standards.	Yes.	
§ 63.7(a)(1)	Performance Test Requirements	Yes.	
§ 63.7(a)(2)	Dates for performance tests	No	§ 63.5716 specifies performance test dates.
§ 63.7(a)(3)	Performance testing at other times	Yes.	
§ 63.7(b)–(h)	Other performance testing requirements	Yes.	
§ 63.8(a)(1)–(2)	Monitoring Requirements—Applicability	Yes	All of § 63.8 applies only to sources with add-on controls. Additional monitoring requirements for sources with add-on controls are found in § 63.5725.
§ 63.8(a)(3)		No	[Reserved].
§ 63.8(a)(4)		No	Subpart VVVV does not refer directly or indirectly to § 63.11.
§ 63.8(b)(1)	Conduct of Monitoring	Yes.	
§ 63.8(b)(2)–(3)	Multiple Effluents and CMS	Yes	Applies to sources that use a CMS on the control device stack.
§ 63.8(c)(1)(i) and (iii)	CMS Operation and Maintenance	No	References to startup, shutdown, malfunction are not applicable.
§ 63.8(c)(1)–(4)	CMS Operation and Maintenance	Yes	Except those provisions in § 63.8(c)(1)(i) and (iii) as noted above.
§ 63.8(c)(5)	Continuous Opacity Monitoring Systems (COMS).	No	Subpart VVVV does not have opacity or visible emission standards.
§ 63.8(c)(6)–(8)	CMS Calibration Checks and Out-of-Control Periods.	Yes.	
§ 63.8(d)	Quality Control Program	Yes	Except those provisions of § 63.8(d)(3) regarding a startup, shutdown, malfunction plan as noted below.
§ 63.8(d)(3)	Quality Control Program	No	No requirement for a startup, shutdown, malfunction plan.
§ 63.8(e)	CMS Performance Evaluation	Yes.	
§ 63.8(f)(1)–(5)	Use of an Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Alternative to Relative Accuracy Test	Yes	Applies only to sources that use continuous emission monitoring systems (CEMS).
§ 63.8(g)	Data Reduction	Yes.	
§ 63.9(a)	Notification Requirements—Applicability	Yes.	
§ 63.9(b)	Initial Notifications	Yes.	
§ 63.9(c)	Request for Compliance Extension	Yes.	
§ 63.9(d)	Notification That a New Source Is Subject to Special Compliance Requirements.	Yes.	
§ 63.9(e)	Notification of Performance Test	Yes	Applies only to sources with add-on controls.

Citation	Requirement	Applies to subpart VVVV	Explanation
§ 63.9(f)	Notification of Visible Emissions/Opacity Test	No	Subpart VVVV does not have opacity or visible emission standards.
§ 63.9(g)(1)	Additional CMS Notifications—Date of CMS Performance Evaluation.	Yes	Applies only to sources with add-on controls.
§ 63.9(g)(2)	Use of COMS Data	No	Subpart VVVV does not require the use of COMS.
§ 63.9(g)(3)	Alternative to Relative Accuracy Testing	Yes	Applies only to sources with CEMS.
§ 63.9(h)	Notification of Compliance Status	Yes.	
§ 63.9(i)	Adjustment of Deadlines	Yes.	
§ 63.9(j)	Change in Previous Information	Yes.	
§ 63.10(a)	Recordkeeping/Reporting—Applicability	Yes.	
§ 63.10(b)(1)	General Recordkeeping Requirements	Yes	§§ 63.567 and 63.5770 specify additional recordkeeping requirements.
§ 63.10(b)(2)(i), (iii), (vi)–(xiv).	General Recordkeeping Requirements	Yes.	
§ 63.10(b)(2)(ii), (iv), (v)	Recordkeeping Relevant to Startup, Shutdown, and Malfunction Periods.	No.	
§ 63.10(b)(3)	Recordkeeping Requirements for Applicability Determinations.	Yes	§ 63.5686 specifies applicability determinations for non-major sources.
§ 63.10(c)(1)–(14)	Additional Recordkeeping for Sources with CMS.	Yes	Applies only to sources with add-on controls.
§ 63.10(c)(15)	Additional Recordkeeping for Sources with CMS.	No	No requirement for a startup, shutdown, malfunction plan.
§ 63.10(d)(1)	General Reporting Requirements	Yes	§ 63.5764 specifies additional reporting requirements.
§ 63.10(d)(2)	Performance Test Results	Yes	§ 63.5764 specifies additional requirements for reporting performance test results.
§ 63.10(d)(3)	Opacity or Visible Emissions Observations	No	Subpart VVVV does not specify opacity or visible emission standards.
§ 63.10(d)(4)	Progress Reports for Sources with Compliance Extensions.	Yes.	
§ 63.10(d)(5)	Startup, Shutdown, and Malfunction Reports	No	Applies only to sources with add-on controls.
§ 63.10(e)(1)	Additional CMS Reports—General	Yes	Applies only to sources with add-on controls.
§ 63.10(e)(2)	Reporting Results of CMS Performance Evaluations.	Yes	Applies only to sources with add-on controls.
§ 63.10(e)(3)	Excess Emissions/CMS Performance Reports	Yes	Applies only to sources with add-on controls.
§ 63.10(e)(4)	COMS Data Reports	No	Subpart VVVV does not specify opacity or visible emission standards.
§ 63.10(f)	Recordkeeping/Reporting Waiver	Yes.	
§ 63.11	Control Device Requirements—Applicability	No	Facilities subject to subpart VVVV do not use flares as control devices.
§ 63.12	State Authority and Delegations	Yes	§ 63.5776 lists those sections of subpart A that are not delegated.
§ 63.13	Addresses	Yes.	
§ 63.14	Incorporation by Reference	Yes.	
§ 63.15	Availability of Information/Confidentiality	Yes.	

Subpart KKKKK—National Emission Standards for Hazardous Air Pollutants for Clay Ceramics Manufacturing

■ 9. Section 63.8635 is amended by revising (g)(1) to read as follows:

§ 63.8635 What reports must I submit and when?

* * * * *

(g) * * *

(1) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (*https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert*) at the time of the test, you must submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*).) Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the EPA's ERT website. If you claim that some of the performance test information being submitted is confidential business information (CBI), you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAPQS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph (g)(1).

* * * * *

■ 10. Table 2 to subpart KKKKK of part 63 is revised to read as follows:

Table 2 to Subpart KKKKK of Part 63—Operating Limits

As stated in § 63.8555, you must meet each operating limit in the following table that applies to you:

For each . . .	You must . . .	Or you must . . .
1. Tunnel or roller kiln equipped with a DIFF or DLS/FF..	a. If you use a bag leak detection system, initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with your OM&M plan; operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period; and b. Maintain free-flowing lime in the feed hopper or silo and to the APCD at all times for continuous injection systems; maintain the feeder setting (on a per ton of throughput basis) at or above the level established during the performance test for continuous injection systems in which compliance was demonstrated.	i. Maintain no VE from the DIFF or DLS/FF stack; or ii. Maintain your kiln operating temperature within the range of acceptable temperatures (*i.e.,* temperature profile) established for each kiln and product.
2. Tunnel or roller kiln equipped with a WS. ...	a. Maintain the average scrubber liquid pH for each 3-hour block period at or above the average scrubber liquid pH established during the HF/HCl performance test in which compliance was demonstrated; and b. Maintain the average scrubber liquid flow rate for each 3-hour block period at or above the highest average scrubber liquid flow rate established during the HF/HCl and PM performance tests in which compliance was demonstrated.	
3. Tunnel or roller kiln equipped with an ACI system..	Maintain the 3-hour block average carbon flow rate at or above the highest average carbon flow rate established during the Hg and dioxin/furan performance tests in which compliance was demonstrated.	
4. Tunnel or roller kiln intending to comply with dioxin/furan emission limit without an ACI system.	Maintain the average operating temperature for each 12-hour block period at or below the highest operating temperature established during the dioxin/furan performance test in which compliance was demonstrated	
5. Tunnel or roller kiln with no add-on control	a. Maintain no VE from the stack; and b. Maintain the kiln process rate at or below the kiln process rate determined according to § 63.8595(g)(1) if your total facility maximum potential HCl-equivalent emissions are greater than the HCl-equivalent limit in Table 1 to this subpart; and c. Maintain the average operating temperature for each 12-hour block period at or below the highest operating temperature established during the dioxin/furan performance test in which compliance was demonstrated.	i. Maintain your kiln operating temperature within the range of acceptable temperatures (*i.e.,* temperature profile) established for each kiln and product.
6. Glaze spray operation equipped with a FF	a. If you use a bag leak detection system, initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with your OM&M plan; operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period.	i. Maintain no VE from the FF stack.
7. Glaze spray operation equipped with a WS.	a. Maintain the average scrubber pressure drop for each 3-hour block period at or above the average pressure drop established during the PM performance test in which compliance was demonstrated; and b. Maintain the average scrubber liquid flow rate for each 3-hour block period at or above the average scrubber liquid flow rate established during the PM performance test in which compliance was demonstrated.	
8. Glaze spray operation equipped with a water curtain..	a. Conduct daily inspections to verify the presence of water flow to the wet control system; and b. Conduct annual inspections of the interior of the control equipment (if applicable) to determine the structural integrity and condition of the control equipment.	
9. Glaze spray operation equipped with baffles.	Conduct an annual visual inspection of the baffles to confirm the baffles are in place.	
10. Spray dryer	Maintain the average operating temperature for each 4-hour block period at or above the average temperature established during the dioxin/furan performance test in which compliance was demonstrated.	
11. Floor tile press dryer	Maintain the average operating temperature for each 4-hour block period at or below the average temperature established during the dioxin/furan performance test in which compliance was demonstrated.	

[FR Doc. 2021–24099 Filed 11–18–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2020–0148; FRL–7527–02–OAR]

RIN 2060–AU67

National Emission Standards for Hazardous Air Pollutants: Refractory Products Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Refractory Products Manufacturing source category regulated under national emission standards for hazardous air pollutants (NESHAP). The Environmental Protection Agency (EPA) found the risks due to emissions of air toxics from this source category to be acceptable and that the standards provide an ample margin of safety to protect public health. As a result, the Agency is making no revisions to the emission limits for this source category based on the residual risk. In our technology review, after reviewing developments in practices, processes, and control technologies, the EPA determined that no revisions to the numeric emission limits is necessary. However, the EPA is revising certain work practice provisions based on the technology review. These final amendments also include new provisions for certain hazardous air pollutants (HAP) and a revision of the alternative fuel provisions. In addition, the Agency is taking final action on the proposed amendments for the source category to address emissions during periods of startup, shutdown, and malfunction (SSM); emissions during periods of scheduled maintenance; electronic reporting of notification of compliance status (NOCS) reports, performance test results, and performance evaluation results; the addition of test methods and guidance materials; updates to several test methods; and other miscellaneous clarifying and technical corrections.

DATES: This final rule is effective on November 19, 2021. The incorporation by reference (IBR) of certain publications listed in the rule is approved by the Director of the Federal Register as of November 19, 2021.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2020–0148. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Ms. Paula Deselich Hirtz, Minerals and Manufacturing Group, Sector Policies and Programs Division (D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2618; fax number: (919) 541–4991; and email address: *hirtz.paula@epa.gov.* For specific information regarding the risk modeling methodology, contact Mr. Chris Sarsony, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4843; fax number: (919) 541–0840; and email address: *sarsony.chris@epa.gov.*

SUPPLEMENTARY INFORMATION: *Preamble acronyms and abbreviations.* The Agency uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms below. Also, throughout this preamble the terms ''we,'' ''us,'' or ''our'' mean the EPA.

BLD bag leak detection
CAA Clean Air Act
CRA Congressional Review Act
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
EJ Environmental Justice
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
FTIR Fourier Transform Infrared
HAP hazardous air pollutants(s)
HQ hazard quotient
IBR incorporation by reference
ICR Information Collection Request
lb/hr pounds per hour
MACT maximum achievable control technology
HCl hydrogen chloride
HF hydrogen fluoride
Hg mercury
MIR maximum individual risk
NAAQS National Ambient Air Quality Standards
NACWA National Association of Clean Water Agencies
NEI National Emission Inventory
NESHAP national emission standards for hazardous air pollutants
NOCS notification of compliance status
OM&M operation, maintenance, and monitoring
OPL operating parameter limit
PDF portable document format
PM Particulate matter
POM polycyclic organic matter
ppmvd per million by volume, dry basis
RFA Regulatory Flexibility Act
RTO regenerative thermal oxidizer
RTR risk and technology review
SSI Sewage Sludge Incinerator
SSM startup, shutdown, and malfunction
THC total hydrocarbons
tpy tons per year
TOSHI target organ specific hazard index
UMRA Unfunded Mandates Reform Act
µg/dscm micrograms per dry standard cubic meter
µg/Nm^3 micrograms per normal cubic meter
UPL upper prediction limit
VCS voluntary consensus standards
VE visible emissions
XML extensible markup language

Background information. On January 14, 2021, the EPA proposed revisions to the Refractory Manufacturing Products NESHAP based on our RTR (86 FR 3095, January 14, 2021). In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in the document titled *Summary of Public Comments and Responses on Proposed Rule: National Emission Standards for HAP from Refractory Products Manufacturing (40 CFR part 63, subpart SSSSS) Residual Risk and Technology Review, Final Amendments,* located in Docket ID No. EPA–HQ–OAR–2020–0148. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. Judicial Review and Administrative Reconsideration
II. Background
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I. General Information

A. Does this action apply to me?

Regulated entities. Refractory Products Manufacturing, the source category that is the subject of this final action, is regulated under 40 CFR part 63, subpart SSSSS. The North American Industry Classification System codes for the refractory products industry are 327124 (clay) and 327125 (nonclay). We estimate that three major source facilities engaged in refractory products manufacturing will be affected by this final rule. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/refractory-products-manufacturing-national-emissions-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR source categories.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by January 18, 2022. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of HAP from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred

to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this rule, see 86 FR 3097 (January 14, 2021).

B. What is the Refractory Products Manufacturing source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the Refractory Products Manufacturing NESHAP on April 16, 2003 (68 FR 18730). The standards are codified at 40 CFR part 63, subpart SSSSS. The Refractory Products Manufacturing industry consists of facilities that manufacture refractory products, such as refractory bricks, refractory shapes, monolithics, kiln furniture, crucibles, and other materials used for lining furnaces and other high temperature process units. The source category covered by this NESHAP includes three major source facilities.

The NESHAP groups refractory product manufacturing processes into four subcategories: Clay refractories, nonclay refractories, chromium refractories (nonclay) and pitch-impregnated refractories (nonclay). The three major source facilities manufacture clay and/or nonclay refractory products and can be grouped into the clay and nonclay refractories subcategories. Chromium refractory products and pitch-impregnated refractory products are not manufactured by any of the three major source facilities.

The Refractory Products Manufacturing NESHAP specifies emission limits, operating limits, and work practice standards for existing affected thermal process units and for new and reconstructed affected thermal process units that emit organic HAP according to refractory product type. For existing clay refractory product kilns, the NESHAP requires the use of natural gas or equivalent fuel at all times, except during periods of natural gas supply interruption or curtailment, to limit metal HAP, hydrogen fluoride (HF) and hydrogen chloride (HCl) emissions. New clay refractory product kilns are required to meet numeric limits for HF and HCl. For existing and new curing ovens, shape dryers, and kilns that are used to process refractory products that use organic HAP (*i.e.,* nonclay refractory product sources), the NESHAP provides the option of meeting a total hydrocarbon (THC) concentration limit or reducing the THC mass emissions by at least 95 percent. The NESHAP also establishes operating limits for thermal process sources and control devices, which are based on operating parameters established during performance testing. Additional detail on the refractory product manufacturing source category and NESHAP requirements are provided in the proposal preamble (86 FR 3083, January 14, 2021).

C. What changes did we propose for the Refractory Products Manufacturing source category in our January 14, 2021 RTR proposal?

On January 14, 2021, the EPA published a proposed rule in the **Federal Register** for the Refractory Products Manufacturing NESHAP, 40 CFR part 63, subpart SSSSS, that took into consideration the RTR analyses (86 FR 3095). For this source category, we proposed that the risks are acceptable, and that additional emission controls are not necessary to provide an ample margin of safety. For the technology review, we proposed improvements to the existing work practice standard for affected continuous kilns using THC emission control devices. We also proposed the following amendments: Standards for previously unregulated HAP for affected sources in the clay and nonclay refractory subcategories; the requirement that NOCS reports, performance test results, and performance evaluation results be electronically submitted; revisions to the SSM provisions of the rule; new test methods and incorporation by reference (IBR) of alternative test methods; and other minor technical and editorial revisions.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Refractory Products Manufacturing source category and amends the Refractory Products Manufacturing NESHAP based on those determinations. This action also

[1] The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

finalizes other changes to the NESHAP, including the proposed changes described above, except we are finalizing a slightly modified version of the proposed work practice standard for affected continuous kilns using THC emission control devices, as explained in section IV.B.2 of this preamble; and we are not finalizing the proposed allowance to use alternative fuels during periods of natural gas supply curtailment or interruption from the natural gas fuel requirement, as explained in section IV.B.3 of this preamble. We are finalizing these requirements as a result of the public comments we received on the proposed rule.

A. What are the final rule amendments based on the risk review for the Refractory Products Manufacturing source category?

This section describes the final amendments to the Refractory Products Manufacturing NESHAP (subpart SSSSS) being promulgated pursuant to CAA section 112(f). In this action, we are finalizing our proposed determination that risks from the Refractory Products Manufacturing source category are acceptable, the standards provide an ample margin of safety to protect public health, and additional standards are not necessary to prevent an adverse environmental effect. The EPA proposed no changes to the subpart based on the risk review conducted pursuant to CAA section 112(f). The EPA received no new data or other information during the comment period that would cause us to change our proposed risk determination. Therefore, we are not requiring additional controls or new requirements under CAA section 112(f)(2) for subpart SSSSS in this action.

B. What are the final rule amendments based on the technology review for the Refractory Products Manufacturing source category?

We determined that there was a development in practice that warranted revision of the MACT standards for this source category. Therefore, to satisfy the requirements of CAA section 112(d)(6), we proposed revisions to the MACT standards to improve the existing work practice standard for affected continuous kilns using emission control devices. The proposed revisions were based on the best practices of one facility and included:

- Limitation of the work practice standard to THC emission control devices only,
- an annual limit on the number of hours for bypass of the control device,
- the requirement to process product containing lower percentages of organic HAP content in the resins, binders and additives (less than the average organic HAP mass fraction),
- an allowance for the processing of five kiln cars per year with greater than average organic HAP mass fraction, and
- reporting of the mass of organic HAP emissions for bypass periods in the semi-annual compliance report.

The EPA received additional data during the comment period that caused us to change these proposed work practice requirements. Therefore, in this action, we are finalizing the following requirements under CAA section 112(d)(6) for subpart SSSSS:

- The proposed limitation of the work practice standard to THC emission control devices only,
- the proposed annual limit on the number of hours for bypass of the control device,
- revised requirement to maintain the organic HAP processing rate below whichever is lower, either (a) the average organic HAP processing rate (*i.e.,* the average organic HAP processing rate (pounds per hour (lb/hr)) based on actual production on a 6-month rolling basis, not to include periods of kiln shut down) or (b) the lowest hourly organic HAP processing rate determined during the most recent performance test,
- removal of the proposed allowance for processing of five kiln cars per year with greater than average organic HAP mass fraction during control device maintenance and bypass,
- revised reporting requirements for the semi-annual compliance report, including:
  - The average organic HAP processing rate based on actual production on a 6-month rolling basis (not to include periods of kiln shut down) or the lowest hourly organic HAP processing rate from the most recent performance test (whichever is lower), for bypass periods,
  - the actual organic HAP processing rate,
  - the amount of product produced and the mass of organic HAP in the product produced,
  - the estimated THC emissions,
  - the number of hours the control device was bypassed during the compliance period, and
  - the cumulative number of hours the control device was bypassed over the last 12-month rolling period.

We are not finalizing the proposed allowance for processing of five kiln cars per year with greater than average organic HAP mass fraction during control device maintenance and bypass. For more information regarding the final improvements to the work practice standard that applies for continuous kilns with THC emissions control devices, see section IV.B of this preamble.

In addition, the EPA received a comment during the comment period that caused us to review the fuel combustion technology used by sources in the source category and consequently revise the existing work practice standard to require the use of natural gas (or equivalent fuel) at all times. After consideration of the comment, under CAA section 112(d)(6), we are removing the allowance to use alternative fuels during periods of natural gas supply curtailment or interruption from the natural gas fuel requirement as explained in section IV.B.3 of this preamble. This finalized amendment applies to existing clay refractory products kilns and new or existing chromium refractory products kilns and reflects a development in our understanding of refractory kiln fuel combustion technology since promulgation of the original standard.

Finally, as part of the technology review, we identified regulatory gaps (previously unregulated processes or pollutants) and are establishing new standards to fill those gaps as described in section III.C of this preamble.

C. What are the final rule amendments pursuant to CAA sections 112(d)(2) and (3) for the Refractory Products Manufacturing source category?

We determined that there are previously unregulated HAP for existing sources in the clay and nonclay refractory subcategories that warrant revisions to the MACT standards for this source category. Therefore, pursuant to the requirements of CAA section 112(d)(2) and (3) we proposed revisions to the MACT standards to include the following:

- New emission limits for particulate matter (PM) as a surrogate for non-mercury (non-Hg) metal HAP and mercury (Hg) for existing clay refractory product kilns, and
- the requirement to use natural gas as fuel, or an equivalent fuel, as the kiln fuel for new and existing curing ovens, shape dryers, and kilns that are used to process refractory products that use organic HAP (*i.e.,* nonclay refractory product sources), except during periods of natural gas supply interruption or curtailment.

As noted in section III.B of this preamble, the EPA received a comment during the comment period that caused us to review the fuel combustion technology used for all refractory

products sources in the source category. Based on that review, we are not finalizing the proposed allowance to use alternative fuels during periods of natural gas supply interruption or curtailment from the natural gas fuel requirement for new and existing nonclay sources. Therefore, we are finalizing the new emission limits for PM (as a surrogate for non-Hg metal HAP) and Hg for existing clay refractory product kilns, as proposed, and we are finalizing a revised requirement to use natural gas, or an equivalent fuel, as the fuel for new and existing nonclay sources, as a result of comments, under CAA section 112(d)(2) and (3) for subpart SSSSS in this action.

D. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?

We are finalizing the proposed amendments to the Refractory Products Manufacturing NESHAP to eliminate the SSM exemption. Consistent with *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008), the EPA is establishing standards in these rules that apply at all times. As detailed in section IV.E of the proposal preamble (86 FR 3099, January 14, 2021), Table 11 to subpart SSSSS of part 63 (General Provisions applicability table) is being revised to change several references related to the provisions that apply during periods of SSM. We also eliminated or revised certain recordkeeping and reporting requirements related to the eliminated SSM exemption. The EPA also made other harmonizing changes to remove or modify inappropriate, unnecessary, or redundant language in the absence of the SSM exemption. We determined that facilities in this source category can meet the applicable emission standards at all times, including periods of startup and shutdown. Therefore, the EPA determined that no additional standards are needed to address emissions during these periods. The legal rationale and explanation of the changes for SSM periods are set forth in the proposed rule. See 86 FR 3079, 3099–3102. Further, the EPA did not propose and is not promulgating standards for malfunctions in this final action. As discussed in section IV.E of the January 14, 2021, proposal preamble, the EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards, although the EPA has the discretion to set standards for malfunctions where feasible. For the Refractory Products Manufacturing source category, it is unlikely that a malfunction would result in a violation of the standards, and no comments or information were submitted during the comment period that support a contrary conclusion. Refer to section IV.E of the January 14, 2021 proposal preamble for further discussion of the EPA's rationale for the decision not to set standards for malfunction events, as well as a discussion of the actions a source could take in the unlikely event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, given that administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply.

E. What other changes have been made to the NESHAP?

In addition to the changes described above we are finalizing other proposed amendments for the Refractory Products Manufacturing NESHAP related to electronic reporting, test methods and minor technical and editorial revisions, as described below.

To increase the ease and efficiency of data submittal and data accessibility, we are finalizing the proposed requirement that owners and operators of facilities in the Refractory Products Manufacturing source category submit electronic copies of required NOCS reports, performance test results, and performance evaluation results through the EPA's Central Data Exchange (CDX) website using an electronic performance test report tool called the Electronic Reporting Tool (ERT). We also are finalizing, as proposed, provisions that allow facility operators the ability to seek extensions for submitting electronic reports for circumstances beyond the control of the facility, *i.e.,* for a possible outage in the CDX or Compliance and Emissions Data Reporting Interface (CEDRI) or for a *force majeure* event in the time just prior to a report's due date, as well as the process to assert such a claim.

We are also finalizing the proposed additional and updated test methods and an EPA guidance document that are incorporated by reference. In accordance with requirements of 1 CFR 51.5, the EPA is incorporating by reference the following documents described in the amendments to 40 CFR 63.14:

- ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981, IBR approved for Table 4 to subpart SSSSS.
- ASTM D6348–12e1, Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, Approved February 1, 2012, IBR approved for Table 4 to subpart SSSSS.
- ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method),'' (Approved March 1, 2016), IBR approved for Table 4 to subpart SSSSS.
- EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, IBR approved for 40 CFR 63.9804(f)(1). This document provides guidance on the use of triboelectric monitors as fabric filter bag leak detectors.

In addition, we are finalizing the following proposed technical and editorial corrections:

- Revise 40 CFR 63.9824 and Table 4 to subpart SSSSS of part 63 to clarify the location in 40 CFR part 60 of applicable EPA test methods; and
- Revise 40 CFR 63.9814 and 63.9816 to include the requirements to record and report information on failures to meet the applicable standard.

Finally, although not addressed in the proposal, we are amending 40 CFR 63.9804(e)(1) to correct a spelling error.

F. What are the effective and compliance dates of the standards?

The revisions to the MACT standards for the Refractory Products Manufacturing source category being promulgated in this action are effective on November 19, 2021. New sources must comply with all of the standards immediately upon the effective date of the standard, November 19, 2021, or upon startup, whichever is later.

The compliance dates for existing affected sources are listed below. Existing affected sources must continue to meet the current requirements of 40 CFR part 63, subpart SSSSS, until the applicable compliance date.

The compliance date for existing affected nonclay sources to comply with the work practice to use natural gas as fuel, or an equivalent fuel, as the kiln fuel at all times, including periods of natural gas supply interruption or curtailment is November 19, 2021. The compliance date for existing affected sources to comply with the electronic reporting requirement for NOCS reports, performance test results, and performance evaluation results is May 19, 2022. The compliance date for existing affected sources with continuous kilns using THC emission control devices to comply with the amended work practice standards (*i.e.,* limit the total number of hours for

bypass of the control device for during scheduled maintenance to 750 hours per year per kiln; maintain the organic HAP processing rate below the average rate based on production or below the lowest hourly rate during the most recent performance test, whichever is lower; update the operation, maintenance, and monitoring (OM&M) plan; include the required information in the semi-annual compliance report) is May 19, 2022. The compliance date for existing affected clay refractory product kilns to comply with the new limits for PM (as a surrogate for non-Hg metal HAP) and Hg is November 20, 2022. The compliance date for existing affected sources to comply with the SSM revisions, in accordance with the SSM court decision, is May 19, 2022.

We determined that an immediate compliance date is practicable for the natural gas requirement and is based on current practices and other information provided by the facilities. We are finalizing the 181-day compliance date for electronic reporting and the scheduled maintenance work practice to require facilities to implement these changes as expeditiously as practicable. For electronic reporting, our experience with similar industries that are required to convert reporting mechanisms to install necessary hardware and software, become familiar with the process of submitting performance test results electronically through the EPA's CEDRI, test these new electronic submission capabilities, and reliably employ electronic reporting shows that a time period of a minimum of 90 days, and, more typically, 180 days, is generally necessary to successfully accomplish these revisions. For the improved scheduled maintenance work practice, we expect facilities would also need this time to seek approval from the Administrator before taking the control device on the affected kiln out of service for scheduled maintenance and update their operation, maintenance, and monitoring plan to reflect the revised requirements. For the new PM (as a surrogate for non-Hg metal HAP) and Hg requirements, we determined the one-year compliance date would provide existing clay sources with sufficient time to plan and schedule facility resources to meet the notification and compliance demonstration testing requirements associated with the new limits. For the SSM changes, excluding the revised requirements for the SSM described above (40 CFR 63.6(f)(1)), our experience with similar industries further shows that this sort of regulated facility generally requires a time period of 181 days to read and understand the amended rule requirements and make any necessary operational adjustments, adjustments to recordkeeping and reporting systems, and/or updates to OM&M plans to reflect the revised requirements.

During proposal we requested information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended requirements and the time needed to make the adjustments for compliance with any of the revised requirements. No comments or information were submitted during the comment period that support a contrary conclusion; therefore, we are finalizing these compliance dates as proposed.

IV. What is the rationale for our final decisions and amendments for the Refractory Products Manufacturing source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document, *Summary of Public Comments and Responses on Proposed Rule: National Emission Standards for HAP for Refractory Products Manufacturing (40 CFR part 63, subpart SSSSS), Residual Risk and Technology Review, Final Amendments,* available in the docket.

A. Residual Risk Review for the Refractory Products Manufacturing Source Category

1. What did we propose pursuant to CAA section 112(f) for the Refractory Products Manufacturing source category?

Pursuant to CAA section 112(f), the EPA conducted a residual risk review and presented the results of this review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in section IV.B of the proposed rule preamble (86 FR 3095, January 14, 2021). The results of this review are presented briefly below in Table 1 of this preamble. Additional detail is provided in the residual risk technical support document titled, *Residual Risk Assessment for the Refractory Products Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed Rule,* which is available in the Refractory Products Manufacturing docket (Docket Item No. EPA–HQ–OAR–2020–0148–0013).

TABLE 1—REFRACTORY PRODUCTS MANUFACTURING SOURCE CATEGORY INHALATION RISK ASSESSMENT RESULTS

Risk assessment	Maximum individual cancer risk (in 1 million)		Estimated population at increased risk of cancer ≥1-in-1 million		Estimated annual cancer incidence (cases per year)		Maximum chronic noncancer target organ specific hazard index (TOSHI) [1]		Maximum screening acute noncancer HQ [2]
	Based on actual emissions	Based on allowable emissions	Based on actual emissions	Based on allowable emissions	Based on actual emissions	Based on allowable emissions	Based on actual emissions	Based on allowable emissions	Based on actual emissions
Source Category	0.7	0.7	0	0	0.0003	0.0003	0.04	0.04	HQREL = 0.09
Whole Facility	0.7	.....	0	.....	0.0004	.....	0.04	.....	

[1] The TOSHI is the sum of the chronic noncancer hazard quotients (HQ) for substances that affect the same target organ or organ system.
[2] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop HQ values.

The results of the proposed inhalation risk modeling, as shown in Table 1 of this preamble, indicate that the maximum individual cancer risk based on actual and allowable emissions (lifetime) is 0.7-in-1 million (driven by trace amounts of chromium, arsenic, nickel and cadmium emissions from tunnel kilns), the maximum chronic noncancer TOSHI value based on actual and allowable emissions is 0.04 (driven by HF from tunnel kilns), and the maximum screening acute noncancer HQ value (off-facility site) is 0.09 (driven by HF). At proposal, the total annual cancer incidence (national) from these facilities based on actual and allowable emission levels was estimated

to be 0.0003 excess cancer cases per year or one case every 3,333 years. The maximum individual cancer risk (lifetime) for the whole facility was determined to be 0.7-in-1 million at proposal, driven by chromium, arsenic, nickel and cadmium emissions from tunnel kilns. The total estimated cancer incidence from the whole facility was determined to be 0.0004 excess cancer cases per year, or one excess case in every 2,500 years. No people were estimated to have cancer risks above 1-in-1 million from exposure to HAP emitted from both MACT and non-MACT sources at the three facilities in this source category. The maximum facility-wide TOSHI for the source category was estimated to be 0.04, driven by HF emissions from tunnel kilns.

We also evaluated multipathway human health risk from the five PB–HAP that are emitted by sources within this source category (arsenic, cadmium, POM, Hg (divalent Hg and methyl mercury), and lead). We evaluated the cadmium emissions from these facilities and concluded this HAP did not exceed the Tier 1 multipathway screening value of 1 for cancer or noncancer. We also evaluated the arsenic, methyl mercury, and POM emissions and found these HAP caused an exceedance of the Tier 1 multipathway screening value of 1 for cancer. Therefore, we conducted a Tier 2 screening assessment for these HAP and concluded that emissions of arsenic, POM and methyl mercury from these facilities did not exceed the Tier 2 multipathway screening value of 1 for cancer. A Tier 2 noncancer screening assessment was also conducted for Hg emissions and resulted in a screening value less than 1. Based upon the results of the screening assessments no further screening or site-specific assessments were conducted for this source category.

In evaluating the potential for multipathway effects from emissions of lead, modeled maximum annual-average lead concentrations were compared to the National Ambient Air Quality Standards (NAAQS) for lead (0.15 μg/m^3). Results of this analysis confirmed that the NAAQS for lead would not be exceeded by any facility.

To evaluate the potential for adverse environmental effects, the EPA focuses on eight HAP, which are referred to as ''environmental HAP,'' in its screening assessment: Six PB–HAP and two acid gases. The PB–HAP emitted by sources in the category are arsenic compounds, cadmium compounds, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment and emitted from the category are HCl and HF. In the Tier 1 screening analysis for PB–HAP (other than lead, which was evaluated differently), arsenic, cadmium, divalent mercury, and POM had no Tier 1 exceedances for any ecological benchmark. Methyl mercury emissions at one facility had a Tier 1 exceedance for the surface soil no-observed-adverse-effect-level (avian ground insectivores) by a maximum SV of 2. A Tier 2 screening assessment was performed for methyl mercury. Methyl mercury had no Tier 2 exceedances for any ecological benchmark. For lead, we did not estimate any exceedances of the secondary lead NAAQS.

Two acid gases are emitted by sources within this source category: HCl HF. We conducted a screening-level evaluation of the potential adverse environmental effects associated with emissions of HCl and HF and found that the average modeled concentration around each facility (*i.e.,* the average concentration of all off-site data points in the modeling domain) did not exceed any ecological benchmark. In addition, each individual modeled concentration of HCl (*i.e.,* each off-site data point in the modeling domain) was below the ecological benchmarks for all facilities. For HF, the maximum facility screening value (based on the average concentration of all off-site data points over the modeling domain) was well below 1 (0.007) and the maximum area that exceeded the ecological benchmark was only 0.002-percent of the modeled area. Based on the results of the environmental risk screening evaluation, we do not expect an adverse environmental effect as a result of HAP emissions from this source category.

We weighed all health risk factors, including those shown in Table 1 of this preamble, in our risk acceptability determination and proposed that the residual risks from the Refractory Products Manufacturing source category are acceptable (section IV.C of the proposed rule preamble, 86 FR 3095, January 14, 2021). We then considered whether 40 CFR part 63, subpart SSSSS provides an ample margin of safety to protect public health and prevents, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. At proposal we determined there are no individuals in the exposed population with lifetime cancer risks above 1-in-1 million as a result of actual or allowable emissions from this category. In addition, in our risk analysis we did not identify a potential for adverse chronic noncancer, acute noncancer, or multipathway health effects. Therefore, we proposed the current standards provide an ample margin of safety to protect public health (section IV.C of the proposed rule preamble, 86 FR 3095, January 14, 2021).

2. How did the risk review change for the Refractory Products Manufacturing source category?

We have not changed any aspect of the risk assessment for this source category as a result of public comments received on the January 2021 proposal.

3. What key comments did we receive on the risk review, and what are our responses?

We received comments in support of and against the proposed residual risk review. Having carefully considered these comments, it is our determination that no revisions are warranted under CAA section 112(f)(2) for the Refractory Products Manufacturing source category. Generally, the comments that were not supportive of the risk review determination suggested changes to the underlying risk assessment methodology. For example, one commenter stated that the EPA should account for the increased risks due to exposure to multiple sources of HAP, use more health-protective dose-response values, and consider increased risks in childhood and from prenatal exposure. After review of all the comments received, we determined that no changes to our Science Advisory Board-approved review process were necessary. The comments and our specific responses can be found in the document, *Summary of Public Comments and Responses on Proposed Rule: National Emission Standards for HAP for Refractory Products Manufacturing (40 CFR part 63, subpart SSSSS), Residual Risk and Technology Review, Final Amendments,* available in the docket for this action (Docket ID No. EPA–HQ–OAR–2020–0148).

4. What is the rationale for our final approach and final decisions for the risk review?

As noted in our proposal, the EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on the maximum individual risk (MIR) of ''approximately 1-in-10 thousand'' (see 54 FR 38045, September 14, 1989). We weigh all health risk factors in our risk acceptability determination, including the cancer MIR, cancer incidence, the maximum cancer TOSHI, the maximum acute noncancer HQ, the extent of

noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and the risk estimation uncertainties.

Since proposal, neither the risk assessment nor our determinations regarding risk acceptability, ample margin of safety, or adverse environmental effects have changed. For the reasons explained in the proposed rule, we have determined that the risks from the Refractory Products Manufacturing source category are acceptable, and that the current standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect. Therefore, we are not revising the subpart to require additional controls pursuant to CAA section 112(f)(2) based on the residual risk review, and we are readopting the existing standards under CAA section 112(f)(2).

B. Technology Review for the Refractory Products Manufacturing Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Refractory Products Manufacturing source category?

Based on our technology review, we proposed improvements to the existing underlying work practices as required by CAA section 112(d)(6) during scheduled maintenance of THC control devices. These revisions are necessary to reflect technical developments in pollution control practices since the promulgation of the original standard for this source category and reflect the best practices of one affected facility. Specifically, for affected continuous kilns using THC emission control devices, we proposed to limit the number of hours for bypass of the control device to conduct scheduled maintenance, schedule the manufacture of product with binder applicability of the standard to THC emission control devices, limit the number of hours for percentages at the lower end of the range produced during periods of control device bypass. We also proposed to include the THC emissions for these periods in the semi-annual compliance report. A brief summary of the EPA's findings in conducting the technology review of refractory products manufacturing operations was included in the preamble to the proposed rule (86 FR 3095, January 14, 2021), and a detailed discussion of the EPA's technology review and findings was included in the memorandum, *Technology Review for the Refractory Products Manufacturing NESHAP,* available in the docket for this action (Docket Item No. EPA–HQ–OAR–2020–0148–0008).

2. How did the technology review change for the Refractory Products Manufacturing source category?

For the final rule, we revised aspects of two work practice standards from the proposal, based on public comments. First, we are finalizing slightly different improvements than proposed for the work practice standard that applies when a continuous kiln THC control device is bypassed for scheduled maintenance. In particular, to demonstrate compliance with the requirement in 40 CFR 63.9792(e)(2) to minimize HAP emissions during the period when the kiln is operating and the control device is out of service, the owner or operator will be required to maintain the organic HAP processing rate (lb/hr) below either the average organic HAP processing rate based on the actual production on a 6-month rolling basis (not to include periods of kiln shut down) or the HAP processing rate (lb/hr) that coincides with the lowest hour of the most recent 3-hour performance test, whichever is lower. This requirement replaces the proposed limitation of five kiln cars with products for which the mass fraction of organic HAP in the resins, binders, and additives is greater than the average for the year. Second, we are revising the work practice standard to use natural gas, or equivalent, as the kiln fuel by removing the exception for periods of natural gas curtailment or supply interruption.

3. What key comments did we receive on the technology review, and what are our responses?

We received both supportive and adverse comments on various aspects of our technology review for refractory products manufacturing. The key comments and responses are provided in this section; summaries of comments not discussed in this preamble and the EPA's responses can be found in the comment summary and response document, available in the docket.

Comment: One commenter provided technical comments on the specific provisions that the EPA proposed to limit production during periods when the THC control device is being bypassed for maintenance. The proposed provisions would have required manufacturing mostly product in the tunnel kiln that contains a mass fraction of organic HAP in the resins, binders, and additives that is less than the average organic HAP mass fraction of these constituents for the year (on a 12-month rolling basis), and manufacture of the product with an organic HAP mass fraction greater than the average for the year would be limited to only five kiln cars during such maintenance periods.

The commenter explained that tunnel kilns comprise a preheating zone, firing zone, and cooling zone in sequence with kiln cars passing through the system containing pressed/formed refractory. Each kiln is designed to hold a set number of kiln cars in the preheating zone position and a separate set number of kiln cars in the firing zone position. The type and amount of resins, binders, and additives in the kiln are dictated by each product type's formulation. During drying in the tunnel kilns, organic HAP in resins, binders, and additives is volatilized and either destroyed in the tunnel kiln or exhausted to a THC control device for destruction.

The commenter noted that according to the memorandum *Technology Review for the Refractory Products Manufacturing NESHAP,* available in the docket for this action (Docket Item No. EPA–HQ–OAR–2020–0148–0008), these proposed provisions are based on the facility's specific internal operation procedures for the regenerative thermal oxidizer (RTO) unit that state that tunnel kiln batches exceeding 90 binder counts can only be pushed in a train of ''five cars or less.'' The commenter asserted that the EPA has catered the five-kiln car provision too specifically to the facility's one tunnel kiln due to extremely limited data, as the facility is the only U.S. nonclay refractory producer using organic binder and a THC control device. The commenter further stated that these procedures only address one of the two continuous kilns at the facility. The commenter also stated that since kiln cars can hold a variety of refractory products of varying dimensions and formulation, the mass of organic HAP emissions from the resins, binders, and additives from car to car is variable. The commenter noted that a new nonclay refractory tunnel kiln could potentially be constructed with larger kiln cars, such that each kiln car could be designed to hold a greater mass of nonclay refractory and emit much more organic HAP while still satisfying the proposed provisions during periods of control device maintenance.

The commenter suggested that instead the proposed requirements that apply during THC control device bypass for continuous kilns should be amended to reflect a more universal operating parameter limit (OPL). The OPL is established during performance testing in accordance with 40 CFR 63.9800 and Table 4 to subpart SSSSS. Each

continuous unit is required to establish a 3-hour block operating limit for maximum allowable organic HAP processing rate, which is calculated as the average organic HAP processing rate from performance testing plus 10 percent in accordance with 40 CFR 63.9798(c) and EPA guidance. The commenter suggested that the organic HAP processing rate during THC control device bypass be limited to the average organic HAP processing rate from the most recent performance test demonstration, as determined on an hourly basis (*i.e.,* 1-hour block average). The commenter also provided suggested revisions to the regulatory language to implement this suggestion.

Response: The EPA proposed an improved work practice standard to further minimize emissions during periods of scheduled maintenance and bypass of the thermal oxidizer as a result of the CAA section 112(d)(6) technology review process. In addition to the current work practice to minimize emissions during these periods, we proposed other measures based on the best practices of one facility. These included: (1) Limiting the applicability to THC control devices; (2) an annual limit on the number of hours for bypass of the control device; (3) the requirement to process product containing lower percentages of organic HAP content in the resins, binders and additives (less than the average organic HAP mass fraction); (4) an allowance for the processing of five kiln cars per year with greater than average organic HAP mass fraction; and (5) reporting of the mass of organic HAP emissions for bypass periods in the semi-annual compliance report.

As a result of the comments regarding these proposed measures, we learned we did not have full knowledge of the details of the facility's internal operating procedures during scheduled maintenance and bypass of the thermal oxidizer. As the commenter clarified, tunnel kiln batches exceeding 90 binder counts (a measure of the volume of binder) can only be pushed in a train of ''five cars or less'' during these periods. The commenter also clarified this procedure applies to only one of the two continuous tunnel kilns. We agree with the commenter that using the ''kiln car'' limitation is an imprecise way of limiting organic HAP emissions due to the potential variation in kiln car size. However, the EPA found the facility's suggestion to set an operating limit during bypass periods equal to the ''average organic HAP processing rate from the most recent performance test, as determined on an hourly basis (1-hour block average)'' and rule language edits to be inconsistent with other rule requirements. Specifically, because performance tests are required to be conducted while the source is operating at the maximum organic HAP processing rate as defined in § 63.9824, we found this suggestion to be inconsistent with the rule requirement to minimize emissions during control device bypass and maintenance required by § 63.9792(e)(2).

We are therefore finalizing revisions to the proposed revised work practice standard that reflect additional improvements as a result of these comments and follow-up discussions with the facility to clarify their best practices. Specifically, we are revising the proposed work practice to limit the organic HAP processing rate rather than the organic HAP content during control device bypass and maintenance as proposed. The proposed rule language that required the facility to minimize HAP emissions during the period when the kiln is operating and the control device is out of service by ''scheduling of the manufacture of product for which the mass fraction of organic HAP in the resins, binders, and additives is at the lower end of the range produced (*i.e.,* below the typical average mass fraction of organic HAP in the resins, binders, and additives)'' is revised to ''maintaining the organic HAP processing rate (lb/hr) below the average organic HAP processing rate based on actual production on a 6-month rolling basis (not to include periods of kiln shut down) or below the organic HAP processing rate (lb/hr) that coincides with the lowest hour of the most recent 3-hour performance test, whichever is lower.'' We are then requiring sources to demonstrate compliance with the requirement to minimize emissions by maintaining the organic HAP processing rate (lb/hr) during control device maintenance and bypass below lower of the two organic HAP processing rates described above. We are also revising the proposed reporting requirements to reflect these changes. In addition, we are removing the allowance for the processing of five kiln cars per year with greater than average organic HAP mass fraction from the work practice. Changing the work practice requirement from the mass fraction of organic HAP in the product to the HAP processing rate while also removing the reference to kiln cars provides a clearer and more consistent metric for demonstrating that HAP emissions have been minimized and provides the facility with options for minimizing emissions during the period when the kiln is operating and the control device is out of service (*e.g.,* loading kiln cars with products with lower HAP contents, reducing the number of kiln cars pushed through the kiln per hour).

In summary, the finalized work practice standard for periods of control device maintenance and bypass includes: (1) The proposed limit of the applicability to THC control devices; (2) the proposed annual limit on the number of hours for bypass of the control device; (3) the revised requirement to maintain the organic HAP processing rate below the average organic HAP processing rate, determined as the lower of either (a) the average organic HAP processing rate (lb/hr) based on actual production on a 6-month rolling basis, not to include periods of kiln shut down) or (b) the organic HAP processing rate determined during the lowest hour of the most recent performance test; and (4) semiannual compliance reporting of the following information: The average organic HAP processing rate based on actual production on a 6-month rolling basis (not to include periods of kiln shut down) or the lowest hour from the most recent performance test (whichever is lower), the actual organic HAP processing rate, the amount of product produced and the mass of organic HAP in the product produced, the estimated THC emissions, the number of hours the control device was bypassed during the compliance period (as proposed), and the cumulative number of hours the control device was bypassed over the last 12-month period (as proposed). The final improvement of the work practice standard as a result of the CAA section 112(d)(6) technology review process does not include the proposed allowance for processing of five kiln cars per year with greater than average organic HAP mass fraction during control device maintenance and bypass.

Meeting minutes from the discussion with the facility and follow-up emails are included in the rulemaking docket (Docket ID No. EPA–HQ–OAR–2020–0148).

Comment: One commenter noted that the EPA proposed to limit the number of hours during which a continuous kiln is operating and the THC control device is bypassed for maintenance to 750 hours per year on a 12-month rolling basis. The commenter noted that the EPA identified this provision as an improvement to the current standard since there is no limit on the total amount of time the provision may be used other than the requirement for the owner or operator to minimize the amount of time for each bypass.

The commenter also noted that per proposed requirements in 40 CFR

63.9792(e) and 63.9812(g), kiln operation during bypass of the THC control device requires advanced approval from the Administrator (86 FR 3079, 3099, January 14, 2021). The commenter noted that the EPA also proposed that affected sources must document the planned maintenance procedures in the OM&M plan, and the proposed requirement in 40 CFR 63.9814(c)(7) would require reporting in the semi-annual compliance report for these periods, including a statement of whether or not the control device maintenance was included in the approved request to bypass the control device while scheduled maintenance is performed. The EPA has proposed to allow 181 days for compliance with the proposed revisions, noting that this time would be used to update the OM&M plans and seek approval from the Administrator before taking the control device on the affected kiln out of service for scheduled maintenance.

The commenter stated that the proposed requirement for Administrator approval is based on its current state-issued title V permit. The commenter noted that the state has delegated authority and is the ''Administrator'' in regard to implementing and enforcing the NESHAP requirements at 40 CFR part 63. The commenter clarified that the current title V permit requires advance notification via email to the state air quality inspector and to the Regional Air Quality staff that the RTO will be out of service for scheduled maintenance, but the permit does not include approval requirements. In addition, the commenter stated that the EPA did not differentiate between THC control device planned and unplanned maintenance and did not specify the scope of maintenance (*e.g.,* washdowns, bakeouts, media placement) to be documented in the OM&M plan. Because the proposed provisions require approval from the Administrator in advance, the commenter noted that it appears kiln operation during unplanned maintenance events is not addressed.

The commenter requested that the EPA amend 40 CFR 63.9792(e), 63.9812(g), 63.9814(c)(7), Table 3, and Table 9 to specify that kiln operation during periods of control device maintenance requires ''Administrator notification'' and not ''Administrator approval.'' The commenter suggested that the notification could include a telephone call or email to the Administrator within 24 hours of a bypass event. The commenter asserted that this provision would allow for unplanned/emergency maintenance, which is common for continuous process units, particularly where facilities operate 24 hours a day, 365 days a year. Additionally, requiring notification rather than approval for each bypass allows facilities to avoid complete shutdown of a process unit if the Administrator cannot be reached for approval (*e.g.,* control device requires unplanned maintenance at 3 a.m. on Saturday and Administrator cannot be reached until 9 a.m. Monday). The commenter noted that the EPA's proposed recordkeeping and reporting requirements related to the 750-hour (12-month rolling basis) limit on use of the bypass provisions would still adequately qualify these bypasses with Administrator notification versus approval. The commenter also asserted that requiring notification instead of approval does not restore ''malfunction'' provisions, as the term is defined under 40 CFR 63.2, as the bypass period is limited to 750 hours per year (12-month rolling basis). Also, per *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016), the Administrator may determine whether the facility took good faith efforts to minimize resulting emissions including preventative and corrective actions and whether excess emissions were caused by poor maintenance or careless operation.

Response: The EPA disagrees with the commenter's characterization of the proposed requirements in 40 CFR 63.9792(e) and 63.9812(g), regarding kiln operation during bypass of the THC control device and advanced approval from the Administrator (86 FR 3099, January 14, 2021). The EPA agrees these citations pertain to kiln operation during bypass of the THC control device and advanced approval from the Administrator, but these provisions are original rule requirements that were not proposed to be amended. The original general requirements for complying with subpart SSSSS are contained in 40 CFR 63.9792, and 40 CFR 63.9792(e) specifically permits the continued operation of a continuous kiln during bypass and scheduled maintenance of the control device for that kiln, provided the owner or operator meets the requirements of the work practice standard and requests and receives approval by the Administrator per 40 CFR 63.9792(e)(1), which requires a separate request each time the owner or operator plans to bypass the control device for scheduled maintenance. Similarly, the original requirements for notifications for subpart SSSSS are contained in 40 CFR 63.9812, and 40 CFR 63.9812(g) specifically states that owner and operators must request approval from the Administrator before bypassing the control device, as specified in 40 CFR 63.9792(e), and that a separate request must be submitted for approval each time.

We also disagree with the statement that the EPA proposed a new requirement that affected sources must document the planned maintenance procedures in the OM&M plan, as this requirement was also required in the original rule at 40 CFR 63.9794(a)(6). The provisions in 40 CFR 63.9794(a)(6) pertain to any maintenance that requires use of the bypass provisions. The provision includes ''procedures for the proper operation and routine and long-term maintenance of each process unit and [air pollution control device],'' which encompasses the more specific types of maintenance described by the commenter (*e.g.,* washdowns, bakeouts, media placement). Further, subpart SSSSS does not include the terms ''planned maintenance'' or ''unplanned maintenance,'' nor does it define ''scheduled maintenance.'' However, as noted earlier in this response, a request for Administrator approval must be submitted each time the owner or operator plans to bypass the control device for ''scheduled maintenance,'' and per Table 2 to subpart SSSSS, the owner or operator must receive approval from the Administrator before taking the control device on the affected kiln out of service for scheduled maintenance.

After review of the commenter's request, we are not amending the requirements to request Administrator approval, and we also disagree with the comment that there is a need to differentiate between THC control device ''planned and unplanned maintenance'' within subpart SSSSS. The EPA did not propose to amend the requirement to request Administrator approval each time an owner or operator plans to bypass the control device, and we conclude that allowing notification rather than approval would not be an improvement to the standard. In particular, if owners and operators were allowed to comply with the work practice standard during periods of maintenance that are only ''scheduled'' a few hours in advance of the control device bypass, those owners and operators would likely find it very challenging to comply with all the specific requirements that must be met during bypass to demonstrate compliance with the requirement in 40 CFR 63.9792(e)(2) to minimize HAP emissions during the bypass. Therefore, the work practice standard we are finalizing for periods of control device bypass and scheduled maintenance applies to all THC control device bypasses for scheduled maintenance for

which the owner or operator receives approval from the Administrator. Most of the maintenance activities described by the commenter are likely to be considered ''scheduled maintenance'' for which the owner or operator will be able to request advanced approval from the Administrator before the control device is bypassed. These maintenance activities are the activities that should be documented in the OM&M plan. Bypass of the control device without Administrator approval would be considered a deviation from the standard.

Finally, the EPA agrees with the commenter that the state has delegated authority and is the ''Administrator'' with regard to implementing and enforcing the 40 CFR subpart SSSSS requirements. However, the state does not have the authority to set standards less stringent than those promulgated by the Administrator in accordance with CAA section 112(l). Therefore, in order for the current title V permit to satisfy the 40 CFR 63.9792(e) and 63.9812(g) requirements, it must require advance approval by the Administrator and not the less stringent notification requirements.

Comment: One commenter stated that the EPA must remove the alternative fuel allowance provision. The commenter noted that the existing standards contain a provision allowing for ''the use of alternative fuels'' (such as fuel oil, propane, and pulverized coal) during certain circumstances as an exception to the work practice standard that requires use of natural gas as the core emission control requirement. The commenter noted that the EPA has recognized this provision allows for an exception from the standards in ''situations analogous to malfunctions'' and explained in 2003 that its justification for this provision was similar to the SSM exemption. At the time, the EPA stated that, ''Just as an exceedance of emission limits during a malfunction is not considered a violation, as indicated in 40 CFR 63.6(f)(1) and (h)(1), we believe that using other fuels during periods when natural gas is unavailable should also not be considered a violation of the work practice standard for clay and chromium refractory products kilns'' (68 FR 18740, April 16, 2003).

The commenter stated that to the extent that the EPA retains this work practice standard as the sole or an additional control, it must remove the illegal alternative fuel allowance provision. The commenter further stated that including this provision means that the emission standard (*i.e.,* the fuel requirement) is not ''continuous'' and does not apply at all times, which is a violation of CAA sections 302(k) and 112. The commenter asserted that the EPA should recognize this allowance is as unlawful as the SSM exemption that it has recognized the need to remove (*Sierra Club,* 551 F.3d at 1022), and therefore the EPA should remove this specific malfunction exemption as well. Failing to do so would violate CAA section 112(d)(6), by refusing to make a ''necessary'' revision to assure compliance with the CAA, and it would be arbitrary because it would leave in place a harmful exemption that allows the release of more pollution than CAA section 112 allows, based on the illegal justification of a ''malfunction.'' In this instance, the commenter noted, such a ''malfunction'' may simply be an increase in natural gas prices, making this allowance particularly arbitrary because it conflicts with the CAA's public health objective and the floor requirement to assure emission standards based on the ''achieved'' emission reductions, without consideration of cost.

Response: The EPA agrees with the commenter that the existing standards require the use of natural gas or equivalent fuel. It also allows ''the use of alternative fuels'' during ''periods of natural gas curtailment or supply interruption'' as defined in 40 CFR 63.9824. Propane is considered to be a fuel that is equivalent to natural gas, not an alternative fuel, as stated by the commenter.

The current rule requirements related to alternative fuel usage state that procedures for alternative fuel usage must be included in the OM&M plan per 40 CFR 63.9794(a)(10)(i), require notification of alternative fuel usage within 48 hours of the declaration of a period of natural gas curtailment or supply interruption per 40 CFR 63.9812(f), and reporting of termination of alternative fuel usage within 10 working days per 40 CFR 63.9814. The ''period of natural gas curtailment or supply interruption'' is defined in 40 CFR 63.9824 as ''the period of time during which the supply of natural gas to an affected facility is halted for reasons beyond the control of the facility. An increase in the cost or unit price of natural gas does not constitute a period of natural gas curtailment or supply interruption.''

The alternative fuel allowance was added to the rule as a result of comments from the industry on the 2002 proposed rule, in which the EPA proposed the use of natural gas or other such clean fuel to prohibit the use of coal, fuel oil, waste oil, or equivalent fuels and the resulting emissions of HF, HCl or HAP metals from existing clay refractories (67 FR 42122, June 20, 2002). The EPA provided the justification for the allowance referenced by the commenter in the memo titled *Summary of Public Comments and Responses on the Proposed NESHAP for Refractory Products Manufacturing* (Docket ID OAR–2002–0088, Item No. V–C–01, page 12). Industry stakeholders opposed the 2002 proposed work practice that required use of natural gas, stating that many kilns were designed to use fuels other than natural gas and the need to use these alternative fuels arises during natural gas shortages or price increases. They also stated that during natural gas shortages, residential users receive priority over industrial users of natural gas and that prohibiting the use of alternative fuels could adversely impact the viability of some refractory operations. After considering those comments, the EPA finalized the alternative fuel allowance (73 FR 18736, April 16, 2003). The EPA did not consider a price increase to be a justification for alternative fuel use at that time and omitted that reason from the natural gas curtailment definition. Contrary to the commenter's argument, this definition expressly states that an increase in natural gas prices does not constitute a period of natural gas curtailment or supply interruption, so the commenter's claim that such a ''malfunction'' may simply be an increase in natural gas prices is not valid.

We acknowledge much has changed since the original NESHAP was promulgated in 2003. For this final action, the facilities in the source category confirmed they use natural gas and propane during normal operations in accordance with the NESHAP and state requirements. In the event of a natural gas curtailment or supply interruption, they indicated they would not switch to another fuel due to the fuel-specific burner technology in use. They stated they would either continue to use equivalent fuel (propane backup) or shut down and retool their process units to use equivalent fuel (propane) or an alternative fuel (fuel oil) since they have no back-up supply of propane and it would likely also be curtailed due to demand. The EPA document titled *AP–42, Section 1.5 Liquified Petroleum Gas Combustion, updated July 2008,* further supports that response, explaining that burner design technology is specific to fuel type and that retooling may even be required when changing the fuel type from natural gas to propane. Retooling may include replacement of fuel injector

tips and/or vaporizers to provide burners with the proper fuel to air ratio. In addition, as noted previously in this preamble, there are no facilities currently subject to subpart SSSSS that manufacture chromium refractory products. Based on the changes in in kiln and burner design technologies since 2003, and on the determination that propane backup is available (or if retooling is required, retooling can be done for propane instead of other alternative fuels) for all existing sources subject to this standard and can be part of the design of new sources, we are removing the alternative fuel usage allowance. As a result, the use of alternative fuels will not be permitted and will be a deviation from the work practice standard, which will apply during normal operation as well as during periods of natural gas curtailment/supply interruption. The removal of the natural gas alternative fuel allowance and the requirement to use natural gas or equivalent fuels reflects a development in our understanding of refractory kiln fuel combustion technology since promulgation of the original standard.

4. What is the rationale for our final approach for the technology review?

For the reasons explained in the preamble to the proposed rule (86 FR 3095, January 14, 2021), we proposed amendments to improve the work practice standard that applies when a continuous kiln THC control device is bypassed for maintenance to reflect technical developments in pollution control practices since the promulgation of the original standard. We evaluated all of the comments received on these improvements and the EPA's proposed amendments, and for the reasons explained in the comment responses in section IV.B.3 of this preamble, we are finalizing amendments to the proposed work practice standard to further improve the work practices based on the best practices of one affected source in the source category. We are also finalizing amendments to the existing work practice standard that permits the use of alternative fuels when natural gas or equivalent fuel is not available, after review of the fuel combustion technology used by sources in the source category in response to public comments. Further explanation is included in the comment responses in section IV.B.3 of this preamble. The removal of the natural gas alternative fuel allowance and the requirement to use natural gas or equivalent fuels reflects a development in our understanding of refractory kiln fuel combustion technology since promulgation of the original standard.

C. CAA Sections 112(d)(2) and (3) Amendments for the Refractory Products Manufacturing Source Category

1. What amendments did we propose pursuant to 112(d)(2) and (3) for the Refractory Products Manufacturing source category?

In the January 14, 2021 action, we proposed amendments to the Refractory Products Manufacturing NESHAP to address previously unregulated HAP for affected sources in the clay and nonclay refractory subcategories pursuant to 112(d)(2) and (3).

a. Clay Refractory Sources

For new and existing clay refractory kilns, we proposed MACT floor limits for Hg and for PM (as a surrogate for non-Hg metal HAP), in addition to the current NESHAP requirements for clay refractory sources, based on emissions test data for existing clay refractory kilns. The emissions test data for existing clay kilns reviewed for this action confirmed trace (but measurable) amounts of non-Hg metal HAP and Hg emissions. As a result, we proposed MACT floor limits of 3.1 lb/hr for PM and 6.1 micrograms per dry standard cubic meter (µg/dscm), corrected to 18 percent oxygen, for Hg for each new kiln used to produce clay refractory products. We proposed MACT floor limits of 9.5 lb/hr for PM and 18 µg/dscm, corrected to 18 percent oxygen, for Hg for each existing kiln used to produce clay refractory products. Similar to other source categories, we proposed a limit for PM (as a surrogate for non-Hg metal HAP) because the metal HAP are contained in the PM and the control techniques that would be used to control PM will equally control non-Hg metal HAP. To demonstrate compliance with the emission limits, we proposed initial and repeat 5-year performance testing for the regulated pollutants, continuous parameter monitoring, and daily visible emissions (VE) checks. Owners and operators whose clay refractory products kilns are equipped with a fabric filter to reduce PM (as a surrogate for non-Hg metal HAP) have the option of demonstrating compliance using a bag leak detection (BLD) system instead of daily VE checks.

We also evaluated the beyond-the-floor option of requiring all existing sources to meet the proposed new source MACT standards for Hg and PM (as a surrogate for total non-Hg metal HAP). We concluded that the costs of the necessary controls were not reasonable relative to the level of emission reduction achieved for either the Hg or PM beyond-the-floor options. In addition, these controls would create additional solid waste, as there would be a need to dispose of the collected metal-contaminated dust. Therefore, we did not propose beyond-the-floor limits for Hg or PM. A brief discussion regarding the derivation of the Hg and PM limits and the beyond-the-floor option was included in the preamble to the proposed rule (86 FR 3095, January 14, 2021), and a detailed discussion is included in the technical memorandum titled *Development of Proposed Standards and Impacts for the Refractory Products Manufacturing NESHAP,* located in the docket for this action (Docket Item No. EPA–HQ–OAR–2020–0148–0014).

b. Nonclay Refractory Sources

For new and existing curing ovens, shape dryers, and kilns that are used to process refractory products that use organic HAP (*i.e.,* nonclay refractory sources), we proposed a work practice standard to use natural gas as fuel to limit metal HAP emissions (except during periods of natural gas curtailment or supply interruption) as provided in CAA section 112(h) in lieu of a numerical emissions standard, in addition to the current NESHAP THC limits for new and existing nonclay refractory sources. These sources currently employ the use of thermal oxidizers, regenerative thermal oxidizers and catalytic oxidizers to meet the THC limit, however, the NESHAP did not require sources to use natural gas as fuel for sources in this subcategory because the metal HAP emissions were determined to be below measurable quantities due to the use of purified nonclay raw materials. Available HAP data for these sources in the 2017 National Emission Inventory (NEI) were found to be outdated and not reflective of current operating conditions. The 2017 NEI included measurable PM emissions for these existing nonclay refractory sources, and the PM would be expected to have trace amounts of metal HAP; however, we have no emission stack test data to indicate measurable emissions of metal HAP for these existing nonclay refractory sources.[2] Therefore, as discussed in the preamble to the

[2] Thus, while we believe that there are metal HAP emissions, the lack of data showing measurable emissions leads the EPA to conclude that the application of measurement methodology to this class of sources is not practicable due to technological and economic limitations. *See* CAA 112(h)(2)(B).

proposed rule (86 FR 3095, January 14, 2021), we proposed a work practice standard to use natural gas as fuel for new and existing nonclay refractory sources to limit metal HAP emissions in lieu of a numerical emissions standard in accordance with CAA section 112(h).

2. How did the 112(d)(2) and (3) amendments change for the Refractory Products Manufacturing source category?

We are making one change to the proposed CAA section 112(d)(2) and (3) amendments. For each new kiln used to produce clay refractory products, we are finalizing the proposed MACT floor limits of 3.1 lb/hr for PM (as a surrogate for metal HAP) and 6.1 µg/dscm, corrected to 18 percent oxygen, for Hg. For each existing kiln used to produce clay refractory products, we are finalizing the proposed MACT floor limits of 9.5 lb/hr for PM (as a surrogate for metal HAP) and 18 µg/dscm, corrected to 18 percent oxygen, for Hg. We are also finalizing the proposed requirements for initial and repeat 5-year performance testing, continuous parameter monitoring, daily VE checks, and the option of demonstrating compliance using a BLD system instead of daily VE checks for clay refractory products kilns equipped with a fabric filter to reduce PM (as a surrogate for metal HAP). For each new and existing affected source used to produce nonclay refractory products, we are finalizing the work practice standard to use natural gas as fuel to limit metal HAP emissions as provided in CAA section 112(h) in lieu of a numerical emissions standard generally as proposed. However, based on the review of combustion technologies prompted by public comments on the existing work practice standard to use natural gas as fuel (see section IV.B.3 of this preamble), the finalized work practice for new and existing sources used to produce nonclay refractory products requires the use natural gas or an equivalent fuel at all times, without an exception during periods when natural gas is not available.

3. What key comments did we receive on the 112(d)(2) and (3) amendments and what are our responses?

We received one general comment supporting the proposed CAA section 112(d)(2) and (3) amendments for refractory products manufacturing. The comment letter also included recommendations for more stringent standards under CAA section 112(d)(2) and (3) for this source category.

Comment: One commenter supported the EPA's proposed decision to set numeric emission standards for Hg and for PM as a surrogate for non-Hg metal HAP for existing clay refractory sources. The commenter noted that setting limits for all unregulated sources of HAP emissions in this category is required by CAA section 112(d)(6) (see *LEAN* v. *EPA,* 955 F.3d 1088). However, the commenter asserted that the proposed limits are not strong enough to satisfy the CAA section 112(d)(2)–(3) requirements and that the standards must reflect the maximum achievable degree of emission limitation. First, the commenter stated that the limits were set using insufficient data and that it is not clear why the EPA did not use its authority under CAA section 114 to collect additional emission data. Second, the commenter stated that the ''upper prediction limit'' (UPL) methodology of setting standards is not consistent with the statutory requirement of the floor as the ''average emission limitation'' achieved by the best-performing sources, which violates CAA section 112(d)(3) and is arbitrary. Therefore, the commenter stated, the proposed standards do not come close to the ''maximum achievable'' degree of emission reduction.

Response: As courts have regularly upheld, the EPA has wide latitude in determining the extent of data gathering necessary to solve a problem and courts generally defer to the Agency's decision to proceed on the basis of imperfect scientific information, rather than to ''invest the resources to conduct the perfect study.'' *Sierra Club* v. *EPA,* 167 F. 3d 658, 662 (D.C. Cir. 1999)) (''If EPA were required to gather exhaustive data about a problem for which gathering such data is not yet feasible, the agency would be unable to act even if such inaction had potentially significant consequences . . . [A]n agency must make a judgment in the face of a known risk of unknown degree.'' *Mexichem Specialty Resins, Inc.,* 787 F.3d. 561 (D.C. Cir. 2015)).

Contrary to the commenter's assertion, the EPA had sufficient data available from the two clay refractory products kilns at Whitacre-Greer to calculate MACT floors, so additional data collection was not necessary. In the case of PM, multiple sets of emissions test data were available for each of the two kilns, allowing for a data set for each kiln that was robust enough that the EPA did not need to evaluate the uncertainty associated with a limited dataset for either kiln. Further, as noted in the memorandum *Emissions Data Used to Develop the Refractory Products Manufacturing Risk and Technology Review (RTR) Risk Modeling Input Files* (Docket Item No. EPA–HQ–OAR–2020–0148–0006), St. Gobain has three batch tunnel kilns and two continuous tunnel kilns capable of producing both clay and nonclay refractories, so they would be subject to the proposed standards for PM and Hg when producing clay refractories. However, 40 CFR 63.9824 defines a clay refractory product as ''a refractory product that contains at least 10 percent uncalcined clay by weight prior to firing in a kiln'' and includes six classifications of clay (ball clay, bentonite, common clay and shale, fire clay, fuller's earth, and kaolin). Based on the 2017 raw material information provided by St. Gobain when the EPA was developing the inputs file for the risk modeling, the quantities of clay fired do not meet the 10 percent threshold for the manufacture of clay refractories and are more consistent with the use of clay as a binder, so these kilns are expected to be subject to the clay refractory kiln standards infrequently. Therefore, it is not clear that using the authority under CAA section 114 for these kilns would have yielded any additional PM or Hg data for clay refractory kilns. In other words, if the EPA had requested emissions testing under CAA section 114 for these five kilns when they manufacture clay refractories, the EPA would have had to wait for the facility to change their product on each kiln, which may not have been feasible.

Regarding the UPL approach, in August 2013, the D.C. Circuit issued its decision in *National Association. of Clean Water Agencies (NACWA)* v. *EPA,* which addressed challenges to the EPA's 2011 Sewage Sludge Incinerator (SSI) rule, issued under section 129 of the CAA. In *NACWA* v. *EPA,* the court remanded the EPA's use of the UPL methodology to the Agency for further explanation of how the methodology reflected the average emissions limitation achieved by the best-performing 12 percent of sources (for existing sources) and the average emissions limitation achieved by the best-performing similar source (for new sources). *NACWA* v. *EPA,* 734 F.3d 1115, 1151. Because the UPL methodology used in the SSI rule was the same as that used in the major source Boiler MACT (40 CFR part 63, subpart DDDDD), the EPA requested a remand of the record in *U.S. Sugar* v. *EPA* in order to address the court's decision in *NACWA* v. *EPA.* The EPA prepared a memorandum explaining the methodology for the UPL. This memorandum, the EPA's *Response to Remand of the Record for Major Source Boilers,* provides a detailed rationale to use the UPL as the basis of setting a

MACT floor for new and existing sources, and the methodology and the explanation in the memorandum were upheld by the D.C. Circuit in *U.S. Sugar* v. *EPA,* 830 F.3d at 639. Following the UPL memorandum, the EPA issued a subsequent memorandum specifically addressing the application of the UPL methodology when setting MACT emission limits with limited datasets, *Approach for Applying the Upper Prediction Limit to Limited Datasets.* In that memorandum, the EPA concluded that there are additional considerations when setting MACT floors for limited datasets. The D.C. Circuit agreed that the EPA sufficiently explained the general application of the UPL approach to small datasets in *Sierra Club* v. *EPA,* 895 F.3d 1, 14 (D.C. Cir. 2018). The MACT floors were set consistent with EPA guidance and with previous court decisions.

4. What is the rationale for our final approach for the 112(d)(2) and (3) amendments?

For the reasons explained in the preamble to the proposed rule (86 FR 3095, January 14, 2021), and in the comment responses in sections IV.B.3 and IV.C.3 of this preamble and the comment summary and response document (available in the docket for this rulemaking), we are finalizing a work practice requirement to use natural gas at all times for new and existing clay refractory product sources, and we are making no changes and are finalizing the proposed 112(d)(2) and (3) amendments for clay refractory kilns in the Refractory Products Manufacturing source category.

D. SSM Amendments for the Refractory Products Manufacturing Source Category

1. What SSM amendments did we propose for the Refractory Products Manufacturing source category?

We proposed amendments to the Refractory Products Manufacturing NESHAP to remove and revise provisions related to SSM that are not consistent with the 2008 court decision that the standards apply at all times. More information concerning the elimination of SSM provisions is provided in the preamble to the proposed rule (86 FR 3095, January 14, 2021).

2. How did the SSM amendments change for the Refractory Products Manufacturing source category?

We are finalizing the SSM provisions as proposed with no changes (86 FR 3095, January 14, 2021).

3. What key comments did we receive on the SSM amendments and what are our responses?

We received one general comment supporting the proposed amendments to the SSM provisions for refractory products manufacturing and three comments requesting that the rule requirements for this source category apply at all times, not just during periods of SSM.

4. What is the rationale for our final approach for the SSM provisions?

For the reasons explained in the proposed rule and after evaluation of the comments on the proposed amendments to the SSM provisions for the Refractory Products Manufacturing NESHAP, we are finalizing the proposed amendments related to SSM that are not consistent with the requirement that the standards apply at all times. More information concerning the proposed amendments to the SSM provisions is in the preamble to the proposed rule (86 FR 3095, January 14, 2021).

E. Electronic Reporting Amendments for the Refractory Products Manufacturing Source Category

1. What electronic reporting amendments did we propose for the Refractory Products Manufacturing source category?

In the January 14, 2021, notice we proposed amendments to subpart SSSSS to require owners and operators of refractory product manufacturing facilities to submit electronic copies of NOCS reports, performance test results, and performance evaluation results through the EPA's CDX using CEDRI.

The proposed amendments apply to the NOCS required by 40 CFR 63.7(b) and (c), 40 CFR 63.8(f)(4), 40 CFR 63.9(b) through (e) and (h) and 40 CFR 63.9812, and performance test results and performance evaluation results required by 40 CFR 63.9(h), 40 CFR 63.9800, and 40 CFR 63.9814. The proposal would require that all NOCS be submitted as portable document format (PDF) files and uploaded to CEDRI. For performance test and performance evaluation results, the proposal would require test results that use test methods supported by the EPA's ERT listed on the ERT website[1] at the time of the test be submitted in the format generated through the use of the ERT or an electronic file consistent with the extensible markup language (XML) schema on the ERT website. Performance test results using test methods that are not supported by the ERT at the time of the test would be required to be submitted as a PDF file using the attachment module of the ERT. In addition, the proposal included two broad circumstances for electronic reporting extensions. A description of the electronic data submission process is provided in the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for NESHAP Rules,* available in the docket for this action (Docket Item No. EPA–HQ–OAR–2020–0148–0003). The proposed rule requirements would replace the current rule requirements to submit the NOCS reports, performance test results, and performance evaluation results to the Administrator at the appropriate address listed in 40 CFR 63.13. The proposed rule requirement would not affect submittals required by state air agencies. The proposed compliance date for existing affected sources to comply with the electronic reporting requirements for NOCS reports, performance test results, and performance evaluation results is 181 days after the final rule is published to begin electronic reporting. New affected sources are required to comply with the electronic reporting requirements for NOCS reports, performance test results, and performance evaluation results on the effective date of the standard or upon startup, whichever is later.

2. How did the electronic reporting provisions change for the Refractory Products Manufacturing source category?

No changes were made to the proposed electronic reporting provisions.

3. What key comments did we receive on the electronic reporting provisions and what are our responses?

We received one comment letter that addressed the proposed electronic reporting provisions for refractory products manufacturing. The commenter generally supported the proposed amendments except for the proposed provisions of 40 CFR 63.9814(k) and (l) that would provide instructions for affected sources unable to submit an electronic report either due to a force majeure event or an outage of CEDRI.

4. What is the rationale for our final approach for the electronic reporting requirements?

For the reasons explained in the preamble to the proposed rule (86 FR 3095, January 14, 2021) and the comment summary and response document (available in the docket for this rulemaking), we are making no

changes and are finalizing the electronic reporting provisions as proposed.

F. Technical Amendments for the Refractory Products Manufacturing Source Category

In the final rule, we are amending 40 CFR 63.9824 and Table 4 to subpart SSSSS of part 63, as proposed, to clarify the location in 40 CFR part 60 of applicable EPA test methods. We are also amending 40 CFR 63.9814 and 63.9816 to include the requirements to record and report information on failures to meet the applicable standard.

In the final rule, as proposed, we are adding and updating test methods that are incorporated by reference. In accordance with requirements of 1 CFR part 51.5, the EPA is incorporating by reference the following voluntary consensus standards (VCS) described in the amendments to 40 CFR 63.14:

- ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981, proposed to be IBR approved for Table 4 to subpart SSSSS. This document specifies methods, apparatus and calculations which are used to determine quantitatively, the gaseous constituents of the exhausts including oxygen and carbon dioxide resulting from station combustions sources.
- ASTM D6348–12e1, Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, Approved February 1, 2012, proposed to be IBR approved for Table 4 to subpart SSSSS.
- ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method),'' (Approved March 1, 2016), proposed to be IBR approved for Table 4 to subpart SSSSS.
- EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, proposed to be IBR approved for 40 CFR 63.9804(f). This document provides guidance on the use of triboelectric monitors as fabric filter bag leak detectors. The document includes fabric filter and monitoring system descriptions; guidance on monitor selection, installation, setup, adjustment, and operation; and quality assurance procedures.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

Currently, three major sources subject to the Refractory Products Manufacturing NESHAP are operating in the United States. The NESHAP applies to each new, reconstructed, and existing affected source located at a refractory products manufacturing facility that is a major source of HAP emissions, is located at a major source of HAP emissions, or is part of a major source of HAP emissions. A refractory products manufacturing facility is a plant site that manufactures refractory products, such as refractory bricks, refractory shapes, monolithics, kiln furniture, crucibles, and other materials used for lining furnaces and other high temperature process units. Refractory products manufacturing facilities typically process raw material by crushing, grinding, and screening; mixing the processed raw materials with binders and other additives; forming the refractory mix into shapes; and drying and firing the shapes. The NESHAP lists the affected sources for four subcategories across the industry as the shape dryers, curing ovens, and kilns that are used to manufacture refractory products that use organic HAP; shape preheaters, pitch working tanks, defumers, and coking ovens that are used to produce pitch-impregnated refractory products; kilns that are used to manufacture chromium refractory products; and kilns that are used to manufacture clay refractory products. The three major sources currently operating in the U.S. can be grouped into two of the subcategories and use curing ovens and kilns that are used to manufacture nonclay refractory products that use organic HAP and kilns that are used to manufacture clay refractory products.

B. What are the air quality impacts?

At the current level of control, the estimated emissions of HAP from the Refractory Products Manufacturing source category are approximately 40 tpy. The final amendments require that all three major sources in the Refractory Products Manufacturing source category comply with the relevant emission standards at all times, including periods of SSM. The final amendments also limit the number of hours a continuous kiln THC control device can be bypassed during scheduled maintenance and require minimizing emissions of THC during bypass periods. We were unable to quantify the emissions that occur during periods of SSM or the specific emissions reductions that would occur as a result of this action. However, eliminating the SSM exemption has the potential to reduce emissions by requiring facilities to meet the applicable standard during SSM periods. Requiring the use of natural gas as kiln fuel at all times also ensures that PM (as a surrogate for non-Hg metal HAP) and Hg will not be emitted from combustion of coal, fuel oil, or waste-derived fuels.

Indirect or secondary air emissions impacts are impacts that would result from the increased electricity usage associated with the operation of control devices (*e.g.,* increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity and steam needed to operate control devices and other equipment. The final amendments would have no effect on the energy needs of the affected facilities in this source category and would, therefore, have no indirect or secondary air emissions impacts.

C. What are the cost impacts?

We estimate that each facility in this source category will experience costs as a result of these final amendments. Estimates for reporting and recordkeeping costs for each facility are associated with the electronic reporting requirements, elimination of the SSM exemption, and revision of the requirements that apply during times of scheduled maintenance of continuous kiln control devices. The costs associated with the electronic reporting requirements are attributed to submittal of NOCS reports, performance test results, and performance evaluation results using CEDRI and include time for becoming familiar with CEDRI. The costs associated with the revised SSM requirements were estimated for re-evaluating previously developed SSM record systems. The costs associated with recordkeeping to document the frequency and duration of scheduled maintenance of control devices for continuous kilns were also estimated. The recordkeeping and reporting costs are presented in section VI.C of this preamble.

We estimate the costs associated with this action are primarily due to the new compliance testing requirements for the clay refractory kilns in this action. Two of the major source refractory manufacturing facilities manufacture clay refractory and are required to conduct periodic compliance testing for PM as a surrogate for non-Hg metal HAP and Hg once every 5 years. One clay refractory manufacturing facility has two continuous kilns and the other has

two continuous kilns and three batch kilns. The costs associated with conducting the combined PM and Hg test for each continuous kiln stack are estimated to be about $23,600. The costs associated with conducting the combined PM and Hg test for each batch kiln stack are estimated to be about $31,800. We also assumed that tests for additional stacks at the same facility would be conducted in the same trip, so the additional cost is less due to reduced travel costs. The total costs for the two facilities to test the seven kilns in a single year would be $115,300. In addition to the testing costs, each facility performing the testing will have an additional $6,900 in reporting costs per facility in the year in which the test occurs.

For kilns that meet the limits without any controls, owners or operators are required to conduct VE monitoring to demonstrate compliance. One of the continuous kilns is controlled with a wet scrubber, but the other six kilns are expected to need to conduct VE monitoring. We estimate that the monitoring will cost $3,740 per year per stack, for a total of $22,400 per year.

For further information on the potential testing and monitoring costs, see the memorandum titled *Development of Proposed Standards and Impacts for the Refractory Products Manufacturing NESHAP,* located in the docket for this action (Docket Item No. EPA–HQ–OAR–2020–0148–0014).

D. What are the economic impacts?

The economic impact analysis is designed to inform decision makers about the potential economic consequences of the compliance costs outlined in section V.C of this preamble. To assess the maximum potential impact, the largest cost expected to be experienced in any one year is compared to the total sales for the ultimate owner of the affected facilities to estimate the total burden for each owner. For these final amendments, the total cost of testing, monitoring, and recordkeeping and reporting is estimated to be $158,140. The total annual costs associated with the requirements range from 0.00008 to 0.18 percent of annual sales revenue per ultimate owner. These costs are not expected to result in a significant market impact, regardless of whether they are passed on to customers or absorbed by the firms.

The EPA also prepared a small business screening assessment to determine whether any of the identified affected facilities are small entities, as defined by the U.S. Small Business Administration. One of the facilities affected by these amendments is a small entity. However, the annual cost associated with the requirements is 0.18 percent of annual sales revenue for the owner of that facility. Therefore, there are no significant economic impacts on a substantial number of small entities from these amendments.

E. What are the benefits?

As stated above in section V.B. of this preamble, we were unable to quantify the specific emissions reductions associated with eliminating the SSM exemption, although this change has the potential to reduce emissions of volatile organic HAP.

Because these final amendments are not considered economically significant, as defined by Executive Order 12866, we did not monetize the benefits of reducing these emissions. This does not mean that there are no benefits associated with the potential reduction in volatile organic HAP from this rule.

F. What analysis of environmental justice did we conduct?

Executive Order 12898 directs the EPA to identify the populations of concern who are most likely to experience unequal burdens from environmental harms; specifically, minority populations, low-income populations, and indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 13985 was signed to advance racial equity and support underserved communities through Federal government actions (86 FR 7009, January 20, 2021). The EPA defines environmental justice (EJ) as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies'' (*https://www.epa.gov/environmentaljustice*). In recognizing that minority and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution.

Based on an analysis of exposed populations, the EPA determined that the Refractory Products Manufacturing source category does not pose a disproportionately high adverse health impact on minority populations and/or low-income populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994) and referenced in Executive Order 13985 (86 FR 7009, January 20, 2021). The EPA remains committed to engaging with communities and stakeholders throughout the development of air pollution regulations.

To examine the potential for any environmental justice issues that might be associated with this source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we also evaluated the distribution of HAP-related cancer and noncancer risks from the Refractory Products Manufacturing source category across different demographic groups within the populations living near facilities.[3]

The results of the demographic analysis for the Refractory Products Manufacturing source category indicates that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1. In addition, no percentages of the populations exposed to emissions from the source category are higher than their respective nationwide average percentages. Thus, the populations living near refractory products manufacturing facilities are similar to the national average in demographic characteristics, and we do not see a disproportionately high exposure to the population groups indicated in the Executive Orders. The methodology and the results of the demographic analysis are presented in more detail in the technical report titled *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Refractory Products Manufacturing Source Category Operations,* September 2020, available in the docket for this action (Docket Item No. EPA–HQ–OAR–2020–0148–0007).

G. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because it is not

[3] Demographic groups included in the analysis are: White, African American, Native American, other races and multiracial, Hispanic or Latino, children 17 years of age and under, adults 18 to 64 years of age, adults 65 years of age and over, adults without a high school diploma, people living below the poverty level, people living two times the poverty level, and linguistically isolated people.

economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section IV.A of this preamble and are further documented in the *Residual Risk Assessment for the Refractory Products Manufacturing Source Category in Support of the 2020 Risk and Technology Review Proposed Rule,* available in the Refractory Products Manufacturing docket (Docket Item No. EPA–HQ–OAR–2020–0148–0013).

VI. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this action have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2040.08. You can find a copy of the ICR in the Refractory Products Manufacturing Docket (Docket ID No. EPA–HQ–OAR–2020–0148), and it is briefly summarized here.

As part of the RTR for the Refractory Products Manufacturing NESHAP, the EPA is not revising the existing emission limit requirements but is adding new emission limit requirements for existing clay refractory sources and is adding new work practices for existing nonclay refractory sources. The EPA is also revising the SSM provisions of the rule and is adding the use of electronic data reporting for future performance test result and performance evaluation result submittals, and NOCS reports. This information is being collected to assure compliance with 40 CFR part 63, subpart SSSSS.

Respondents/affected entities: Facilities manufacturing refractory products.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart SSSSS).

Estimated number of respondents: In the 3 years after the amendments are final, approximately three respondents per year will be subject to the NESHAP and no additional respondents are expected to become subject to the NESHAP during that period.

Frequency of response: The total number of responses is 15 per year.

Total estimated burden: The average annual burden to the three refractory products manufacturing facilities over the 3 years after the amendments are final is estimated to be 230 hours (per year). The average annual burden to the Agency over the 3 years after the amendments are final is estimated to be 202 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The average annual cost to the refractory products manufacturing facilities is $27,100 in labor costs in the first 3 years after the amendments are final. The average annual capital and operation and maintenance (O&M) cost is $69,900. The total average annual Agency cost over the first 3 years after the amendments are final is estimated to be $9,990.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The annualized costs associated with the requirements in this action for the affected small entities is described in section V.C. above.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. While this action creates an enforceable duty on the private sector, the cost does not exceed $100 million or more.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. No tribal facilities are known to be engaged in any of the industries that would be affected by this action. In addition, the EPA conducted a proximity analysis for this source category and found that no refractory products manufacturing facilities are located within 50 miles of tribal lands. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section IV.A of this preamble and are further documented in the Refractory Products Manufacturing Docket.

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

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

I. National Technology Transfer and Advancement Act and 1 CFR Part 51

This action involves technical standards. The EPA amended the Refractory Products Manufacturing NESHAP in this action with two methods that can be used as alternatives to the EPA methods in the current NESHAP: ANSI/ASME PTC 19.10–1981, ''Flue and Exhaust Gas Analyses'' and ASTM D6348–12e1, ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy''. The EPA also amended the Refractory Products Manufacturing NESHAP in this action with two new methods: EPA Method 29 (portion for Hg only) and alternative method ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)''. The EPA also added new guidance to the NESHAP: EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997. The methods and guidance will be incorporated by reference as described below.

The EPA is incorporating by reference the VCS ANSI/ASME PTC 19.10–1981,

''Flue and Exhaust Gas Analyses.'' This method determines quantitatively the gaseous constituents of exhausts resulting from stationary combustion sources. The manual procedures (but not instrumental procedures) of VCS ANSI/ASME PTC 19.10–1981—Part 10 may be used as an alternative to EPA Method 3B for measuring the oxygen or carbon dioxide content of the exhaust gas. The gases covered in ANSI/ASME PTC 19.10–1981 are oxygen, carbon dioxide, carbon monoxide, nitrogen, sulfur dioxide, sulfur trioxide, nitric oxide, nitrogen dioxide, hydrogen sulfide, and hydrocarbons, however the use in this rule is only applicable to oxygen and carbon dioxide and is an acceptable alternative to the manual portion only and not the instrumental portion.

The EPA is incorporating by reference the VCS ASTM D6348–12e1, ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy'' as an acceptable alternative to EPA Method 320. ASTM D6348–03(2010) was determined to be equivalent to EPA Method 320 with caveats. ASTM D6348–12e1 is a revised version of ASTM D6348–03(2010) and includes a new section on accepting the results from the direct measurement of a certified spike gas cylinder, but lacks the caveats placed on the D6348–03(2010) version. The VCS ASTM D6348–12e1 ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy'' is an extractive FTIR field test method used to quantify gas phase concentrations of multiple analytes from stationary source effluent and is an acceptable alternative to EPA Method 320 at this time with caveats requiring inclusion of selected annexes to the standard as mandatory. When using ASTM D6348–12e1, the following conditions must be met:

(1) The test plan preparation and implementation in the Annexes to ASTM D6348–03, sections A1 through A8 are mandatory; and

(2) In ASTM D6348–03 Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5).

In order for the test data to be acceptable for a compound, %R must be $70\% \geq R \leq 130\%$. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the following equation: Reported Results = ((Measured Concentration in Stack))/(%R) × 100.

The EPA is also incorporating by reference the VCS ASTM D6784–16, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)'' as an acceptable alternative to EPA Method 29 (portion for Hg only) as a method for measuring elemental, oxidized, particle-bound, and total Hg concentrations ranging from approximately 0.5–100 micrograms per normal cubic meter (μg/Nm^3). This test method describes equipment and procedures for obtaining samples from effluent ducts and stacks, equipment and procedures for laboratory analysis, and procedures for calculating results. VCS ASTM D6784–16 allows for additional flexibility in the sampling and analytical procedures for the earlier version of the same standard VCS ASTM D6784–02 (Reapproved 2008).

The EPA is also incorporating by reference EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, IBR for 40 CFR 63.9804(f). This document provides guidance on the use of triboelectric monitors as fabric filter bag leak detectors and includes fabric filter and monitoring system descriptions; guidance on monitor selection, installation, setup, adjustment, and operation; and quality assurance procedures.

Guidance document EPA–454/R–98–015 and ASTM D6784–16 are available electronically through *https://www.regulations.gov/* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information). The ANSI/ASME document (ANSI/ASME PTC 19.10–1981) is available from the American Society of Mechanical Engineers (ASME) at *http://www.asme.org;* by mail at Three Park Avenue, New York, NY 10016–5990; or by telephone at (800) 843–2763. The ASTM methods are available from ASTM International at *https://www.astm.org;* by mail at 100 Barr Harbor Drive, Post Office Box C700, West Conshohocken, PA 19428–2959; or by telephone at (610) 832–9585.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the technical report titled *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Refractory Products Manufacturing Source Category Operations,* September 2020, available in the Refractory Products Manufacturing Docket for this action (Docket Item No. EPA–HQ–OAR–2020–0148–0007).

The EPA provided opportunities to engage with the EPA on this action. The Agency offered a public hearing and reached out to communities in other ways, including meetings to exchange information with stakeholders about this action. We did not receive a request for a public hearing, and we did not receive feedback regarding EJ during the meetings.

K. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set out in the preamble, 40 CFR part 63 is amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

Subpart A—General Provisions

■ 2. Section 63.14 is amended by:

■ a. Revising paragraphs (e)(1) and (h)(86);

■ b. Redesignating paragraphs (h)(104) through (118) as paragraphs (h)(105) through (119);

■ c. Adding new paragraph (h)(104); and

■ d. Revising paragraph (n)(4).

The revisions and additions read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(e) * * *

(1) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], issued August 31, 1981, IBR approved for §§ 63.309(k), 63.457(k), 63.772(e) and (h), 63.865(b), 63.997(e), 63.1282(d) and (g), and 63.1625(b), table 5 to subpart EEEE, §§ 63.3166(a), 63.3360(e), 63.3545(a), 63.3555(a), 63.4166(a), 63.4362(a), 63.4766(a), 63.4965(a), and 63.5160(d), table 4 to subpart UUUU, table 3 to subpart YYYY, §§ 63.7822(b), 63.7824(e), 63.7825(b), 63.8000(d), 63.9307(c), 63.9323(a), 63.9621(b) and (c), 63.11148(e), 63.11155(e), 63.11162(f), 63.11163(g), 63.11410(j), 63.11551(a), 63.11646(a), and 63.11945, and table 4 to subpart AAAAA, table 5 to subpart DDDDD, table 4 to subpart JJJJJ, table 4 to subpart KKKKK, table 4 to subpart SSSSS, tables 4 and 5 of subpart UUUUUU, table 1 to subpart ZZZZZZ, and table 4 to subpart JJJJJJ.

* * * * *

(h) * * *

(86) ASTM D6348–12e1, Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, Approved February 1, 2012, IBR approved for §§ 63.997(e), 63.1571(a), and 63.2354(b), table 5 to subpart EEEE, table 4 to subpart UUUU, §§ 63.7142(a) and (b) and 63.8000(d), and table 4 to subpart SSSSS.

* * * * *

(104) ASTM D6784–16, Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), Approved March 1, 2016, IBR approved for table 4 to subpart SSSSS.

* * * * *

(n) * * *

(4) EPA–454/R–98–015, Office of Air Quality Planning and Standards (OAQPS), Fabric Filter Bag Leak Detection Guidance, September 1997, *https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000D5T6.PDF,* IBR approved for §§ 63.548(e), 63.864(e), 63.7525(j), 63.8450(e), 63.8600(e), 63.9632(a), 63.9804(f), and 63.11224(f).

* * * * *

Subpart SSSSS—National Emission Standards for Hazardous Air Pollutants for Refractory Products Manufacturing

■ 3. Section 63.9786 is amended by revising paragraphs (a), (b), and (d)(2) to read as follows:

§ 63.9786 When do I have to comply with this subpart?

(a) If you have a new or reconstructed affected source, you must comply with this subpart according to paragraphs (a)(1) and (2) of this section.

(1) If the initial startup of your affected source is before April 16, 2003, then you must comply with the emission limitations for new and reconstructed sources in this subpart no later than April 16, 2003, except as otherwise specified in §§ 63.9792, 63.9812(c) and (e), and 63.9814(b)(6) and Tables 1 through 11 to this subpart.

(2) If the initial startup of your affected source is after April 16, 2003, then you must comply with the emission limitations for new and reconstructed sources in this subpart upon initial startup of your affected source, except as otherwise specified in §§ 63.9792, 63.9812(c) and (e), and 63.9814(b)(6) and Tables 1 through 11 to this subpart.

(b) If you have an existing affected source, you must comply with the emission limitations for existing sources no later than April 17, 2006, except as otherwise specified in §§ 63.9792, 63.9812(c) and (e), and 63.9814(b)(6) and Tables 1 through 11 to this subpart.

* * * * *

(d) * * *

(2) All other parts of the existing facility must be in compliance with this subpart by 3 years after the date the area source becomes a major source, except as otherwise specified in §§ 63.9792, 63.9812(c) and (e), and 63.9814(b)(6) and Tables 1 through 11 to this subpart.

* * * * *

■ 4. Section 63.9792 is amended by revising paragraph (a) introductory text, paragraphs (b) and (c), paragraph (e) introductory text, and paragraphs (e)(2) and (3) to read as follows:

§ 63.9792 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations (including operating limits and work practice standards) in this subpart at all times, except during periods specified in paragraphs (a)(1) and (2) of this section before May 19, 2022. You must be in compliance with the emission limitations (including operating limits and work practice standards) in this subpart at all times, on or after May 19, 2022.

* * * * *

(b) Except as specified in paragraph (e) of this section, before May 19, 2022, you must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the provisions in § 63.6(e)(1)(i). During the period between the compliance date specified for your affected source in § 63.9786 and the date upon which continuous monitoring systems have been installed and validated and any applicable operating limits have been established, you must maintain a log detailing the operation and maintenance of the process and emissions control equipment. On and after May 19, 2022, at all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator that may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the affected source.

(c) Before May 19, 2022, you must develop a written startup, shutdown, and malfunction plan (SSMP) according to the provisions in § 63.6(e)(3). On or after May 19, 2022, you are not required to develop a written SSMP according to the provisions in § 63.6(e)(3).

* * * * *

(e) If you own or operate an affected continuous kiln used to manufacture refractory products that use organic HAP and you must perform scheduled maintenance on the THC control device for that kiln, you may bypass the kiln THC control device and continue operating the kiln subject to the alternative standard established in this paragraph upon approval by the Administrator, provided you satisfy the conditions listed in paragraphs (e)(1) through (3) of this section.

* * * * *

(2) Before May 19, 2022, you must minimize HAP emissions during the period when the kiln is operating, and the control device is out of service. On

and after May 19, 2022, you must minimize HAP emissions during the period when the kiln is operating and the control device is out of service by complying with the applicable standard in Table 3 to this subpart.

(3) You must minimize the time period during which the kiln is operating and the control device is out of service. On and after May 19, 2022, the total time during which the kiln is operating and the control device is out of service for each year on a 12-month rolling basis must not exceed 750 hours.

* * * * *

■ 5. Section 63.9794 is amended by revising paragraphs (a)(7), (8), (12), and (13) and paragraph (b)(2) to read as follows:

§ 63.9794 What do I need to know about operation, maintenance, and monitoring plans?

(a) * * *

(7) Before May 19, 2022, procedures for the proper operation and maintenance of monitoring equipment consistent with the requirements in §§ 63.8(c)(1), (3), (4)(ii), (7), and (8), and 63.9804. On or after May 19, 2022, procedures for the proper operation and maintenance of monitoring equipment consistent with the requirements in §§ 63.8(c)(3), (4)(ii), (7), and (8), and 63.9804.

(8) Before May 19, 2022, ongoing data quality assurance procedures in accordance with the general requirements of § 63.8(d). On or after May 19, 2022, ongoing data quality assurance procedures consistent with the requirements in § 63.8(d)(1) and (2). You must keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan in § 63.8(d)(2) is revised, you must keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

* * * * *

(12) Before Novermber 19, 2021, if you operate a kiln that is subject to the limits on the type of fuel used, as specified in items 3 and 4 of Table 3 to subpart SSSSS, procedures for using alternative fuels. On and after Novermber 19, 2021, you may not use a fuel other than natural gas or equivalent to fire the affected kiln.

(13) If you operate an affected continuous kiln used to manufacture refractory products that use organic HAP and you plan to take the kiln THC control device out of service for scheduled maintenance, as specified in § 63.9792(e), the procedures specified in paragraphs (a)(13)(i) and (ii) of this section.

(i) Procedures for minimizing HAP emissions from the kiln during periods of scheduled maintenance of the kiln control device when the kiln is operating and the control device is out of service. On or after May 19, 2022, document the average organic HAP processing rate for that kiln (*i.e.,* the average organic HAP processing rate based on (a) the actual production on a 6-month rolling basis (not to include periods of kiln shut down) or (b) the HAP processing rate (lb/hr) that coincides with the lowest hour of the most recent 3-hour performance test, whichever is lower), the mass fraction of organic HAP in the resins, binders, and additives for each product manufactured in the kiln and procedures for ensuring that the actual organic HAP processing rate on an hourly basis does not exceed the average organic HAP processing rate.

(ii) Procedures for minimizing any period of scheduled maintenance on the kiln control device when the kiln is operating and the control device is out of service. On or after May 19, 2022, procedures for ensuring that the total time during which the kiln is operating and the control device is out of service does not exceed 750 hours for each year on a 12-month rolling basis.

(b) * * *

(2) After completing the performance tests to demonstrate that compliance with the emission limits can be achieved at the revised operating limit parameter value, you must submit the summary of the performance test results and the revised operating limits as part of the Notification of Compliance Status required under § 63.9(h) and the complete test report according to § 63.9814(h).

* * * * *

■ 6. Section 63.9800 is amended by revising paragraphs (c) and (d) and paragraph (g) introductory text and adding paragraph (g)(4) to read as follows:

§ 63.9800 How do I conduct performance tests and establish operating limits?

* * * * *

(c) Before May 19, 2022, each performance test must be conducted according to the requirements in § 63.7 and under the specific conditions in Table 4 to this subpart. On or after May 19, 2022, each performance test must be conducted under the specific conditions in Table 4 to this subpart.

(d) Before May 19, 2022, you may not conduct performance tests during periods of startup, shutdown, or malfunction, as specified in § 63.7(e)(1). On or after May 19, 2022, you may not conduct performance tests during periods of malfunction. You also may not conduct performance tests during periods of startup or shutdown. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. You must make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

(g) You must use the data gathered during the performance test and the equations in paragraphs (g)(1) through (4) of this section to determine compliance with the emission limitations.

* * * * *

(4) To determine compliance with the Hg emission concentration limit listed in Table 1 to this subpart, you must calculate your emission concentration corrected to 18 percent oxygen for each test run using Equation 4 of this section:

$$C_{Hg\text{-}C} = \frac{2.9 \times C_{Hg}}{\left(20.9 - C_{O_2}\right)} \qquad \text{(Eq. 4)}$$

Where:

$C_{Hg\text{-}C}$ = Hg concentration, corrected to 18 percent oxygen, micrograms per dry standard cubic meters (µg/dscm)

C_{Hg} = Hg concentration (uncorrected), µg/dscm

C_{O2} = oxygen concentration, percent.

* * * * *

■ 7. Section 63.9804 is amended by revising paragraphs (a)(13), (e)(1), and (f)(1) to read as follows:

§ 63.9804 What are my monitoring system installation, operation, and maintenance requirements?

(a) * * *

(13) At all times, you must maintain your CPMS in accordance with § 63.9792(b), including, but not limited to, keeping the necessary parts readily available for routine repairs of the CPMS.

* * * * *

(e) * * *

(1) Use a pH CPMS with a minimum accuracy of ±0.2 pH units.

* * * * *

(f) * * *

(1) Each triboelectric bag leak detection system must be installed, calibrated, operated, and maintained according to the ''Fabric Filter Bag Leak Detection Guidance'' (EPA–454/R–98–015, September 1997) (incorporated by reference, see § 63.14). Other types of bag leak detection systems must be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations.

* * * * *

■ 8. Section 63.9806 is amended by revising paragraph (d) to read as follows:

§ 63.9806 How do I demonstrate initial compliance with the emission limits, operating limits, and work practice standards?

* * * * *

(d) You must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.9812(e). After Novermber 19, 2021 for affected sources that commence construction or reconstruction after January 14, 2021, and on and after May 19, 2022 for all other affected sources, you must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.9812(e) and 63.9814(j).

■ 9. Section 63.9808 is amended by revising paragraph (b) to read as follows:

§ 63.9808 How do I monitor and collect data to demonstrate continuous compliance?

* * * * *

(b) At all times, you must maintain your monitoring systems in accordance with § 63.9792(b), including, but not limited to, keeping the necessary parts readily available for routine repairs of the monitoring equipment.

* * * * *

■ 10. Section 63.9810 is amended by revising paragraph (e) and adding paragraph (f) to read as follows:

§ 63.9810 How do I demonstrate continuous compliance with the emission limits, operating limits, and work practice standards?

* * * * *

(e) Before May 19, 2022, you must report each instance in which you did not meet each emission limit and each operating limit in this subpart that applies to you. This includes periods of SSM. These instances are deviations from the emission limitations in this subpart. These deviations must be reported according to the requirements in § 63.9814. On or after May 19, 2022, you must report each instance in which you did not meet each emission limit and each operating limit in this subpart that applies to you. These instances are deviations from the emission limitations in this subpart. These deviations must be reported according to the requirements in § 63.9814.

(1) [Reserved]

(2) Before May 19, 2022, consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with § 63.6(e)(1) and your OM&M plan. The Administrator will determine whether deviations that occur during a period of startup, shutdown, or malfunction are violations, according to the provisions in § 63.6(e). On or after May 19, 2022, consistent with §§ 63.9792(b) and 63.9800(d), deviations are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with § 63.9792(b) and your OM&M plan. The Administrator will determine whether deviations are violations, according to the provisions in § 63.9792(b).

(f) You must demonstrate continuous compliance with the operating limits in Table 2 to this subpart for visible emissions (VE) from clay refractory products kilns that are uncontrolled or equipped with DLA, dry lime injection fabric filter (DIFF), dry lime scrubber/fabric filter (DLS/FF) or other dry control device as described in paragraph (f)(1) or (2) of this section.

(1) *VE testing.* Monitoring VE at each kiln stack according to the requirements in paragraphs (f)(1)(i) through (v) of this section.

(i) Perform daily VE observations of each kiln stack according to the procedures of EPA Method 22 of 40 CFR part 60, appendix A–7. You must conduct the EPA Method 22 test while the affected source is operating under normal conditions. The duration of each EPA Method 22 test must be at least 15 minutes.

(ii) If VE are observed during any daily test conducted using EPA Method 22 of 40 CFR part 60, appendix A–7, you must promptly conduct an opacity test, according to the procedures of EPA Method 9 of 40 CFR part 60, appendix A–4. If opacity greater than 10 percent is observed, you must initiate and complete corrective actions according to your OM&M plan.

(iii) You may decrease the frequency of EPA Method 22 testing from daily to weekly for a kiln stack if one of the conditions in paragraph (f)(1)(iii)(A) or (B) of this section is met.

(A) No VE are observed in 30 consecutive daily EPA Method 22 tests for any kiln stack; or

(B) No opacity greater than 10 percent is observed during any of the EPA Method 9 tests for any kiln stack.

(iv) If VE are observed during any weekly test and opacity greater than 10 percent is observed in the subsequent EPA Method 9 test, you must promptly initiate and complete corrective actions according to your OM&M plan, resume testing of that kiln stack following EPA Method 22 of 40 CFR part 60, appendix A–7, on a daily basis, as described in paragraph (f)(1)(i) of this section, and maintain that schedule until one of the conditions in paragraph (f)(1)(iii)(A) or (B) of this section is met, at which time you may again decrease the frequency of EPA Method 22 testing to a weekly basis.

(v) If greater than 10 percent opacity is observed during any test conducted using EPA Method 9 of 40 CFR part 60, appendix A–4, you must report these deviations by following the requirements in § 63.9814.

(2) *Alternative to VE testing.* In lieu of meeting the requirements under paragraph (f)(1) of this section, you may conduct a PM test at least once every year following the initial performance test, according to the procedures of EPA Method 5 of 40 CFR part 60, appendix A–3, and the provisions of § 63.9800(e) and (f).

■ 11. Section 63.9812 is amended by revising paragraphs (b) and (c), paragraph (e) introductory text, paragraph (e)(1), paragraph (f) introductory text, and paragraph (g) to read as follows:

§ 63.9812 What notifications must I submit and when?

* * * * *

(b) As specified in § 63.9(b)(2) and (3), if you start up your affected source before April 16, 2003, you must submit an Initial Notification not later than 120 calendar days after April 16, 2003, or no later than 120 days after the source becomes subject to this subpart, whichever is later.

(c) As specified in § 63.9(b)(3), if you start up your new or reconstructed affected source on or after April 16, 2003, you must submit an Initial Notification not later than 120 calendar days after you become subject to this subpart. Initial Notifications required to be submitted after November 19, 2021 for affected sources that commence construction or reconstruction after January 14, 2021, and on and after May 19, 2022 for all other affected sources submitting initial notifications required in § 63.9(b) must be submitted following the procedure specified in § 63.9814(h) through (l).

* * * * *

(e) If you are required to conduct a performance test, you must submit a Notification of Compliance Status as specified in § 63.9(h) and paragraphs (e)(1) and (2) of this section. After November 19, 2021 for affected sources that commence construction or reconstruction after January 14, 2021, and on and after May 19, 2022 for all other affected sources, submit all subsequent Notifications of Compliance Status following the procedure specified in § 63.9814(h) through (l).

(1) For each compliance demonstration that includes a performance test conducted according to the requirements in Table 4 to this subpart, you must submit the Notification of Compliance Status, including the summary of the performance test results, before the close of business on the 60th calendar day following the completion of the performance test.

* * * * *

(f) Before November 19, 2021, if you operate a clay refractory products kiln or a chromium refractory products kiln that is subject to the work practice standard specified in item 3 or 4 of Table 3 to this subpart, and you intend to use a fuel other than natural gas or equivalent to fire the affected kiln, you must submit a notification of alternative fuel use within 48 hours of the declaration of a period of natural gas curtailment or supply interruption, as defined in § 63.9824. The notification must include the information specified in paragraphs (f)(1) through (5) of this section. On and after November 19, 2021, you may not use a fuel other than natural gas or equivalent to fire the affected kiln.

* * * * *

(g) If you own or operate an affected continuous kiln used to manufacture refractory products that use organic HAP and must perform scheduled maintenance on the THC control device for that kiln, you must request approval from the Administrator before bypassing the control device, as specified in § 63.9792(e). You must submit a separate request for approval each time you plan to bypass the kiln control device.

■ 12. Section 63.9814 is amended by:
■ a. Revising paragraph (c) introductory text and paragraph (c)(4);
■ b. Adding paragraph (c)(7);
■ c. Revising paragraphs (d) and (e) and paragraph (g) introductory text; and
■ d. Adding paragraphs (h) through (l).

The revisions and additions read as follows:

§ 63.9814 What reports must I submit and when?

* * * * *

(c) The compliance report must contain the information in paragraphs (c)(1) through (7) of this section.

* * * * *

(4) Before May 19, 2022, if you had a startup, shutdown, or malfunction during the reporting period, and you took actions consistent with your SSMP and OM&M plan, the compliance report must include the information specified in § 63.10(d)(5)(i). On or after May 19, 2022, if you had a deviation from any emission limitations (emission limit, operating limit, or work practice standard) during the reporting period that apply to you, and you took actions consistent with your OM&M plan, the compliance report must include the information specified in (d) and (e) of this section.

* * * * *

(7) For each period when an affected continuous kiln used to manufacture refractory products that use organic HAP was operating while the THC control device was out of service, the compliance report must include a description of the control device maintenance performed, including the information specified in paragraphs (c)(7)(i) through (vi) of this section.

(i) The date and time when the control device was shut down and restarted.

(ii) Identification of the kiln that was operating and the number of hours that the kiln operated while the control device was out of service.

(iii) A statement of whether or not the control device maintenance was included in your approved request to bypass the control device while scheduled maintenance is performed, developed as specified in § 63.9792(e).

(iv) Before May 19, 2022, a statement of whether emissions were minimized while the control device was out of service in accordance with your OM&M plan. After May 19, 2022, a statement of whether emissions were minimized while the control device was out of service in accordance with your OM&M plan and the information specified in paragraphs (c)(7)(iv)(A) through (C) of this section.

(A) The average organic HAP processing rate based on actual production on a 6-month rolling basis (not to include periods of kiln shut down) or the lowest hourly organic HAP processing rate from the most recent performance test on that kiln, whichever is lower.

(B) The actual hourly organic HAP processing rate for the kiln while the control device was out of service.

(C) The amount of product manufactured and the mass of organic HAP in the product manufactured in the kiln while the control device was out of service.

(v) After May 19, 2022, an estimate of the THC emissions from the continuous kiln stack while the control device was out of service.

(vi) After May 19, 2022, the total number of hours that the kiln has operated while the control device was out of service during the last year on a 12-month rolling basis.

(d) Before May 19, 2022, for each deviation from an emission limitation (emission limit, operating limit, or work practice standard) that occurs at an affected source where you are not using a CPMS to comply with the emission limitations in this subpart, the compliance report must contain the information in paragraphs (c)(1) through (4) and (d)(1) and (2) of this section. This includes periods of SSM. On or after May 19, 2022, for each deviation from an emission limitation (emission limit, operating limit, or work practice standard) that occurs at an affected source where you are not using a CPMS to comply with the emission limitations in this subpart, the compliance report must contain the information in paragraphs (c)(1) through (4) and (d)(1) through (3) of this section.

(1) The compliance report must include the total operating time of each affected source during the reporting period.

(2) The compliance report must include information on the number,

duration in hours, and cause of deviations (including unknown cause, if applicable) and the corrective action taken.

(3) The compliance report must include the date and time of each deviation, a list of the affected sources or equipment, and an estimate of each regulated pollutant emitted over the emission limit and a description of the method used to estimate the emissions.

(e) Before May 19, 2022, for each deviation from an emission limitation (emission limit, operating limit, or work practice standard) occurring at an affected source where you are using a CPMS to comply with the emission limitation in this subpart, the compliance report must include the information in paragraphs (c)(1) through (4) and (e)(1) through (13) of this section. This includes periods of SSM. On or after May 19, 2022, for each deviation from an emission limitation (emission limit, operating limit, or work practice standard) occurring at an affected source where you are using a CPMS to comply with the emission limitation in this subpart, the compliance report must include the information in paragraphs (c)(1) through (4) and (e)(1) through (13) of this section.

(1) The total operating time of each affected source during the reporting period.

(2) Before May 19, 2022, the date and time that each startup, shutdown, or malfunction started and stopped. On or after May 19, 2022, the date and time that each startup, shutdown, or malfunction started and stopped is not required.

(3) The date, time, and duration in hours that each CPMS was inoperative.

(4) The date, time and duration in hours that each CPMS was out of control, including the information in § 63.8(c)(8), as required by your OM&M plan.

(5) Before May 19, 2022, the date and time that each deviation from an emission limitation (emission limit, operating limit, or work practice standard) started and stopped, and whether each deviation occurred during a period of startup, shutdown, or malfunction. On or after May 19, 2022, for each deviation from an emission limitation (emission limit, operating limit, or work practice standard), the date and time that each deviation started and stopped, the duration in hours, a list of the affected sources or equipment, an estimate of each regulated pollutant emitted over the emission limit, and a description of the method used to estimate the emissions.

(6) A description of corrective action taken in response to a deviation.

(7) The total number of deviations during the reporting period, a summary of the total duration in hours of the deviations during the reporting period, and the total duration as a percentage of the total source operating time during that reporting period.

(8) Before May 19, 2022, a breakdown of the total duration of the deviations during the reporting period into those that are due to startup, shutdown, control equipment problems, process problems, other known causes, and other unknown causes. On or after May 19, 2022, a breakdown of the total duration of the deviations during the reporting period into those that are due to control equipment problems, process problems, other known causes, and other unknown causes.

(9) A summary of the total duration in hours of CPMS downtime during the reporting period and the total duration of CPMS downtime as a percentage of the total source operating time during that reporting period.

(10) A brief description of the process units.

(11) A brief description of the CPMS.

(12) The date of the latest CPMS initial validation or accuracy audit.

(13) A description of any changes in CPMS, processes, or controls since the last reporting period.

* * * * *

(g) Before November 19, 2021, if you operate a clay refractory products kiln or a chromium refractory products kiln that is subject to the work practice standard specified in item 3 or 4 of Table 3 to this subpart, and you use a fuel other than natural gas or equivalent to fire the affected kiln, you must submit a report of alternative fuel use within 10 working days after terminating the use of the alternative fuel. The report must include the information in paragraphs (g)(1) through (6) of this section. On and after November 19, 2021, you may not use a fuel other than natural gas or equivalent to fire the affected kiln.

* * * * *

(h) Beginning on May 19, 2022, within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (h)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's CDX (*https://cdx.epa.gov/).* The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *Confidential business information (CBI).* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (h)(1) or (2) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAPQS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (h)(1) and (2) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(i) Beginning on May 19, 2022, within 60 days after the date of completing each continuous emissions monitoring system (CEMS) performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (i)(1) through (3) of this section.

(1) *Performance evaluations of CEMS measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through the EPA's CDX. The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) *Performance evaluations of CEMS measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* The results of the performance evaluation must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *CBI.* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (i)(1) or (2) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (h)(1) and (2) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(j) Beginning May 19, 2022, you must submit all subsequent Notification of Compliance Status reports in PDF format to the EPA via CEDRI, which can be accessed through EPA's CDX (*https://cdx.epa.gov/*).The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, submit a complete report, including information claimed to be CBI, to the EPA. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Refractory Lead MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph (j). All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(k) If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with that reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (k)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(5) You must provide to the Administrator a written description identifying:

(i) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(6) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(l) If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of *force majeure* for failure to timely comply with that reporting requirement. To assert a claim of *force majeure,* you must meet the requirements outlined in paragraphs (l)(1) through (5) of this section.

(1) You may submit a claim if a *force majeure* event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a *force majeure* event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(2) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(3) You must provide to the Administrator:

(i) A written description of the *force majeure* event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the *force majeure* event;

(iii) A description of measures taken or to be taken to minimize the delay in reporting; and

(iv) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(4) The decision to accept the claim of *force majeure* and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(5) In any circumstance, the reporting must occur as soon as possible after the *force majeure* event occurs.

■ 13. Section 63.9816 is amended by revising paragraph (a)(2) and paragraphs (c)(5), (8), and (10) to read as follows:

§ 63.9816 What records must I keep?

(a) * * *

(2) Before May 19, 2022, the records in § 63.6(e)(3)(iii) through (v) related SSM.

* * * * *

(c) * * *

(5) For each deviation of an operating limit parameter value, record the information in paragraphs (c)(5)(i) through (iv) of this section.

(i) The date, time, and duration in hours of the deviation.

(ii) On or after May 19, 2022, a list of the affected sources or equipment.

(iii) On or after May 19, 2022, an estimate of the quantity in pounds of each regulated pollutant over any emission limit and a description of the method used to estimate emissions.

(iv) Actions taken to minimize emissions in accordance with § 63.9792(b), a brief explanation of the cause of the deviation, and the corrective action taken to return the affected unit to its normal or usual manner of operation.

* * * * *

(8) Records of maintenance activities and inspections performed on control devices, including all records associated with the scheduled maintenance of the THC control devices on continuous kilns used to manufacture refractory products that use organic HAP, as specified in § 63.9792(e).

* * * * *

(10) Current copies of the OM&M plan, including any revisions and records documenting conformance with those revisions.

■ 14. Section 63.9820 is revised to read as follows:

§ 63.9820 What parts of the General Provisions apply to me?

Table 11 to this subpart shows which parts of the General Provisions specified in §§ 63.1 through 63.16 apply to you.

■ 15. Section 63.9822 is amended by revising paragraph (c) introductory text and adding paragraph (c)(5) to read as follows:

§ 63.9822 Who implements and enforces this subpart?

* * * * *

(c) The authorities that cannot be delegated to state, local, or tribal agencies are as specified in paragraphs (c)(1) through (5) of this section.

* * * * *

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 16. Section 63.9824 is amended by revising the definition of ''Particulate matter (PM)'' to read as follows:

§ 63.9824 What definitions apply to this subpart?

* * * * *

Particulate matter (PM) means, for the purposes of this subpart, emissions of particulate matter that serve as a measure of total particulate emissions as measured by EPA Method 5 of 40 CFR part 60, appendix A–3.

* * * * *

■ 17. Table 1 to Subpart SSSSS is revised to read as follows:

Table 1 to Subpart SSSSS of Part 63—Emission Limits

As stated in § 63.9788, you must comply with the emission limits for affected sources in the following table:

For . . .	You must meet the following emission limits . . .
1. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP; each new or existing coking oven and defumer that is used to produce pitch-impregnated refractory products; each new shape preheater that is used to produce pitch-impregnated refractory products; AND each new or existing process unit that is exhausted to a thermal or catalytic oxidizer that also controls emissions from an affected shape preheater or pitch working tank.	As specified in items 2 through 9 of this table.
2. Continuous process units that are controlled with a thermal or catalytic oxidizer.	a. The 3-hour block average THC concentration must not exceed 20 parts per million by volume, dry basis (ppmvd), corrected to 18 percent oxygen, at the outlet of the control device; or b. The 3-hour block average THC mass emissions rate must be reduced by at least 95 percent.
3. Continuous process units that are equipped with a control device other than a thermal or catalytic oxidizer.	a. The 3-hour block average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen, at the outlet of the control device; or b. The 3-hour block average THC mass emissions rate must be reduced by at least 95 percent.
4. Continuous process units that use process changes to reduce organic HAP emissions.	The 3-hour block average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen, at the outlet of the process gas stream.
5. Continuous kilns that are not equipped with a control device.	The 3-hour block average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen, at the outlet of the process gas stream.
6. Batch process units that are controlled with a thermal or catalytic oxidizer.	a. The 2-run block average THC concentration for the 3-hour peak emissions period must not exceed 20 ppmvd, corrected to 18 percent oxygen, at the outlet of the control device; or b. The 2-run block average THC mass emissions rate for the 3-hour peak emissions period must be reduced by at least 95 percent.
7. Batch process units that are equipped with a control device other than a thermal or catalytic oxidizer.	a. The 2-run block average THC concentration for the 3-hour peak emissions period must not exceed 20 ppmvd, corrected to 18 percent oxygen, at the outlet of the control device; or b. The 2-run block average THC mass emissions rate for the 3-hour peak emissions period must be reduced by at least 95 percent.

For . . .	You must meet the following emission limits . . .
8. Batch process units that use process changes to reduce organic HAP emissions.	The 2-run block average THC concentration for the 3-hour peak emissions period must not exceed 20 ppmvd, corrected to 18 percent oxygen, at the outlet of the process gas stream.
9. Batch process kilns that are not equipped with a control device.	The 2-run block average THC concentration for the 3-hour peak emissions period must not exceed 20 ppmvd, corrected to 18 percent oxygen, at the outlet of the process gas stream.
10. Each new continuous kiln that is used to produce clay refractory products.	a. The 3-hour block average HF emissions must not exceed 0.019 kilograms per megagram (kg/Mg) (0.038 pounds per ton (lb/ton)) of uncalcined clay processed, OR the 3-hour block average HF mass emissions rate must be reduced by at least 90 percent; and b. The 3-hour block average HCl emissions must not exceed 0.091 kg/Mg (0.18 lb/ton) of uncalcined clay processed, OR the 3-hour block average HCl mass emissions rate must be reduced by at least 30 percent; and c. The 3-hour block average PM emissions must not exceed 1.4 kg/Mg (3.1 lb/hr); and d. The 3-hour block average Hg concentration must not exceed 6.1 micrograms per dry standard cubic meter (μg/dscm), corrected to 18 percent oxygen, at the outlet of the control device or the process gas stream.
11. Each new batch process kiln that is used to produce clay refractory products.	a. The 2-run block average HF mass emissions rate for the 3-hour peak emissions period must be reduced by at least 90 percent; and b. The 2-run block average HCl mass emissions rate for the 3-hour peak emissions period must be reduced by at least 30 percent; and c. The 2-run block average PM emissions for the 3-hour peak emissions period must not exceed 1.4 kg/Mg (3.1 lb/hr); and d. The 2-run block average Hg concentration for the 3-hour peak emissions period must not exceed 6.1 μg/dscm, corrected to 18 percent oxygen, at the outlet of the control device or the process gas stream.
12. Each existing continuous kiln that is used to produce clay refractory products on and after November 20, 2022.	a. The 3-hour block average PM emissions must not exceed 4.3 kg/Mg (9.5 lb/hr); and b. The 3-hour block average Hg concentration must not exceed 18 μg/dscm, corrected to 18 percent oxygen, at the outlet of the control device or the process gas stream.
13. Each existing batch kiln that is used to produce clay refractory products on and after November 20, 2022.	a. The 2-run block average PM emissions for the 3-hour peak emissions period must not exceed 4.3 kg/Mg (9.5 lb/hr); and b. The 2-run block average Hg concentration for the 3-hour peak emissions period must not exceed 18 μg/dscm, corrected to 18 percent oxygen, at the outlet of the control device or the process gas stream.

■ 18. Table 2 to Subpart SSSSS is revised to read as follows:

Table 2 to Subpart SSSSS of Part 63—Operating Limits

As stated in § 63.9788, you must comply with the operating limits for affected sources in the following table:

For . . .	You must . . .
1. Each affected source listed in Table 1 to this subpart.	a. Operate all affected sources according to the requirements to this subpart on and after the date on which the initial performance test is conducted or required to be conducted, whichever date is earlier; and b. Capture emissions and vent them through a closed system; and c. Operate each control device that is required to comply with this subpart on each affected source during all periods that the source is operating, except where specified in § 63.9792(e), item 2 of this table, item 5 of Table 3 to this subpart, item 13 of Table 4 to this subpart, and item 6 of Table 9 to this subpart for THC control devices on continuous kilns used to manufacture refractory products that use organic HAP; and d. Record all operating parameters specified in Table 8 to this subpart for the affected source; and e. Prepare and implement a written OM&M plan as specified in § 63.9792(d).
2. Each affected continuous kiln used to manufacture refractory products that use organic HAP that is equipped with an emission control device for THC.	a. Receive approval from the Administrator before taking the control device on the affected kiln out of service for scheduled maintenance, as specified in § 63.9792(e); and b. Before May 19, 2022, minimize HAP emissions from the affected kiln during all periods of scheduled maintenance of the kiln control device when the kiln is operating and the control device is out of service; on and after May 19, 2022, you must minimize HAP emissions during the period when the kiln is operating and the control device is out of service by complying with the applicable standard in Table 3 to this subpart; and c. Minimize the duration of all periods of scheduled maintenance of the kiln control device when the kiln is operating and the control device is out of service. On and after May 19, 2022, the total time during which the kiln is operating and the control device is out of service for the each year on a 12-month rolling basis must not exceed 750 hours.

For . . .	You must . . .
3. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP; each new or existing coking oven and defumer that is used to produce pitch-impregnated refractory products; each new shape preheater that is used to produce pitch-impregnated refractory products; AND each new or existing process unit that is exhausted to a thermal or catalytic oxidizer that also controls emissions from an affected shape preheater or pitch working tank.	Satisfy the applicable operating limits specified in items 4 through 9 of this table.
4. Each affected continuous process unit.	Maintain the 3-hour block average organic HAP processing rate (pounds per hour) at or below the maximum organic HAP processing rate established during the most recent performance test.
5. Continuous process units that are equipped with a thermal oxidizer.	Maintain the 3-hour block average operating temperature in the thermal oxidizer combustion chamber at or above the minimum allowable operating temperature for the oxidizer established during the most recent performance test.
6. Continuous process units that are equipped with a catalytic oxidizer.	a. Maintain the 3-hour block average operating temperature at the inlet of the catalyst bed of the oxidizer at or above the minimum allowable operating temperature for the oxidizer established during the most recent performance test; and b. Check the activity level of the catalyst at least every 12 months.
7. Each affected batch process unit	For each batch cycle, maintain the organic HAP processing rate (pounds per batch) at or below the maximum organic HAP processing rate established during the most recent performance test.
8. Batch process units that are equipped with a thermal oxidizer.	a. From the start of each batch cycle until 3 hours have passed since the process unit reached maximum temperature, maintain the hourly average operating temperature in the thermal oxidizer combustion chamber at or above the minimum allowable operating temperature established for the corresponding period during the most recent performance test, as determined according to item 11 of Table 4 to this subpart; and b. For each subsequent hour of the batch cycle, maintain the hourly average operating temperature in the thermal oxidizer combustion chamber at or above the minimum allowable operating temperature established for the corresponding hour during the most recent performance test, as specified in item 13 of Table 4 to this subpart.
9. Batch process units that are equipped with a catalytic oxidizer.	a. From the start of each batch cycle until 3 hours have passed since the process unit reached maximum temperature, maintain the hourly average operating temperature at the inlet of the catalyst bed at or above the minimum allowable operating temperature established for the corresponding period during the most recent performance test, as determined according to item 12 of Table 4 to this subpart; and b. For each subsequent hour of the batch cycle, maintain the hourly average operating temperature at the inlet of the catalyst bed at or above the minimum allowable operating temperature established for the corresponding hour during the most recent performance test, as specified in item 13 of Table 4 to this subpart; and c. Check the activity level of the catalyst at least every 12 months.
10. Each new kiln that is used to process clay refractory products.	Satisfy the applicable operating limits specified in items 11 through 13 of this table.
11. Each affected kiln that is equipped with a DLA.	a. Maintain the 3-hour block average pressure drop across the DLA at or above the minimum levels established during the most recent performance test; and b. Maintain free-flowing limestone in the feed hopper, silo, and DLA at all times; and c. Maintain the limestone feeder at or above the level established during the most recent performance test; and d. Use the same grade of limestone from the same source as was used during the most recent performance test and maintain records of the source and type of limestone used; and e. Maintain no VE from the stack.
12. Each affected kiln that is equipped with a DIFF or DLS/FF.	a. Initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with the OM&M plan; and b. Verify at least once each 8-hour shift that lime is free-flowing by means of a visual check, checking the output of a load cell, carrier gas/lime flow indicator, or carrier gas pressure drop measurement system; and c. Record the lime feeder setting daily to verify that the feeder setting is at or above the level established during the most recent performance test.
13. Each affected kiln that is equipped with a wet scrubber.	a. Maintain the 3-hour block average pressure drop across the scrubber, liquid pH, and liquid flow rate at or above the minimum levels established during the most recent performance test; and b. If chemicals are added to the scrubber liquid, maintain the 3-hour block average chemical feed rate at or above the minimum chemical feed rate established during the most recent performance test.
14. Each new and existing kiln used to process clay refractory products that is equipped with an activated carbon injection system.	Maintain the average carbon flow rate for each 3-hour block period at or above the average carbon flow rate established during the Hg performance test in which compliance was demonstrated.

For . . .	You must . . .
15. Each new and existing kiln that is used to process clay refractory products with no add-on control and each existing kiln that is equipped with a DLA.	Maintain no VE from the stack.
16. Each existing kiln used to process clay refractory products that is equipped with a FF.	Initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with the OM&M plan OR maintain no VE from the stack.
17. Each existing kiln used to process clay refractory products that is equipped with a wet scrubber.	Maintain the 3-hour block average pressure drop across the scrubber and liquid flow rate at or above the minimum levels established during the most recent performance test.

■ 19. Table 3 to Subpart SSSSS is revised to read as follows:

Table 3 to Subpart SSSSS of Part 63—Work Practice Standards

As stated in § 63.9788, you must comply with the work practice standards for affected sources in the following table:

For . . .	You must . . .	According to one of the following requirements . . .
1. Each basket or container that is used for holding fired refractory shapes in an existing shape preheater and autoclave during the pitch impregnation process.	a. Control POM emissions from any affected shape preheater.	i. At least every 10 preheating cycles, clean the residual pitch from the surfaces of the basket or container by abrasive blasting prior to placing the basket or container in the affected shape preheater; or ii. At least every 10 preheating cycles, subject the basket or container to a thermal process cycle that meets or exceeds the operating temperature and cycle time of the affected preheater, AND is conducted in a process unit that is exhausted to a thermal or catalytic oxidizer that is comparable to the control device used on an affected defumer or coking oven; or iii. Capture emissions from the affected shape preheater and vent them to the control device that is used to control emissions from an affected defumer or coking oven, or to a comparable thermal or catalytic oxidizer.
2. Each new or existing pitch working tank	Control POM emissions.	Capture emissions from the affected pitch working tank and vent them to the control device that is used to control emissions from an affected defumer or coking oven, OR to a comparable thermal or catalytic oxidizer.
3. Each new or existing chromium refractory products kiln.	Minimize fuel-based HAP emissions.	Before May 19, 2022, use natural gas, or equivalent, as the kiln fuel, except during periods of natural gas curtailment or supply interruption, as defined in § 63.9824. On and after May 19, 2022, use natural gas, or equivalent, as the kiln fuel at all times.
4. Each existing clay refractory products kiln	Minimize fuel-based HAP emissions.	Before May 19, 2022, use natural gas, or equivalent, as the kiln fuel, except during periods of natural gas curtailment or supply interruption, as defined in § 63.9824. On and after May 19, 2022, use natural gas, or equivalent, as the kiln fuel at all times.
5. Each affected continuous kiln used to manufacture refractory products that use organic HAP that is equipped with an emission control device for THC with Administrator approval to take the control device out of service for scheduled maintenance, as specified in § 63.9792(e).	Minimize HAP emissions.	i. Before May 19, 2022, minimize HAP emissions from the affected kiln during all periods of scheduled maintenance of the kiln control device when the kiln is operating and the control device is out of service consistent with your OM&M plan and minimize the time period during which the kiln is operating and the control device is out of service; or ii. On and after May 19, 2022, minimize HAP emissions during the period when the kiln is operating and the control device is out of service by maintaining the organic HAP processing rate (lb/hr) below the average organic HAP processing rate based on actual production on a 6-month rolling basis (not to include periods of kiln shut down) or below the organic HAP processing rate (lb/hr) that coincides with the lowest hour of the most recent 3-hour performance test, whichever is lower); and minimize the time period during which the kiln is operating and the control device is out of service, not to exceed 750 hours for the year (on a 12-month rolling basis).
6. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP, on and after Novermber 19, 2021.	Minimize fuel-based HAP emissions.	Use natural gas, or equivalent, as the kiln fuel, at all times.

■ 20. Table 4 to Subpart SSSSS is revised to read as follows:

Table 4 to Subpart SSSSS to Part 63—Requirements for Performance Tests

As stated in § 63.9800, you must comply with the requirements for performance tests for affected sources in the following table:

For . . .	You must . . .	Using . . .	According to the following requirements . . .
1. Each affected source listed in Table 1 to this subpart.	a. Conduct performance tests.	i. The requirements of the general provisions in subpart A of this part and the requirements to this subpart.	(1) Record the date of the test; and (2) Identify the emission source that is tested; and (3) Collect and record the corresponding operating parameter and emission test data listed in this table for each run of the performance test; and (4) Repeat the performance test at least every 5 years; and (5) Repeat the performance test before changing the parameter value for any operating limit specified in your OM&M plan; and (6) If complying with the THC concentration or THC percentage reduction limits specified in items 2 through 9 of Table 1 to this subpart, repeat the performance test under the conditions specified in items 2.a.2. and 2.a.3. of this table; and (7) If complying with the emission limits for new clay refractory products kilns specified in items 10 and 11 of Table 1 to this subpart, repeat the performance test under the conditions specified in items 14.a.i.4. and 17.a.i.4. of this table.
	b. Select the locations of sampling ports and the number of traverse points.	i. Method 1 or 1A of 40 CFR part 60, appendix A–1.	(1) To demonstrate compliance with the percentage reduction limits specified in items 2.b., 3.b., 6.b., 7.b., 10, and 11 of Table 1 to this subpart, locate sampling sites at the inlet of the control device and at either the outlet of the control device or at the stack prior to any releases to the atmosphere; and (2) To demonstrate compliance with any other emission limit specified in Table 1 to this subpart, locate all sampling sites at the outlet of the control device or at the stack prior to any releases to the atmosphere.
	c. Determine gas velocity and volumetric flow rate.	Method 2, 2A, 2C, 2D, 2F, or 2G of 40 CFR part 60, appendix A–1 and A–2.	Measure gas velocities and volumetric flow rates at 1-hour intervals throughout each test run.
	d. Conduct gas molecular weight analysis.	i. Method 3, 3A, or 3B of 40 CFR part 60, appendix A–2; or. ii. ASME PTC 19.10–1981—Part 10 [a]	As specified in the applicable test method. You may use the manual procedures (but not instrumental procedures) of ASME PTC 19.10–1981—Part 10 [a] as an alternative to EPA Method 3B.
	e. Measure gas moisture content.	Method 4 of 40 CFR part 60, appendix A–3.	As specified in the applicable test method.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
2. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP; each new or existing coking oven and defumer that is used to produce pitch-impregnated refractory products; each new shape preheater that is used to produce pitch-impregnated refractory products; AND each new or existing process unit that is exhausted to a thermal or catalytic oxidizer that also controls emissions from an affected shape preheater or pitch working tank.	a. Conduct performance tests.	.....	(1) Conduct the performance test while the source is operating at the maximum organic HAP processing rate, as defined in § 63.9824, reasonably expected to occur; and (2) Repeat the performance test before starting production of any product for which the organic HAP processing rate is likely to exceed the maximum organic HAP processing rate established during the most recent performance test by more than 10 percent, as specified in § 63.9798(c); and (3) Repeat the performance test on any affected uncontrolled kiln following process changes (*e.g.,* shorter curing oven cycle time) that could increase organic HAP emissions from the affected kiln, as specified in § 63.9798(d).
	b. Satisfy the applicable requirements listed in items 3 through 13 of this table.		
3. Each affected continuous process unit.	a. Perform a minimum of 3 test runs.	The appropriate test methods specified in items 1, 4, and 5 of this table.	Each test run must be at least 1 hour in duration.
	b. Establish the operating limit for the maximum organic HAP processing rate.	i. Method 311 of 40 CFR part 63, appendix A, OR material safety data sheets (MSDS), OR product labels to determine the mass fraction of organic HAP in each resin, binder, or additive; and	(1) Calculate and record the organic HAP content of all refractory shapes that are processed during the performance test, based on the mass fraction of organic HAP in the resins, binders, or additives; the mass fraction of each resin, binder, or additive, in the product; and the process feed rate; and
		ii. Product formulation data that specify the mass fraction of each resin, binder, and additive in the products that are processed during the performance test; and.	(2) Calculate and record the organic HAP processing rate (pounds per hour) for each test run; and
		iii. Process feed rate data (tons per hour).	(3) Calculate and record the maximum organic HAP processing rate as the average of the organic HAP processing rates for the three test runs.
	c. Record the operating temperature of the affected source.	Process data	During each test run and at least once per hour, record the operating temperature in the highest temperature zone of the affected source.
4. Each continuous process unit that is subject to the THC emission limit listed in item 2.a., 3.a., 4, or 5 of Table 1 to this subpart.	a. Measure THC concentrations at the outlet of the control device or in the stack.	i. Method 25A of 40 CFR part 60, appendix A–7.	(1) Each minute, measure and record the concentrations of THC in the exhaust stream; and (2) Provide at least 50 1-minute measurements for each valid hourly average THC concentration.
	b. Measure oxygen concentrations at the outlet of the control device or in the stack.	i. Method 3A of 40 CFR part 60, appendix A–2.	(1) Each minute, measure and record the concentrations of oxygen in the exhaust stream; and (2) Provide at least 50 1-minute measurements for each valid hourly average THC concentration.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
	c. Determine the hourly average THC concentration, corrected to 18 percent oxygen.	i. Equation 1 of § 63.9800(g)(1); and ii. The 1-minute THC and oxygen concentration data.	(1) Calculate the hourly average THC concentration for each hour of the performance test as the average of the 1-minute THC measurements; and (2) Calculate the hourly average oxygen concentration for each hour of the performance test as the average of the 1-minute oxygen measurements; and (3) Correct the hourly average THC concentrations to 18 percent oxygen using Equation 1 of § 63.9800(g)(1).
	d. Determine the 3-hour block average THC emission concentration, corrected to 18 percent oxygen.	The hourly average concentration of THC, corrected to 18 percent oxygen, for each test run.	Calculate the 3-hour block average THC emission concentration, corrected to 18 percent oxygen, as the average of the hourly average THC emission concentrations, corrected to 18 percent oxygen.
5. Each continuous process unit that is subject to the THC percentage reduction limit listed in item 2.b. or 3.b. of Table 1 to this subpart.	a. Measure THC concentrations at the inlet and outlet of the control device.	i. Method 25A of 40 CFR part 60, appendix A–7.	(1) Each minute, measure and record the concentrations of THC at the inlet and outlet of the control device; and (2) Provide at least 50 1-minute measurements for each valid hourly average THC concentration at the control device inlet and outlet.
	b. Determine the hourly THC mass emissions rates at the inlet and outlet of the control device.	i. The 1-minute THC concentration data at the control device inlet and outlet; and ii. The volumetric flow rates at the control device inlet and outlet.	Calculate the hourly THC mass emissions rates at the control device inlet and outlet for each hour of the performance test.
	c. Determine the 3-hour block average THC percentage reduction.	i. The hourly THC mass emissions rates at the inlet and outlet of the control device.	(1) Calculate the hourly THC percentage reduction for each hour of the performance test using Equation 2 of § 63.9800(g)(1); and (2) Calculate the 3-hour block average THC percentage reduction.
6. Each continuous process unit that is equipped with a thermal oxidizer.	a. Establish the operating limit for the minimum allowable thermal oxidizer combustion chamber temperature.	i. Continuous recording of the output of the combustion chamber temperature measurement device.	(1) At least every 15 minutes, measure and record the thermal oxidizer combustion chamber temperature; and (2) Provide at least one measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average thermal oxidizer combustion chamber temperature for each hour of the performance test; and (4) Calculate the minimum allowable combustion chamber temperature as the average of the combustion chamber temperatures for the three test runs, minus 14 °C (25 °F).
7. Each continuous process unit that is equipped with a catalytic oxidizer.	a. Establish the operating limit for the minimum allowable temperature at the inlet of the catalyst bed.	i. Continuous recording of the output of the temperature measurement device.	(1) At least every 15 minutes, measure and record the temperature at the inlet of the catalyst bed; and (2) Provide at least one catalyst bed inlet temperature measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average catalyst bed inlet temperature for each hour of the performance test; and (4) Calculate the minimum allowable catalyst bed inlet temperature as the average of the catalyst bed inlet temperatures for the three test runs, minus 14 °C (25 °F).
8. Each affected batch process unit.	a. Perform a minimum of two test runs.	i. The appropriate test methods specified in items 1, 9, and 10 of this table.	(1) Each test run must be conducted over a separate batch cycle unless you satisfy the requirements of § 63.9800(f)(3) and (4); and (2) Each test run must begin with the start of a batch cycle, except as specified in item 8.a.i.4. of this table; and (3) Each test run must continue until the end of the batch cycle, except as specified in items 8.a.i.4. and 8.a.i.5. of this table; and (4) If you develop an emissions profile, as described in § 63.9802(a), AND for sources equipped with a thermal or catalytic oxidizer, you do not reduce the oxidizer operating temperature, as specified in item 13 of this table, you can limit each test run to the 3-hour peak THC emissions period; and

For . . .	You must . . .	Using . . .	According to the following requirements . . .
			(5) If you do not develop an emissions profile, a test run can be stopped, and the results of that run considered complete, if you measure emissions continuously until at least 3 hours after the affected process unit has reached maximum temperature, AND the hourly average THC mass emissions rate has not increased during the 3-hour period since maximum process temperature was reached, and the hourly average concentrations of THC at the inlet of the control device have not exceeded 20 ppmvd, corrected to 18 percent oxygen, during the 3-hour period since maximum process temperature was reached or the hourly average THC percentage reduction has been at least 95 percent during the 3-hour period since maximum process temperature was reached, AND, for sources equipped with a thermal or catalytic oxidizer, at least 1 hour has passed since any reduction in the operating temperature of the oxidizer, as specified in item 13 of this table.
	b. Establish the operating limit for the maximum organic HAP processing rate.	i. Method 311 of 40 CFR part 63, appendix A, OR MSDS, OR product labels to determine the mass fraction of organic HAP in each resin, binder, or additive; and	(1) Calculate and record the organic HAP content of all refractory shapes that are processed during the performance test, based on the mass fraction of HAP in the resins, binders, or additives; the mass fraction of each resin, binder, or additive, in the product, and the batch weight prior to processing; and
		ii. Product formulation data that specify the mass fraction of each resin, binder, and additive in the products that are processed during the performance test; and.	(2) Calculate and record the organic HAP processing rate (pounds per batch) for each test run; and (3) Calculate and record the maximum organic HAP processing rate as the average of the organic HAP processing rates for the two test runs.
		iii. Batch weight (tons)	
	c. Record the batch cycle time.	Process data	Record the total elapsed time from the start to the completion of the batch cycle.
	d. Record the operating temperature of the affected source.	Process data	Record the operating temperature of the affected source at least once every hour from the start to the completion of the batch cycle.
9. Each batch process unit that is subject to the THC emission limit listed in item 6.a., 7.a., 8, or 9 of Table 1 to this subpart.	a. Measure THC concentrations at the outlet of the control device or in the stack.	i. Method 25A of 40 CFR part 60, appendix A–7.	(1) Each minute, measure and record the concentrations of THC in the exhaust stream; and (2) Provide at least 50 1-minute measurements for each valid hourly average THC concentration.
	b. Measure oxygen concentrations at the outlet of the control device or in the stack.	i. Method 3A of 40 CFR part 60, appendix A–2.	(1) Each minute, measure and record the concentrations of oxygen in the exhaust stream; and (2) Provide at least 50 1-minute measurements for each valid hourly average oxygen concentration.
	c. Determine the hourly average THC concentration, corrected to 18 percent oxygen.	i. Equation 1 of § 63.9800(g)(1); and ii. The 1-minute THC and oxygen concentration data.	(1) Calculate the hourly average THC concentration for each hour of the performance test as the average of the 1-minute THC measurements; and (2) Calculate the hourly average oxygen concentration for each hour of the performance test as the average of the 1-minute oxygen measurements; and (3) Correct the hourly average THC concentrations to 18 percent oxygen using Equation 1 of § 63.9800(g)(1).
	d. Determine the 3-hour peak THC emissions period for each test run.	The hourly average THC concentrations, corrected to 18 percent oxygen.	Select the period of 3 consecutive hours over which the sum of the hourly average THC concentrations, corrected to 18 percent oxygen, is greater than the sum of the hourly average THC emission concentrations, corrected to 18 percent oxygen, for any other period of 3 consecutive hours during the test run.
	e. Determine the average THC concentration, corrected to 18 percent oxygen, for each test run.	The hourly average THC emission concentrations, corrected to 18 percent oxygen, for the 3-hour peak THC emissions period.	Calculate the average of the hourly average THC concentrations, corrected to 18 percent oxygen, for the 3 hours of the peak emissions period for each test run.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
	f. Determine the 2-run block average THC concentration, corrected to 18 percent oxygen, for the emission test.	The average THC concentration, corrected to 18 percent oxygen, for each test run.	Calculate the average of the average THC concentrations, corrected to 18 percent oxygen, for each run.
10. Each batch process unit that is subject to the THC percentage reduction limit listed in item 6.b. or 7.b. of Table 1 to this subpart.	a. Measure THC concentrations at the inlet and outlet of the control device.	i. Method 25A of 40 CFR part 60, appendix A–7.	(1) Each minute, measure and record the concentrations of THC at the control device inlet and outlet; and (2) Provide at least 50 1-minute measurements for each valid hourly average THC concentration at the control device inlet and outlet.
	b. Determine the hourly THC mass emissions rates at the control device inlet and outlet.	i. The 1-minute THC concentration data at the control device inlet and outlet; and ii. The volumetric flow rates at the control device inlet and outlet.	(1) Calculate the hourly mass emissions rates at the control device inlet and outlet for each hour of the performance test.
	c. Determine the 3-hour peak THC emissions period for each test run.	The hourly THC mass emissions rates at the control device inlet.	Select the period of 3 consecutive hours over which the sum of the hourly THC mass emissions rates at the control device inlet is greater than the sum of the hourly THC mass emissions rates at the control device inlet for any other period of 3 consecutive hours during the test run.
	d. Determine the average THC percentage reduction for each test run.	i. Equation 2 of § 63.9800(g)(2); and ii. The hourly THC mass emissions rates at the control device inlet and outlet for the 3-hour peak THC emissions period.	Calculate the average THC percentage reduction for each test run using Equation 2 of § 63.9800(g)(2).
	e. Determine the 2-run block average THC percentage reduction for the emission test.	The average THC percentage reduction for each test run.	Calculate the average of the average THC percentage reductions for each test run.
11. Each batch process unit that is equipped with a thermal oxidizer.	a. Establish the operating limit for the minimum thermal oxidizer combustion chamber temperature.	i. Continuous recording of the output of the combustion chamber temperature measurement device.	(1) At least every 15 minutes, measure and record the thermal oxidizer combustion chamber temperature; and (2) Provide at least one temperature measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average combustion chamber temperature for each hour of the 3-hour peak emissions period, as defined in item 9.d. or 10.c. of this table, whichever applies; and (4) Calculate the minimum allowable thermal oxidizer combustion chamber operating temperature as the average of the hourly combustion chamber temperatures for the 3-hour peak emissions period, minus 14 °C (25 °F).
12. Each batch process unit that is equipped with a catalytic oxidizer.	a. Establish the operating limit for the minimum temperature at the inlet of the catalyst bed.	i. Continuous recording of the output of the temperature measurement device.	(1) At least every 15 minutes, measure and record the temperature at the inlet of the catalyst bed; and (2) Provide at least one catalyst bed inlet temperature measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average catalyst bed inlet temperature for each hour of the 3-hour peak emissions period, as defined in item 9.d. or 10.c. of this table, whichever applies; and (4) Calculate the minimum allowable catalytic oxidizer catalyst bed inlet temperature as the average of the hourly catalyst bed inlet temperatures for the 3-hour peak emissions period, minus 14 °C (25 °F).

For . . .	You must . . .	Using . . .	According to the following requirements . . .
13. Each batch process unit that is equipped with a thermal or catalytic oxidizer.	a. During each test run, maintain the applicable operating temperature of the oxidizer until emission levels allow the oxidizer to be shut off or the operating temperature of the oxidizer to be reduced.	.....	(1) The oxidizer can be shut off or the oxidizer operating temperature can be reduced if you do not use an emission profile to limit testing to the 3-hour peak emissions period, as specified in item 8.a.i.4. of this table; and (2) At least 3 hours have passed since the affected process unit reached maximum temperature; and (3) The applicable emission limit specified in item 6.a. or 6.b. of Table 1 to this subpart was met during each of the previous three 1-hour periods; and (4) The hourly average THC mass emissions rate did not increase during the 3-hour period since maximum process temperature was reached; and (5) The applicable emission limit specified in item 6.a. and 6.b. of Table 1 to this subpart was met during each of the four 15-minute periods immediately following the oxidizer temperature reduction; and (6) If the applicable emission limit specified in item 6.a. or 6.b. of Table 1 to this subpart was not met during any of the four 15-minute periods immediately following the oxidizer temperature reduction, you must return the oxidizer to its normal operating temperature as soon as possible and maintain that temperature for at least 1 hour; and (7) Continue the test run until the applicable emission limit specified in items 6.a. and 6.b. of Table 1 to this subpart is met for at least four consecutive 15-minute periods that immediately follow the temperature reduction; and (8) Calculate the hourly average oxidizer operating temperature for each hour of the performance test since the affected process unit reached maximum temperature.
14. Each new continuous kiln that is used to process clay refractory products.	a. Measure emissions of HF and HCl.	i. Method 26A of 40 CFR part 60, appendix A–8; or. ii. Method 26 of 40 CFR part 60, appendix A–8; or. iii. Method 320 of 40 CFR part 63, appendix A	(1) Conduct the test while the kiln is operating at the maximum production level; and (2) You may use EPA Method 26 of 40 CFR part 60, appendix A–8, only if no acid PM (*e.g.,* HF or HCl dissolved in water droplets emitted by sources controlled by a wet scrubber) is present; and (3) If you use EPA Method 320 of 40 CFR part 63, appendix A, you must follow the analyte spiking procedures of Section 13 of EPA Method 320 unless you can demonstrate that the complete spiking procedure has been conducted at a similar source. ASTM D6348–12e1 [a] may be used as an alternative to EPA Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte and is equal or greater than 70 percent and less than or equal to 130 percent; and (4) Repeat the performance test if the affected source is controlled with a DLA and you change the source of the limestone used in the DLA.
	b. Perform a minimum of 3 test runs.	The appropriate test methods specified in items 1 and 14.a. of this table.	Each test run must be at least 1 hour in duration.
15. Each new continuous kiln that is subject to the production-based HF and HCl emission limits specified in items 10.a. and 10.b. of Table 1 to this subpart.	a. Record the uncalcined clay processing rate.	i. Production data; and ii. Product formulation data that specify the mass fraction of uncalcined clay in the products that are processed during the performance test.	(1) Record the production rate (tons per hour of fired product); and (2) Calculate and record the average rate at which uncalcined clay is processed (tons per hour) for each test run; and (3) Calculate and record the 3-run average uncalcined clay processing rate as the average of the average uncalcined clay processing rates for each test run.
	b. Determine the HF mass emissions rate at the outlet of the control device or in the stack.	i. Method 26A of 40 CFR part 60, appendix A–8; or. ii. Method 26 of 40 CFR part 60, appendix A–8; or. iii. Method 320 of 40 CFR part 63, appendix A	Calculate the HF mass emissions rate for each test. ASTM D6348–12e1 [a] may be used as an alternative to EPA Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte and is equal or greater than 70 percent and less than or equal to 130 percent.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
	c. Determine the 3-hour block average production-based HF emissions rate.	i. The HF mass emissions rate for each test run; and. ii. The average uncalcined clay processing rate	(1) Calculate the hourly production-based HF emissions rate for each test run using Equation 3 of § 63.9800(g)(3); and (2) Calculate the 3-hour block average production-based HF emissions rate as the average of the hourly production-based HF emissions rates for each test run.
	d. Determine the HCl mass emissions rate at the outlet of the control device or in the stack.	i. Method 26A of 40 CFR part 60, appendix A–8; or. ii. Method 26 of 40 CFR part 60, appendix A–8; or. iii. Method 320 of 40 CFR part 63, appendix A	Calculate the HCl mass emissions rate for each test run. ASTM D6348–12e1 [a] may be used as an alternative to EPA Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte and is equal or greater than 70 percent and less than or equal to 130 percent.
	e. Determine the 3-hour block average production-based HCl emissions rate.	i. The HCl mass emissions rate for each test run; and. ii. The average uncalcined clay processing rate	(1) Calculate the hourly production-based HCl emissions rate for each test run using Equation 3 of § 63.9800(g)(3); and (2) Calculate the 3-hour block average production-based HCl emissions rate as the average of the production-based HCl emissions rates for each test run.
16. Each new continuous kiln that is subject to the HF and HCl percentage reduction limits specified in items 10.a. and 10.b. of Table 1 to this subpart.	a. Measure the HF mass emissions rates at the inlet and outlet of the control device.	i. Method 26A of 40 CFR part 60, appendix A–8; or. ii. Method 26 of 40 CFR part 60, appendix A–8; or. iii. Method 320 of 40 CFR part 63, appendix A	Calculate the HF mass emissions rates at the control device inlet and outlet for each test run. ASTM D6348–12e1 [a] may be used as an alternative to EPA Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte and is equal or greater than 70 percent and less than or equal to 130 percent.
	b. Determine the 3-hour block average HF percentage reduction.	i. The HF mass emissions rates at the inlet and outlet of the control device for each test run.	(1) Calculate the hourly HF percentage reduction using Equation 2 of § 63.9800(g)(2); and (2) Calculate the 3-hour block average HF percentage reduction as the average of the HF percentage reductions for each test run.
	c. Measure the HCl mass emissions rates at the inlet and outlet of the control device.	i. Method 26A of 40 CFR part 60, appendix A–8; or. ii. Method 26 of 40 CFR part 60, appendix A–8; or. iii. Method 320 of 40 CFR part 63, appendix A	Calculate the HCl mass emissions rates at the control device inlet and outlet for each test run. ASTM D6348–12e1 [a] may be used as an alternative to EPA Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte and is equal or greater than 70 percent and less than or equal to 130 percent.
	d. Determine the 3-hour block average HCl percentage reduction..	i. The HCl mass emissions rates at the inlet and outlet of the control device for each test run.	(1) Calculate the hourly HCl percentage reduction using Equation 2 of § 63.9800(g)(2); and (2) Calculate the 3-hour block average HCl percentage reduction as the average of HCl percentage reductions for each test run.
17. Each new batch process kiln that is used to process clay refractory products.	a. Measure emissions of HF and HCl at the inlet and outlet of the control device.	i. Method 26A of 40 CFR part 60, appendix A–8; or. ii. Method 26 of 40 CFR part 60, appendix A–8; or. iii. Method 320 of 40 CFR part 63, appendix A	(1) Conduct the test while the kiln is operating at the maximum production level; and (2) You may use EPA Method 26 of 40 CFR part 60, appendix A, only if no acid PM (*e.g.,* HF or HCl dissolved in water droplets emitted by sources controlled by a wet scrubber) is present; and (3) If you use EPA Method 320 of 40 CFR part 63, you must follow the analyte spiking procedures of Section 13 of EPA Method 320 unless you can demonstrate that the complete spiking procedure has been conducted at a similar source ASTM D6348–12e1 [a] may be used as an alternative to EPA Method 320 if the test plan preparation and implementation in Annexes A1–A8 are mandatory and the %R in Annex A5 is determined for each target analyte and is equal or greater than 70 percent and less than or equal to 130 percent.; and (4) Repeat the performance test if the affected source is controlled with a DLA and you change the source of the limestone used in the DLA.
	b. Perform a minimum of 2 test runs.	i. The appropriate test methods specified in items 1 and 17.a. of this table.	(1) Each test run must be conducted over a separate batch cycle unless you satisfy the requirements of § 63.9800(f)(3) and (4); and (2) Each test run must consist of a series of 1-hour runs at the inlet and outlet of the control device, beginning with the start of a batch cycle, except as specified in item 17.b.i.4. of this table; and

For . . .	You must . . .	Using . . .	According to the following requirements . . .
			(3) Each test run must continue until the end of the batch cycle, except as specified in item 17.b.i.4. of this table; and (4) If you develop an emissions profile, as described in § 63.9802(b), you can limit each test run to the 3-hour peak HF emissions period.
	c. Determine the hourly HF and HCl mass emissions rates at the inlet and outlet of the control device.	i. The appropriate test methods specified in items 1 and 17.a. of this table.	Determine the hourly mass HF and HCl emissions rates at the inlet and outlet of the control device for each hour of each test run.
	d. Determine the 3-hour peak HF emissions period.	The hourly HF mass emissions rates at the inlet of the control device.	Select the period of 3 consecutive hours over which the sum of the hourly HF mass emissions rates at the control device inlet is greater than the sum of the hourly HF mass emissions rates at the control device inlet for any other period of 3 consecutive hours during the test run.
	e. Determine the 2-run block average HF percentage reduction for the emissions test.	i. The hourly average HF emissions rates at the inlet and outlet of the control device.	(1) Calculate the HF percentage reduction for each hour of the 3-hour peak HF emissions period using Equation 2 of § 63.9800(g)(2); and (2) Calculate the average HF percentage reduction for each test run as the average of the hourly HF percentage reductions for the 3-hour peak HF emissions period for that run; and (3) Calculate the 2-run block average HF percentage reduction for the emission test as the average of the average HF percentage reductions for the two test runs.
	f. Determine the 2-run block average HCl percentage reduction for the emission test.	i. The hourly average HCl emissions rates at the inlet and outlet of the control device.	(1) Calculate the HCl percentage reduction for each hour of the 3-hour peak HF emissions period using Equation 2 § 63.9800(g)(2); and (2) Calculate the average HCl percentage reduction for each test run as the average of the hourly HCl percentage reductions for the 3-hour peak HF emissions period for that run; and (3) Calculate the 2-run block average HCl percentage reduction for the emission test as the average of the average HCl percentage reductions for the two test runs.
18. Each new kiln that is used to process clay refractory products and is equipped with a DLA.	a. Establish the operating limit for the minimum pressure drop across the DLA.	Data from the pressure drop measurement device during the performance test.	(1) At least every 15 minutes, measure the pressure drop across the DLA; and (2) Provide at least one pressure drop measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average pressure drop across the DLA for each hour of the performance test; and (4) Calculate and record the minimum pressure drop as the average of the hourly average pressure drops across the DLA for the two or three test runs, whichever applies.
	b. Establish the operating limit for the limestone feeder setting.	Data from the limestone feeder during the performance test.	(1) Ensure that limestone in the feed hopper, silo, and DLA is free-flowing at all times during the performance test; and (2) Establish the limestone feeder setting 1 week prior to the performance test; and (3) Record and maintain the feeder setting for the 1-week period that precedes the performance test and during the performance test.
19. Each new kiln that is used to process clay refractory products and is equipped with a DIFF or DLS/FF.	a. Document conformance with specifications and requirements of the bag leak detection system.	Data from the installation and calibration of the bag leak detection system.	Submit analyses and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems as part of the Notification of Compliance Status.
	b. Establish the operating limit for the lime feeder setting.	i. Data from the lime feeder during the performance test.	(1) For continuous lime injection systems, ensure that lime in the feed hopper or silo is free-flowing at all times during the performance test; and (2) Record the feeder setting for the three test runs; and (3) If the feed rate setting varies during the three test runs, calculate and record the average feed rate for the two or three test runs, whichever applies.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
20. Each new kiln that is used to process clay refractory products and is equipped with a wet scrubber.	a. Establish the operating limit for the minimum scrubber pressure drop.	i. Data from the pressure drop measurement device during the performance test.	(1) At least every 15 minutes, measure the pressure drop across the scrubber; and (2) Provide at least one pressure drop measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average pressure drop across the scrubber for each hour of the performance test; and (4) Calculate and record the minimum pressure drop as the average of the hourly average pressure drops across the scrubber for the two or three test runs, whichever applies.
	b. Establish the operating limit for the minimum scrubber liquid pH.	i. Data from the pH measurement device during the performance test.	(1) At least every 15 minutes, measure scrubber liquid pH; and (2) Provide at least one pH measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average pH values for each hour of the performance test; and (4) Calculate and record the minimum liquid pH as the average of the hourly average pH measurements for the two or three test runs, whichever applies.
	c. Establish the operating limit for the minimum scrubber liquid flow rate.	i. Data from the flow rate measurement device during the performance test.	(1) At least every 15 minutes, measure the scrubber liquid flow rate; and (2) Provide at least one flow rate measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average liquid flow rate for each hour of the performance test; and (4) Calculate and record the minimum liquid flow rate as the average of the hourly average liquid flow rates for the two or three test runs, whichever applies.
	d. If chemicals are added to the scrubber liquid, establish the operating limit for the minimum scrubber chemical feed rate.	i. Data from the chemical feed rate measurement device during the performance test.	(1) At least every 15 minutes, measure the scrubber chemical feed rate; and (2) Provide at least one chemical feed rate measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average chemical feed rate for each hour of the performance test; and (4) Calculate and record the minimum chemical feed rate as the average of the hourly average chemical feed rates for the two or three test runs, whichever applies.
21. Each new and existing kiln that is used to process clay refractory products that is subject to the PM limits specified in items 10.c. 11.c, 12.a, and 13.a of Table 1 to this subpart.	Measure PM emissions.	Method 5 of 40 CFR part 60, appendix A–3.	
22. Each new and existing kiln that is used to process clay refractory products that is subject to the Hg limits specified in items 10.d. 11.d, 12.b, and 13.b of Table 1 to this subpart.	Measure Hg emissions.	Method 29 of 40 CFR part 60, appendix A–8.	ASTM D6784–16 [a] may be used as an alternative to EPA Method 29 (portion for Hg only).
23. Each new and existing kiln that is used to process clay refractory products and is equipped with an activated carbon injection system.	Establish the operating limit for the average carbon flow rate.	Data from the carbon flow rate measurement conducted during the Hg performance test.	You must measure the carbon flow rate during each test run, determine and record the block average carbon flow rate values for the three test runs, and determine and record the 3-hour block average of the recorded carbon flow rate measurements for the three test runs. The average of the three test runs establishes your minimum site-specific activated carbon flow rate operating limit.

For . . .	You must . . .	Using . . .	According to the following requirements . . .
24. Each existing kiln that is used to process clay refractory products and is equipped with a FF and a bag leak detection system.	Document conformance with specifications and requirements of the bag leak detection system.	Data from the installation and calibration of the bag leak detection system.	Submit analyses and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems as part of the Notification of Compliance Status.
25. Each existing kiln that is used to process clay refractory products and is equipped with a wet scrubber.	a. Establish the operating limit for the minimum scrubber pressure drop.	i. Data from the pressure drop measurement device during the performance test.	(1) At least every 15 minutes, measure the pressure drop across the scrubber; and (2) Provide at least one pressure drop measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average pressure drop across the scrubber for each hour of the performance test; and (4) Calculate and record the minimum pressure drop as the average of the hourly average pressure drops across the scrubber for the two or three test runs, whichever applies.
	b. Establish the operating limit for the minimum scrubber liquid flow rate.	i. Data from the flow rate measurement device during the performance test.	(1) At least every 15 minutes, measure the scrubber liquid flow rate; and (2) Provide at least one flow rate measurement during at least three 15-minute periods per hour of testing; and (3) Calculate the hourly average liquid flow rate for each hour of the performance test; and (4) Calculate and record the minimum liquid flow rate as the average of the hourly average liquid flow rates for the two or three test runs, whichever applies.

[a] Incorporated by reference, see § 63.14.

■ 21. Table 5 to Subpart SSSSS is revised to read as follows:

Table 5 to Subpart SSSSS of Part 63—Initial Compliance With Emission Limits

As stated in § 63.9806, you must show initial compliance with the emission limits for affected sources according to the following table:

For . . .	For the following emission limit . . .	You have demonstrated compliance if . . .
1. Each affected source listed in Table 1 to this subpart.	a. Each applicable emission limit listed in Table 1 to this subpart.	i. Emissions measured using the test methods specified in Table 4 to this subpart satisfy the applicable emission limits specified in Table 1 to this subpart; and ii. You establish and have a record of the operating limits listed in Table 2 to this subpart over the performance test period; and iii. You report the results of the performance test in the Notification of Compliance Status, as specified by § 63.9812(e)(1) and (2).
2. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP; each new or existing coking oven and defumer that is used to produce pitch-impregnated refractory products; each new shape preheater that is used to produce pitch-impregnated refractory products; AND each new or existing process unit that is exhausted to a thermal or catalytic oxidizer that also controls emissions from an affected shape preheater or pitch working tank.	As specified in items 3 through 8 of this table.	You have satisfied the applicable requirements specified in items 3 through 8 of this table.
3. Each affected continuous process unit that is subject to the THC emission concentration limit listed in item 2.a., 3.a., 4, or 5 of Table 1 to this subpart.	The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen.	The 3-hour block average THC emission concentration measured during the performance test using EPA Methods 25A and 3A is equal to or less than 20 ppmvd, corrected to 18 percent oxygen.

For . . .	For the following emission limit . . .	You have demonstrated compliance if . . .
4. Each affected continuous process unit that is subject to the THC percentage reduction limit listed in item 2.b. or 3.b. of Table 1 to this subpart.	The average THC percentage reduction must equal or exceed 95 percent.	The 3-hour block average THC percentage reduction measured during the performance test using EPA Method 25A is equal to or greater than 95 percent.
5. Each affected batch process unit that is subject to the THC emission concentration limit listed in item 6.a., 7.a., 8, or 9 of Table 1 to this subpart.	The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen.	The 2-run block average THC emission concentration for the 3-hour peak emissions period measured during the performance test using EPA Methods 25A and 3A is equal to or less than 20 ppmvd, corrected to 18 percent oxygen.
6. Each affected batch process unit that is subject to the THC percentage reduction limit listed in item 6.b. or 7.b. of Table 1 to this subpart.	The average THC percentage reduction must equal or exceed 95 percent.	The 2-run block average THC percentage reduction for the 3-hour peak emissions period measured during the performance test using EPA Method 25A is equal to or exceeds 95 percent.
7. Each affected continuous or batch process unit that is equipped with a control device other than a thermal or catalytic oxidizer and is subject to the emission limit listed in item 3 or 7 of Table 1 to this subpart.	a. The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen; or b. The average THC percentage reduction must equal or exceed 95 percent.	i. You have installed a THC CEMS at the outlet of the control device or in the stack of the affected source; and ii. You have satisfied the requirements of PS–8 of 40 CFR part 60, appendix B.
8. Each affected continuous or batch process unit that uses process changes to reduce organic HAP emissions and is subject to the emission limit listed in item 4 or 8 of Table 1 to this subpart.	The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen.	i. You have installed a THC CEMS at the outlet of the control device or in the stack of the affected source; and ii. You have satisfied the requirements of PS–8 of 40 CFR part 60, appendix B.
9. Each new continuous kiln that is used to process clay refractory products.	a. The average HF emissions must not exceed 0.019 kg/Mg (0.038 lb/ton) of uncalcined clay processed; OR the average uncontrolled HF emissions must be reduced by at least 90 percent.	i. The 3-hour block average production-based HF emissions rate measured during the performance test using one of the methods specified in item 14.a.i. of Table 4 to this subpart is equal to or less than 0.019 kg/Mg (0.038 lb/ton) of uncalcined clay processed; or The 3-hour block average HF emissions reduction measured during the performance test is equal to or greater than 90 percent.
	b. The average HCl emissions must not exceed 0.091 kg/Mg (0.18 lb/ton) of uncalcined clay processed; OR the average uncontrolled HCl emissions must be reduced by at least 30 percent.	i. The 3-hour block average production-based HCl emissions rate measured during the performance test using one of the methods specified in item 14.a.i. of Table 4 to this subpart is equal to or less than 0.091 kg/Mg (0.18 lb/ton) of uncalcined clay processed; or ii. The 3-hour block average HCl emissions reduction measured during the performance test is equal to or greater than 30 percent.
	c. The average PM emissions must not exceed 1.4 kg/Mg (3.1 lb/hr).	i. The 3-hour block average PM emissions measured during the performance test using one of the methods specified in item 21 of Table 4 to this subpart is equal to or less than 1.4 kg/Mg (3.1 lb/hr).
	d. The average Hg emissions must not exceed 6.1 μg/dscm at 18 percent oxygen.	i. The 3-hour block average Hg emissions measured during the performance test using one of the methods specified in item 22 of Table 4 to this subpart is equal to or less than 6.1 μg/dscm at 18 percent oxygen.
10. Each new batch process kiln that is used to process clay refractory products.	a. The average uncontrolled HF emissions must be reduced by at least 90 percent.	The 2-run block average HF emission reduction measured during the performance test is equal to or greater than 90 percent.
	b. The average uncontrolled HCl emissions must be reduced by at least 30 percent.	The 2-run block average HCl emissions reduction measured during the performance test is equal to or greater than 30 percent.
	c. The average PM emissions must not exceed 1.4 kg/Mg (3.1 lb/hr).	i. The 2-run block average PM emissions measured during the performance test using one of the methods specified in item 21 of Table 4 to this subpart is equal to or less than 1.4 kg/Mg (3.1 lb/hr).
	d. The average Hg emissions must not exceed 6.1 μg/dscm at 18 percent oxygen.	i. The 2-run block average Hg emissions measured during the performance test using one of the methods specified in item 22 of Table 4 to this subpart is equal to or less than 6.1 μg/dscm at 18 percent oxygen.
11. Each existing continuous kiln that is used to produce clay refractory products on and after November 20, 2022.	a. The average PM emissions must not exceed 4.3 kg/Mg (9.5 lb/hr).	i. The 3-hour block average PM emissions measured during the performance test using one of the methods specified in item 21 of Table 4 to this subpart is equal to or less than 4.3 kg/Mg (9.5 lb/hr).

For . . .	For the following emission limit . . .	You have demonstrated compliance if . . .
	b. The average Hg emissions must not exceed 18 μg/dscm at 18 percent oxygen.	i. The 3-hour block average Hg emissions measured during the performance test using one of the methods specified in item 22 of Table 4 to this subpart is equal to or less than 18 μg/dscm at 18 percent oxygen.
12. Each existing batch kiln that is used to produce clay refractory products on and after November 20, 2022.	a. The average PM emissions must not exceed 4.3 kg/Mg (9.5 lb/hr).	i. The 2-run block average PM emissions measured during the performance test using one of the methods specified in item 21 of Table 4 to this subpart is equal to or less than 4.3 kg/Mg (9.5 lb/hr).
	b. The average Hg emissions must not exceed 18 μg/dscm at 18 percent oxygen.	i. The 2-run block average Hg emissions measured during the performance test using one of the methods specified in item 22 of Table 4 to this subpart is equal to or less than 18 μg/dscm at 18 percent oxygen.

■ 22. Table 6 to Subpart SSSSS is revised to read as follows:

Table 6 to Subpart SSSSS of Part 63—Initial Compliance With Work Practice Standards

As stated in § 63.9806, you must show initial compliance with the work practice standards for affected sources according to the following table:

For each . . .	For the following standard . . .	You have demonstrated initial compliance if . . .
1. Each affected source listed in Table 3 to this subpart.	a. Each applicable work practice standard listed in Table 3 to this subpart.	i. You have selected a method for performing each of the applicable work practice standards listed in Table 3 to this subpart; and ii. You have included in your Initial Notification a description of the method selected for complying with each applicable work practice standard, as required by § 63.9(b); and iii. You submit a signed statement with the Notification of Compliance Status that you have implemented the applicable work practice standard listed in Table 3 to this subpart; and iv. You have described in your OM&M plan the method for complying with each applicable work practice standard specified in Table 3 to this subpart.
2. Each basket or container that is used for holding fired refractory shapes in an existing shape preheater and autoclave during the pitch impregnation process.	a. Control POM emissions from any affected shape preheater.	i. You have implemented at least one of the work practice standards listed in item 1 of Table 3 to this subpart; and ii. You have established a system for recording the date and cleaning method for each time you clean an affected basket or container.
3. Each affected new or existing pitch working tank.	Control POM emissions	You have captured and vented emissions from the affected pitch working tank to the device that is used to control emissions from an affected defumer or coking oven, or to a thermal or catalytic oxidizer that is comparable to the control device used on an affected defumer or coking oven.
4. Each new or existing chromium refractory products kiln.	Minimize fuel-based HAP emissions.	You use natural gas, or equivalent, as the kiln fuel.
5. Each existing clay refractory products kiln.	Minimize fuel-based HAP emissions.	You use natural gas, or equivalent, as the kiln fuel.
6. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP, on and after November 19, 2021.	Minimize fuel-based HAP emissions.	You use natural gas, or equivalent, as the kiln fuel.

■ 23. Table 7 to Subpart SSSSS is revised to read as follows:

Table 7 to Subpart SSSSS of Part 63—Continuous Compliance With Emission Limits

As stated in § 63.9810, you must show continuous compliance with the emission limits for affected sources according to the following table:

For . . .	For the following emission limit . . .	You must demonstrate continuous compliance by . . .
1. Each affected source listed in Table 1 to this subpart.	a. Each applicable emission limit listed in Table 1 to this subpart.	i. Collecting and recording the monitoring and process data listed in Table 2 (operating limits) to this subpart; and ii. Reducing the monitoring and process data associated with the operating limits specified in Table 2 to this subpart; and iii. Recording the results of any control device inspections; and

For . . .	For the following emission limit . . .	You must demonstrate continuous compliance by . . .
		iv. Reporting, in accordance with § 63.9814(e), any deviation from the applicable operating limits specified in Table 2 to this subpart.
2. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP; each new or existing coking oven and defumer that is used to produce pitch-impregnated refractory products; each new shape preheater that is used to produce pitch-impregnated refractory products; AND each new or existing process unit that is exhausted to a thermal or catalytic oxidizer that also controls emissions from an affected shape preheater or pitch working tank.	As specified in items 3 through 7 of this table.	Satisfying the applicable requirements specified in items 3 through 7 of this table.
3. Each affected process unit that is equipped with a thermal or catalytic oxidizer.	a. The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen; OR the average THC percentage reduction must equal or exceed 95 percent.	i. Collecting the applicable data measured by the control device temperature monitoring system, as specified in items 5, 6, 8, and 9 of Table 8 to this subpart; and ii. Reducing the applicable data measured by the control device temperature monitoring system, as specified in items 5, 6, 8, and 9 of Table 8 to this subpart; and iii. Maintaining the average control device operating temperature for the applicable averaging period specified in items 5, 6, 8, and 9 of Table 2 to this subpart at or above the minimum allowable operating temperature established during the most recent performance test.
4. Each affected process unit that is equipped with a control device other than a thermal or catalytic oxidizer.	The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen; OR the average THC performance reduction must equal or exceed 95 percent.	Operating and maintaining a THC CEMS at the outlet of the control device or in the stack of the affected source, according to the requirements of Procedure 1 of 40 CFR part 60, appendix F.
5. Each affected process unit that uses process changes to meet the applicable emission limit.	The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen.	Operating and maintaining a THC CEMS at the outlet of the control device or in the stack of the affected source, according to the requirements of Procedure 1 of 40 CFR part 60, appendix F.
6. Each affected continuous process unit.	The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen; OR the average THC percentage reduction must equal or exceed 95 percent.	Recording the organic HAP processing rate (pounds per hour) and the operating temperature of the affected source, as specified in items 3.b. and 3.c. of Table 4 to this subpart.
7. Each affected batch process unit	The average THC concentration must not exceed 20 ppmvd, corrected to 18 percent oxygen; OR the average THC percentage reduction must equal or exceed 95 percent.	Recording the organic HAP processing rate (pounds per batch); and process cycle time for each batch cycle; and hourly average operating temperature of the affected source, as specified in items 8.b. through 8.d. of Table 4 to this subpart.
8. Each new kiln that is used to process clay refractory products.	As specified in items 9 through 11 of this table.	Satisfying the applicable requirements specified in items 9 through 11 of this table.
9. Each new affected kiln that is equipped with a DLA.	a. The average HF emissions must not exceed 0.019 kg/Mg (0.038 lb/ton) of uncalcined clay processed, OR the average uncontrolled HF emissions must be reduced by at least 90 percent; and b. The average HCl emissions must not exceed 0.091 kg/Mg (0.18 lb/ton) of uncalcined clay processed, or the average uncontrolled HCl emissions must be reduced by at least 30 percent.	i. Maintaining the pressure drop across the DLA at or above the minimum levels established during the most recent performance test; and ii. Verifying that the limestone hopper contains an adequate amount of free-flowing limestone by performing a daily visual check of the limestone in the feed hopper; and iii. Recording the limestone feeder setting daily to verify that the feeder setting is at or above the level established during the most recent performance test; and iv. Using the same grade of limestone as was used during the most recent performance test and maintaining records of the source and grade of limestone.

For . . .	For the following emission limit . . .	You must demonstrate continuous compliance by . . .
	c. The average PM emissions must not exceed 1.4 kg/Mg (3.1 lb/hr); and d. The average Hg emissions must not exceed 6.1 μg/dscm, corrected to 18 percent oxygen.	i. Performing VE observations of the stack at the frequency specified in § 63.9810(f) using EPA Method 22 of 40 CFR part 60, appendix A–7; maintaining no VE from the stack.
10. Each new affected kiln that is equipped with a DIFF or DLS/FF.	a. The average HF emissions must not exceed 0.019 kg/Mg (0.038 lb/ton) of uncalcined clay processed; OR the average uncontrolled HF emissions must be reduced by at least 90 percent; and b. The average HCl emissions must not exceed 0.091 kg/Mg (0.18 lb/ton) of uncalcined clay processed; OR the average uncontrolled HCl emissions must be reduced by at least 30 percent; and c. The average PM emissions must not exceed 1.4 kg/Mg (3.1 lb/hr); and d. The average Hg emissions must not exceed 6.1 μg/dscm, corrected to 18 percent oxygen.	i. Verifying at least once each 8-hour shift that lime is free-flowing by means of a visual check, checking the output of a load cell, carrier gas/lime flow indicator, or carrier gas pressure drop measurement system; and ii. Recording feeder setting daily to verify that the feeder setting is at or above the level established during the most recent performance test; and iii. Initiating corrective action within 1 hour of a bag leak detection system alarm AND completing corrective actions in accordance with the OM&M plan, AND operating and maintaining the fabric filter such that the alarm does not engage for more than 5 percent of the total operating time in a 6-month block reporting period.
11. Each new affected kiln that is equipped with a wet scrubber.	a. The average HF emissions must not exceed 0.019 kg/Mg (0.038 lb/ton) of uncalcined clay processed; OR the average uncontrolled HF emissions must be reduced by at least 90 percent; and b. The average HCl emissions must not exceed 0.091 kg/Mg (0.18 lb/ton) of uncalcined clay processed; OR the average uncontrolled HCl emissions must be reduced by at least 30 percent; and c. The average PM emissions must not exceed 1.4 kg/Mg (3.1 lb/hr); and d. The average Hg emissions must not exceed 6.1 μg/dscm, corrected to 18 percent oxygen.	i. Maintaining the pressure drop across the scrubber, liquid pH, and liquid flow rate at or above the minimum levels established during the most recent performance test; and ii. If chemicals are added to the scrubber liquid, maintaining the average chemical feed rate at or above the minimum chemical feed rate established during the most recent performance test.
12. Each new affected kiln that is equipped with an activated carbon injection system.	The average Hg emissions must not exceed 6.1 μg/dscm, corrected to 18 percent oxygen.	Collecting the carbon flow rate data according to § 63.9804(a); reducing the carbon flow rate data to 3-hour block averages according to § 63.9804(a); maintaining the average carbon flow rate for each 3-hour block period at or above the average carbon flow rate established during the Hg performance test in which compliance was demonstrated.
13. Each existing affected kiln that is equipped with a DLA or no add-on control.	a. The average PM emissions must not exceed 4.3 kg/Mg (9.5 lb/hr); and. b. The average Hg emissions must not exceed 18 μg/dscm, corrected to 18 percent oxygen.	i. Performing VE observations of the stack at the frequency specified in § 63.9810(f) using EPA Method 22 of 40 CFR part 60, appendix A–7; maintaining no VE from the stack.
14. Each existing affected kiln that is equipped with a DIFF or DLS/FF.	a. The average PM emissions must not exceed 4.3 kg/Mg (9.5 lb/hr).	i. If you use a bag leak detection system, as prescribed in § 63.9804(f), initiating corrective action within 1 hour of a bag leak detection system alarm AND completing corrective actions in accordance with the OM&M plan, AND operating and maintaining the fabric filter such that the alarm does not engage for more than 5 percent of the total operating time in a 6-month block reporting period; OR ii. Performing VE observations of the stack at the frequency specified in § 63.9810(f) using EPA Method 22 of 40 CFR part 60, appendix A–7; maintaining no VE from the stack.

For . . .	For the following emission limit . . .	You must demonstrate continuous compliance by . . .
15. Each existing affected kiln that is equipped with a wet scrubber.	a. The average PM emissions must not exceed 4.3 kg/Mg (9.5 lb/hr); and b. The average Hg emissions must not exceed 18 μg/dscm, corrected to 18 percent oxygen.	i. Maintaining the pressure drop across the scrubber and liquid flow rate at or above the minimum levels established during the most recent performance test.
16. Each existing affected kiln that is equipped with an activated carbon injection system.	The average Hg emissions must not exceed 18 μg/dscm, corrected to 18 percent oxygen.	Collecting the carbon flow rate data according to § 63.9804(a); reducing the carbon flow rate data to 3-hour block averages according to § 63.9804(a); maintaining the average carbon flow rate for each 3-hour block period at or above the average carbon flow rate established during the Hg performance test in which compliance was demonstrated.

■ 24. Table 8 to Subpart SSSSS is revised to read as follows:

Table 8 to Subpart SSSSS of Part 63—Continuous Compliance With Operating Limits

As stated in § 63.9810, you must show continuous compliance with the operating limits for affected sources according to the following table:

For . . .	For the following operating limit . . .	You must demonstrate continuous compliance by . . .
1. Each affected source listed in Table 2 to this subpart.	a. Each applicable operating limit listed in Table 2 to this subpart.	i. Maintaining all applicable process and control device operating parameters within the limits established during the most recent performance test; and ii. Conducting annually an inspection of all duct work, vents, and capture devices to verify that no leaks exist and that the capture device is operating such that all emissions are properly vented to the control device in accordance with the OM&M plan.
2. Each affected continuous kiln used to manufacture refractory products that use organic HAP that is equipped with a THC control device.	a. The operating limits specified in items 2.a. through 2.c. of Table 2 to this subpart.	i. Operating the control device on the affected kiln during all times except during periods of approved scheduled maintenance, as specified in § 63.9792(e); and ii. Before May 19, 2022, minimizing HAP emissions from the affected kiln during all periods of scheduled maintenance of the kiln control device when the kiln is operating and the control device is out of service; on and after May 19, 2022, minimizing HAP emissions during the period when the kiln is operating and the control device is out of service by complying with the applicable standard in Table 3 to this subpart; and iii. Minimizing the duration of all periods of scheduled maintenance of the kiln control device when the kiln is operating and the control device is out of service; on and after May 19, 2022, the total time during which the kiln is operating and the control device is out of service for the each year on a 12-month rolling basis must not exceed 750 hours.
3. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP; each new or existing coking oven and defumer that is used to produce pitch-impregnated refractory products; each new shape preheater that is used to produce pitch-impregnated refractory products; AND each new or existing process unit that is exhausted to a thermal or catalytic oxidizer that also controls emissions from an affected shape preheater or pitch working tank.	As specified in items 4 through 9 of this table.	Satisfying the applicable requirements specified in items 4 through 9 of this table.
4. Each affected continuous process unit.	Maintain process operating parameters within the limits established during the most recent performance test.	i. Recording the organic HAP processing rate (pounds per hour); and ii. Recording the operating temperature of the affected source at least hourly; and iii. Maintaining the 3-hour block average organic HAP processing rate at or below the maximum organic HAP processing rate established during the most recent performance test.

For . . .	For the following operating limit . . .	You must demonstrate continuous compliance by . . .
5. Continuous process units that are equipped with a thermal oxidizer.	Maintain the 3-hour block average operating temperature in the thermal oxidizer combustion chamber at or above the minimum allowable operating temperature established during the most recent performance test.	i. Measuring and recording the thermal oxidizer combustion chamber temperature at least every 15 minutes; and ii. Calculating the hourly average thermal oxidizer combustion chamber temperature; and iii. Maintaining the 3-hour block average thermal oxidizer combustion chamber temperature at or above the minimum allowable operating temperature established during the most recent performance test; and iv. Reporting, in accordance with § 63.9814(e), any 3-hour block average operating temperature measurements below the minimum allowable thermal oxidizer combustion chamber operating temperature established during the most recent performance test.
6. Continuous process units that are equipped with a catalytic oxidizer.	a. Maintain the 3-hour block average temperature at the inlet of the catalyst bed at or above the minimum allowable catalyst bed inlet temperature established during the most recent performance test.	i. Measuring and recording the temperature at the inlet of the catalyst bed at least every 15 minutes; and ii. Calculating the hourly average temperature at the inlet of the catalyst bed; and iii. Maintaining the 3-hour block average temperature at the inlet of the catalyst bed at or above the minimum allowable catalyst bed inlet temperature established during the most recent performance test; and iv. Reporting, in accordance with § 63.9814(e), any 3-hour block average catalyst bed inlet temperature measurements below the minimum allowable catalyst bed inlet temperature established during the most recent performance; and v. Checking the activity level of the catalyst at least every 12 months and taking any necessary corrective action, such as replacing the catalyst, to ensure that the catalyst is performing as designed.
7. Each affected batch process unit	Maintain process operating parameters within the limits established during the most recent performance test.	i. Recording the organic HAP processing rate (pounds per batch); and ii. Recording the hourly average operating temperature of the affected source; and iii. Recording the process cycle time for each batch cycle; and iv. Maintaining the organic HAP processing rate at or below the maximum organic HAP processing rate established during the most recent performance test.
8. Batch process units that are equipped with a thermal oxidizer.	Maintain the hourly average temperature in the thermal oxidizer combustion chamber at or above the hourly average temperature established for the corresponding 1-hour period of the cycle during the most recent performance test.	i. Measuring and recording the thermal oxidizer combustion chamber temperature at least every 15 minutes; and ii. Calculating the hourly average thermal oxidizer combustion chamber temperature; and iii. From the start of each batch cycle until 3 hours have passed since the process unit reached maximum temperature, maintaining the hourly average operating temperature in the thermal oxidizer combustion chamber at or above the minimum allowable operating temperature established for the corresponding period during the most recent performance test, as determined according to item 11 of Table 4 to this subpart; and iv. For each subsequent hour of the batch cycle, maintaining the hourly average operating temperature in the thermal oxidizer combustion chamber at or above the minimum allowable operating temperature established for the corresponding hour during the most recent performance test, as specified in item 13 of Table 4 to this subpart; and v. Reporting, in accordance with § 63.9814(e), any temperature measurements below the minimum allowable thermal oxidizer combustion chamber temperature measured during the most recent performance test.

For . . .	For the following operating limit . . .	You must demonstrate continuous compliance by . . .
9. Batch process units that are equipped with a catalytic oxidizer.	Maintain the hourly average temperature at the inlet of the catalyst bed at or above the corresponding hourly average temperature established for the corresponding 1-hour period of the cycle during the most recent performance test.	i. Measuring and recording temperatures at the inlet of the catalyst bed at least every 15 minutes; and ii. Calculating the hourly average temperature at the inlet of the catalyst bed; and iii. From the start of each batch cycle until 3 hours have passed since the process unit reached maximum temperature, maintaining the hourly average operating temperature at the inlet of the catalyst bed at or above the minimum allowable bed inlet temperature established for the corresponding period during the most recent performance test, as determined according to item 12 of Table 4 to this subpart; and iv. For each subsequent hour of the batch cycle, maintaining the hourly average operating temperature at the inlet of the catalyst bed at or above the minimum allowable bed inlet temperature established for the corresponding hour during the most recent performance test, as specified in item 13 of Table 4 to this subpart; and v. Reporting, in accordance with § 63.9814(e), any catalyst bed inlet temperature measurements below the minimum allowable bed inlet temperature measured during the most recent performance test; and vi. Checking the activity level of the catalyst at least every 12 months and taking any necessary corrective action, such as replacing the catalyst, to ensure that the catalyst is performing as designed.
10. Each new kiln that is used to process clay refractory products.	As specified in items 11 through 13 of this table.	Satisfying the applicable requirements specified in items 11 through 13 of this table.
11. Each new kiln that is equipped a DLA.	a. Maintain the average pressure drop across the DLA for each 3-hour block period at or above the minimum pressure drop established during the most recent performance test.	i. Collecting the DLA pressure drop data, as specified in item 18.a. of Table 4 to this subpart; and ii. Reducing the DLA pressure drop data to 1-hour and 3-hour block averages; and iii. Maintaining the 3-hour block average pressure drop across the DLA at or above the minimum pressure drop established during the most recent performance test.
	b. Maintain free-flowing limestone in the feed hopper, silo, and DLA.	Verifying that the limestone hopper has an adequate amount of free-flowing limestone by performing a daily visual check of the limestone hopper.
	c. Maintain the limestone feeder setting at or above the level established during the most recent performance test.	Recording the limestone feeder setting at least daily to verify that the feeder setting is being maintained at or above the level established during the most recent performance test.
	d. Use the same grade of limestone from the same source as was used during the most recent performance test.	Using the same grade of limestone as was used during the most recent performance test and maintaining records of the source and grade of limestone.
	e. Maintain no VE from the stack ..	i. Performing VE observations of the stack at the frequency specified in § 63.9810(f) using EPA Method 22 of 40 CFR part 60, appendix A–7; and ii. Maintaining no VE from the stack.
12. Each new kiln that is equipped with a DIFF or DLS/FF.	a. Initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with the OM&M plan; AND operate and maintain the fabric filter such that the alarm does not engage for more than 5 percent of the total operating time in a 6-month block reporting period.	i. Initiating corrective action within 1 hour of a bag leak detection system alarm and completing corrective actions in accordance with the OM&M plan; and ≤ii. Operating and maintaining the fabric filter such that the alarm does not engage for more than 5 percent of the total operating time in a 6-month block reporting period; in calculating this operating time fraction, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted; if corrective action is required, each alarm shall be counted as a minimum of 1 hour; if you take longer than 1 hour to initiate corrective action, the alarm time shall be counted as the actual amount of time taken by you to initiate corrective action.

For . . .	For the following operating limit . . .	You must demonstrate continuous compliance by . . .
	b. Maintain free-flowing lime in the feed hopper or silo at all times for continuous injection systems; AND maintain feeder setting at or above the level established during the most recent performance test for continuous injection systems.	i. Verifying at least once each 8-hour shift that lime is free-flowing via a load cell, carrier gas/lime flow indicator, carrier gas pressure drop measurement system, or other system; recording all monitor or sensor output, and if lime is found not to be free flowing, promptly initiating and completing corrective actions; and ii. Recording the feeder setting once each day of operation to verify that the feeder setting is being maintained at or above the level established during the most recent performance test.
13. Each new kiln that is used to process clay refractory products and is equipped with a wet scrubber.	a. Maintain the average pressure drop across the scrubber for each 3-hour block period at or above the minimum pressure drop established during the most recent performance test.	i. Collecting the scrubber pressure drop data, as specified in item 20.a. of Table 4 to this subpart; and ii. Reducing the scrubber pressure drop data to 1-hour and 3-hour block averages; and iii. Maintaining the 3-hour block average scrubber pressure drop at or above the minimum pressure drop established during the most recent performance test.
	b. Maintain the average scrubber liquid pH for each 3-hour block period at or above the minimum scrubber liquid pH established during the most recent performance test.	i. Collecting the scrubber liquid pH data, as specified in item 20.b. of Table 4 to this subpart; and ii. Reducing the scrubber liquid pH data to 1-hour and 3-hour block averages; and iii. Maintaining the 3-hour block average scrubber liquid pH at or above the minimum scrubber liquid pH established during the most recent performance test.
	c. Maintain the average scrubber liquid flow rate for each 3-hour block period at or above the minimum scrubber liquid flow rate established during the most recent performance test.	i. Collecting the scrubber liquid flow rate data, as specified in item 20.c. of Table 4 to this subpart; and ii. Reducing the scrubber liquid flow rate data to 1-hour and 3-hour block averages; and iii. Maintaining the 3-hour block average scrubber liquid flow rate at or above the minimum scrubber liquid flow rate established during the most recent performance test.
	d. If chemicals are added to the scrubber liquid, maintain the average scrubber chemical feed rate for each 3-hour block period at or above the minimum scrubber chemical feed rate established during the most recent performance test.	i. Collecting the scrubber chemical feed rate data, as specified in item 20.d. of Table 4 to this subpart; and ii. Reducing the scrubber chemical feed rate data to 1-hour and 3-hour block averages; and iii. Maintaining the 3-hour block average scrubber chemical feed rate at or above the minimum scrubber chemical feed rate established during the most recent performance test.
14. Each new and existing affected kiln that is equipped with an activated carbon injection system.	a. Maintain the average carbon flow rate for each 3-hour block period at or above the average carbon flow rate established during the Hg performance test in which compliance was demonstrated.	i. Collecting the carbon flow rate data, as specified in item 23 of Table 4 to this subpart; and ii. Reducing the carbon flow rate data to 3-hour block averages; and iii. Maintaining the average carbon flow rate for each 3-hour block period at or above the average carbon flow rate established during the Hg performance test in which compliance was demonstrated.
15. Each existing affected kiln that is equipped with a DLA or no add-on control.	a. Maintain no VE from the stack ..	i. Performing VE observations of the stack at the frequency specified in § 63.9810(f) using EPA Method 22 of 40 CFR part 60, appendix A–7; and ii. Maintaining no VE from the stack.
16. Each existing affected kiln that is equipped with a FF.	a. Maintain no VE from the stack; OR.	i. Performing VE observations of the stack at the frequency specified in § 63.9810(f) using EPA Method 22 of 40 CFR part 60, appendix A–7; and ii. Maintaining no VE from the stack.

For . . .	For the following operating limit . . .	You must demonstrate continuous compliance by . . .
	b. Initiate corrective action within 1 hour of a bag leak detection system alarm and complete corrective actions in accordance with the OM&M plan; AND operate and maintain the fabric filter such that the alarm does not engage for more than 5 percent of the total operating time in a 6-month block reporting period.	i. Initiating corrective action within 1 hour of a bag leak detection system alarm and completing corrective actions in accordance with the OM&M plan; and ii. Operating and maintaining the fabric filter such that the alarm does not engage for more than 5 percent of the total operating time in a 6-month block reporting period; in calculating this operating time fraction, if inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted; if corrective action is required, each alarm shall be counted as a minimum of 1 hour; if you take longer than 1 hour to initiate corrective action, the alarm time shall be counted as the actual amount of time taken by you to initiate corrective action.
17. Each existing affected kiln that is equipped with a wet scrubber.	a. Maintain the average pressure drop across the scrubber for each 3-hour block period at or above the minimum pressure drop established during the most recent performance test.	i. Collecting the scrubber pressure drop data, as specified in item 25.a of Table 4 to this subpart; and ii. Reducing the scrubber pressure drop data to 1-hour and 3-hour block averages; and iii. Maintaining the 3-hour block average scrubber pressure drop at or above the minimum pressure drop established during the most recent performance test.
	b. Maintain the average scrubber liquid flow rate for each 3-hour block period at or above the minimum scrubber liquid flow rate established during the most recent performance test.	i. Collecting the scrubber liquid flow rate data, as specified in item 25.b. of Table 4 to this subpart; and ii. Reducing the scrubber liquid flow rate data to 1-hour and 3-hour block averages; and iii. Maintaining the 3-hour block average scrubber liquid flow rate at or above the minimum scrubber liquid flow rate established during the most recent performance test.

■ 25. Table 9 to Subpart SSSSS is revised to read as follows:

Table 9 to Subpart SSSSS of Part 63—Continuous Compliance With Work Practice Standards

As stated in § 63.9810, you must show continuous compliance with the work practice standards for affected sources according to the following table:

For . . .	For the following work practice standard . . .	You must demonstrate continuous compliance by . . .
1. Each affected source listed in Table 3 to this subpart.	Each applicable work practice requirement listed in Table 3 to this subpart.	i. Performing each applicable work practice standard listed in Table 3 to this subpart; and ii. Maintaining records that document the method and frequency for complying with each applicable work practice standard listed in Table 3 to this subpart, as required by §§ 63.10(b) and 63.9816(c)(2).
2. Each basket or container that is used for holding fired refractory shapes in an existing shape preheater and autoclave during the pitch impregnation process.	Control POM emissions from any affected shape preheater.	i. Controlling emissions from the volatilization of residual pitch by implementing one of the work practice standards listed in item 1 of Table 3 to this subpart; and ii. Recording the date and cleaning method each time you clean an affected basket or container.
3. Each new or existing pitch working tank.	Control POM emissions	Capturing and venting emissions from the affected pitch working tank to the control device that is used to control emissions from an affected defumer or coking oven, or to a thermal or catalytic oxidizer that is comparable to the control device used on an affected defumer or coking oven.
4. Each new or existing chromium refractory products kiln.	Minimize fuel-based HAP emissions.	i. Before November 19, 2021, using natural gas, or equivalent, as the kiln fuel at all times except during periods of natural gas curtailment or supply interruption; on and after November 19, 2021, using natural gas, or equivalent, as the kiln fuel at all times; and ii. Before November 19, 2021, if you intend to use an alternative fuel, submitting a notification of alternative fuel use within 48 hours of the declaration of a period of natural gas curtailment or supply interruption, as defined in § 63.9824; and iii. Before November 19, 2021, submitting a report of alternative fuel use within 10 working days after terminating the use of the alternative fuel, as specified in § 63.9814(g).

For . . .	For the following work practice standard . . .	You must demonstrate continuous compliance by . . .
5. Each existing clay refractory products kiln.	Minimize fuel-based HAP emissions.	i. Before November 19, 2021, using natural gas, or equivalent, as the kiln fuel at all times except during periods of natural gas curtailment or supply interruption; on and after November 19, 2021, using natural gas, or equivalent, as the kiln fuel at all times; and ii. Before November 19, 2021, if you intend to use an alternative fuel, submitting a notification of alternative fuel use within 48 hours of the declaration of a period of natural gas curtailment or supply interruption, as defined in § 63.9824; and iii. Before November 19, 2021, submitting a report of alternative fuel use within 10 working days after terminating the use of the alternative fuel, as specified in § 63.9814(g).
6. Each affected continuous kiln used to manufacture refractory products that use organic HAP that is equipped with an emission control device for THC.	Minimize organic HAP emissions ..	i. Operating the control device at all times unless you receive Administrator approval to take the control device out of service for scheduled maintenance, as specified in § 63.9792(e); and ii. Minimizing HAP emissions during the period when the kiln is operating and the control device is out of service as specified in item 5 of Table 3 to this subpart; and iii. On and after November 19, 2021, recording the actual hourly organic HAP processing rate for the kiln while the control device was out of service and the amount of product manufactured in the kiln while the control device was out of service; and iv. Recording the duration of each period when the kiln is operating and the control device is out of service and, on and after November 19, 2021, the total amount of time per year on a 12-month rolling basis that the kiln has operated and the control device has been out of service.
7. Each new or existing curing oven, shape dryer, and kiln that is used to process refractory products that use organic HAP, on and after November 19, 2021.	Minimize fuel-based HAP emissions.	Using natural gas, or equivalent, as the kiln fuel at all times.

■ 26. Table 10 to Subpart SSSSS is revised to read as follows:

Table 10 to Subpart SSSSS of Part 63—Requirements for Reports

As stated in § 63.9814, you must comply with the requirements for reports in the following table:

You must submit a(n) . . .	The report must contain . . .	You must submit the report . . .
1. Compliance report	The information in § 63.9814(c) through (f).	Semiannually according to the requirements in § 63.9814(a) through (f).
2. Before May 19, 2022, immediate SSM report if you had a startup, shutdown, or malfunction during the reporting period that is not consistent with your SSMP, on and after May 19, 2022, immediate SSM report is not required.	a. Actions taken for the event	By fax or telephone within 2 working days after starting actions inconsistent with the plan.
	b. The information in § 63.10(d)(5)(ii).	By letter within 7 working days after the end of the event unless you have made alternative arrangements with the permitting authority.
3. Before May 19, 2022, report of alternative fuel use.	The information in § 63.9814(g) and items 4 and 5 of Table 9 to this subpart.	If you are subject to the work practice standard specified in item 3 or 4 of Table 3 to this subpart, and you use an alternative fuel in the affected kiln, by letter within 10 working days after terminating the use of the alternative fuel.
4. Performance test report	The information in § 63.7(g)	According to the requirements of § 63.9814(h).
5. CMS performance evaluation, as required for CEMS.	The information in § 63.7(g)	According to the requirements of § 63.9814(i).

■ 27. Table 11 to Subpart SSSSS is revised to read as follows:

Table 11 to Subpart SSSSS of Part 63—Applicability of General Provisions to Subpart SSSSS

As stated in § 63.9820, you must comply with the applicable General Provisions requirements according to the following table:

Citation	Subject	Brief description	Applies to subpart SSSSS
§ 63.1	Applicability		Yes.
§ 63.2	Definitions		Yes.
§ 63.3	Units and Abbreviations		Yes.
§ 63.4	Prohibited Activities	Compliance date; circumvention, severability	Yes.
§ 63.5	Construction/Reconstruction.	Applicability; applications; approvals	Yes.
§ 63.6(a)	Applicability	General Provisions (GP) apply unless compliance extension; GP apply to area sources that become major.	Yes.
§ 63.6(b)(1)–(4)	Compliance Dates for New and Reconstructed Sources.	Standards apply at effective date; 3 years after effective date; upon startup; 10 years after construction or reconstruction commences for section 112(f).	Yes.
§ 63.6(b)(5)	Notification		Yes.
§ 63.6(b)(6)	[Reserved].		
§ 63.6(b)(7)	Compliance Dates for New and Reconstructed Area Sources That Become Major.	Area sources that become major must comply with major source standards immediately upon becoming major, regardless of whether required to comply when they were area sources.	Yes.
§ 63.6(c)(1)–(2)	Compliance Dates for Existing Sources.	Comply according to date in subpart, which must be no later than 3 years after effective date; for section 112(f) standards, comply within 90 days of effective date unless compliance extension.	Yes.
§ 63.6(c)(3)–(4)	[Reserved].		
§ 63.6(c)(5)	Compliance Dates for Existing Area Sources That Become Major.	Area sources that become major must comply with major source standards by date indicated in subpart or by equivalent time period (for example, 3 years).	Yes.
§ 63.6(d)	[Reserved].		
§ 63.6(e)(1)–(2)	Operation & Maintenance	Operate to minimize emissions at all times; correct malfunctions as soon as practicable; requirements independently enforceable; information Administrator will use to determine if operation and maintenance requirements were met; see § 63.9792(b) for general duty requirement..	Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.6(e)(3)	SSMP requirements		Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.6(f)(1)	Compliance Except During SSM.	You must comply with emission standards at all times except during SSM.	No.
§ 63.6(f)(2)–(3)	Methods for Determining Compliance.	Compliance based on performance test, operation and maintenance plans, records, inspection.	Yes.
§ 63.6(g)(1)–(3)	Alternative Standard	Procedures for getting an alternative standard.	Yes.
§ 63.6(h)(1)–(9)	Opacity/Visible Emission (VE) Standards.		Not applicable.
§ 63.6(i)(1)–(14)	Compliance Extension	Procedures and criteria for Administrator to grant compliance extension.	Yes.
§ 63.6(j)	Presidential Compliance Exemption.	President may exempt source category	Yes.
§ 63.7(a)(1)–(2)	Performance Test Dates	Dates for conducting initial performance testing and other compliance demonstrations; must conduct 180 days after first subject to rule.	Yes.
§ 63.7(a)(3)	Section 114 Authority	Administrator may require a performance test under CAA section 114 at any time.	Yes.
§ 63.7(b)(1)	Notification of Performance Test.	Must notify Administrator 60 days before the test	Yes.
§ 63.7(b)(2)	Notification of Rescheduling.	Must notify Administrator 5 days before scheduled date and provide rescheduled date.	Yes.
§ 63.7(c)	Quality Assurance/Test Plan.	Requirements; test plan approval procedures; performance audit requirements; internal and external QA procedures for testing.	Yes.
§ 63.7(d)	Testing Facilities		Yes.
§ 63.7(e)(1)	Conditions for Conducting Performance Tests.	See § 63.9800.	No, § 63.9800 specifies requirements.
§ 63.7(e)(2)	Conditions for Conducting Performance Tests.	Must conduct according to subpart and EPA test methods unless Administrator approves alternative.	Yes.
§ 63.7(e)(3)	Test Run Duration	Must have three test runs of at least 1 hour each; compliance is based on arithmetic mean of three runs; conditions when data from an additional test run can be used.	Yes; Yes, except where specified in § 63.9800 for batch process sources; Yes.
§ 63.7(f)	Alternative Test Method		Yes.
§ 63.7(g)	Performance Test Data Analysis.		Yes, except this subpart specifies how and when the performance test and performance evaluation results are reported.

Citation	Subject	Brief description	Applies to subpart SSSSS
§ 63.7(h)	Waiver of Test		Yes.
§ 63.8(a)(1)	Applicability of Monitoring Requirements.		Yes.
§ 63.8(a)(2)	Performance Specifications	Performance Specifications in appendix B of 40 CFR part 60 apply.	Yes.
§ 63.8(a)(3)	[Reserved].		
§ 63.8(a)(4)	Monitoring with Flares		Not applicable.
§ 63.8(b)(1)	Monitoring	Must conduct monitoring according to standard unless Administrator approves alternative.	Yes.
§ 63.8(b)(2)–(3)	Multiple Effluents and Multiple Monitoring Systems.	Specific requirements for installing and reporting on monitoring systems.	Yes.
§ 63.8(c)(1)	Continuous Monitoring System Operation and Maintenance.	Maintenance consistent with good air pollution control practices.	Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.8(c)(2)–(3)	Monitoring System Installation.	Must install to get representative emission and parameter measurements.	Yes.
§ 63.8(c)(4)	CMS Requirements		No, § 63.9808 specifies requirements.
§ 63.8(c)(5)	COMS Minimum Procedures.		Not applicable.
§ 63.8(c)(6)	CMS Requirements		Applies only to sources required to install and operate a THC CEMS.
§ 63.8(c)(7)(i)(A)	CMS Requirements		Applies only to sources required to install and operate a THC CEMS.
§ 63.8(c)(7)(i)(B)	CMS Requirements		Applies only to sources required to install and operate a THC CEMS.
§ 63.8(c)(7)(i)(C)	CMS Requirements		Not applicable.
§ 63.8(c)(7)(ii)	CMS Requirements	Corrective action required when CMS is out of control	Yes.
§ 63.8(c)(8)	CMS Requirements		Yes.
§ 63.8(d)(1) and (2)	CMS Quality Control		Yes.
§ 63.8(d)(3)	Written procedures for CMS.		No, § 63.9794(a)(8) specifies requirements.
§ 63.8(e)	CMS Performance Evaluation.		Applies only to sources required to install and operate a THC CEMS, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.8(f)(1)–(5)	Alternative Monitoring Method.		Yes.
§ 63.8(f)(6)	Alternative to Relative Accuracy Test.		Yes.
§ 63.8(g)	Data Reduction		Applies only to sources required to install and operate a THC CEMS.
§ 63.9(a)	Notification Requirements		Yes.
§ 63.9(b)(1)–(5)	Initial Notifications		Yes.
§ 63.9(c)	Request for Compliance Extension.		Yes.
§ 63.9(d)	Notification of Special Compliance Requirements for New Source.		Yes.
§ 63.9(e)	Notification of Performance Test.	Notify Administrator 60 days prior	Yes.
§ 63.9(f)	Notification of VE/Opacity Test.		Not applicable.
§ 63.9(g)	Additional Notifications When Using CMS.		Applies only to sources required to install and operate a THC CEMS.
§ 63.9(h)	Notification of Compliance Status.		Yes.
§ 63.9(i)	Adjustment of Submittal Deadlines.		Yes.
§ 63.9(j)	Change in Previous Information.		Yes.
§ 63.9(k)	Notifications	Electronic reporting procedures	Yes, only as specified in § 63.9(j).
§ 63.10(a)	Recordkeeping/Reporting		Yes.
§ 63.10(b)(1)	General Recordkeeping Requirements.		Yes.

Citation	Subject	Brief description	Applies to subpart SSSSS
§ 63.10(b)(2)(i)–(ii)	Recordkeeping of Occurrence and Duration of Startups and Shutdowns and Failures to Meet Standards.	See § 63.9816	Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.10(b)(2)(iii)	Recordkeeping Relevant to Maintenance of Air Pollution Control and Monitoring Equipment.		Yes.
§ 63.10(b)(2)(iv)–(v)	Actions Taken to Minimize Emissions during SSM.		Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.10(b)(2)(vi)	Recordkeeping for CMS Malfunctions.	See § 63.9816(c)(5)	Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.10(b)(2)(vii)–(xi)	Records	Measurements to demonstrate compliance with emission limitations; performance test, performance evaluation, and visible emission observation results; measurements to determine conditions of performance tests and performance evaluations.	Yes.
§ 63.10(b)(2)(xii)	Records	Records when under waiver	Yes.
§ 63.10(b)(2)(xiii)	Records	Records when using alternative to relative accuracy test.	Not applicable.
§ 63.10(b)(2)(xiv)	Records	All documentation supporting Initial Notification and Notification of Compliance Status.	Yes.
§ 63.10(b)(3)	Records	Applicability Determinations	Yes.
§ 63.10(c)(1), (c)(5)–(6)	Additional Records for CMS.		Yes.
§ 63.10(c)(2)–(4)	Records	Additional Records for CMS	Not applicable.
§ 63.10(c)(7)–(8)	Records of excess emissions and parameter monitoring exceedances for CMS.	§ 63.9816 specifies requirements.	No.
§ 63.10(c)(9)	Records	Additional Records for CMS	Not applicable.
§ 63.10(c)(10)–(14)	Additional Records for CMS.		Yes.
§ 63.10(c)(15)	Records Regarding the SSMP.		Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.10(d)(1)	General Reporting Requirements.	Requirements for reporting	Yes.
§ 63.10(d)(2)	Report of Performance Test Results.	When to submit to Federal or State authority	No. This subpart specifies how and when the performance test results are reported.
§ 63.10(d)(3)	Reporting Opacity or VE Observations.		Not applicable.
§ 63.10(d)(4)	Progress Reports	Must submit progress reports on schedule if under compliance extension.	Yes.
§ 63.10(d)(5)	SSM Reports	Contents and submission See § 63.9814 (d) and (e) for malfunction reporting requirements..	Yes before May 19, 2022. No on and after May 19, 2022.
§ 63.10(e)(1)–(2)	Additional CMS Reports		Applies only to sources required to install and operate a THC CEMS, except this subpart specifies how and when the performance evaluation results are reported.
§ 63.10(e)(3)	Reports		No, § 63.9814 specifies requirements.
§ 63.10(e)(4)	Reporting COMS data		Not applicable.
§ 63.10(f)	Waiver for Recordkeeping/Reporting.		Yes.
§ 63.11	Flares		Not applicable.
§ 63.12	Delegation		Yes.
§ 63.13	Addresses		Yes.
§ 63.14	Incorporation by Reference		Yes.
§ 63.15	Availability of Information and Confidentiality.		Yes.
§ 63.16	Performance Track Provisions.		Yes.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2020–0505, EPA–HQ–OAR–2020–0532; FRL–7523–03–OAR]

RIN 2060–AU66

National Emission Standards for Hazardous Air Pollutants: Carbon Black Production and Cyanide Chemicals Manufacturing Residual Risk and Technology Reviews, and Carbon Black Production Area Source Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology reviews (RTR) conducted for the Carbon Black Production and Cyanide Chemicals Manufacturing major source categories, and the technology review conducted for Carbon Black Production area sources, regulated under National Emission Standards for Hazardous Air Pollutants (NESHAP). In addition, we are taking final action to add new emissions standards for the Carbon Black Production and Cyanide Chemicals Manufacturing major source categories to address hazardous air pollutant (HAP) emissions not previously covered by these NESHAP. The EPA is also finalizing amendments for both source categories that address the startup, shutdown, and malfunction (SSM) provisions of the existing standards, and require electronic reporting of certain notifications, performance test results, and semiannual reports.

DATES: These final rules are effective on November 19, 2021. The incorporation by reference (IBR) of certain publications listed in the final rule is approved by the Director of the Federal Register as of November 19, 2021.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for the Carbon Black Production source category under Docket ID No. EPA–HQ–OAR–2020–0505, and a docket for the Cyanide Chemicals Manufacturing source category under Docket ID EPA–HQ–OAR–2020–0532. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742. Hand Deliveries and couriers may be received by scheduled appointment only. For further information and updates on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about the Carbon Black Production source category final action, contact Korbin Smith, Sector Policies and Programs Division (D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2416; fax number: (919) 541–4991; and email address: *smith.korbin@epa.gov.* For questions about the Cyanide Chemicals Manufacturing source category final action, contact Nathan Topham, Sector Policies and Programs Division (D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0483; fax number: (919) 541–4991; and email address: *topham.nathan@epa.gov.*

For specific information regarding the risk modeling methodology for both Carbon Black Production and Cyanide Chemicals Manufacturing, contact James Hirtz, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0881; fax number: (919) 541–0840; and email address: *hirtz.james@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CCD combustion control device
CCMPU cyanide chemicals manufacturing process unit
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CFR Code of Federal Regulations
CO carbon monoxide
CRA Congressional Review Act
EAV equivalent annual value
EPA U.S. Environmental Protection Agency
GMACT Generic Maximum Achievable Control Technology
HAP hazardous air pollutant(s)
HCN hydrogen cyanide
HON Hazardous Organic NESHAP
HQ hazard quotient
ICBA International Carbon Black Association
ICR Information Collection Request
LEL lower explosive limit
MACT maximum achievable control technology
MUF main unit filter
NAICS North American Industry Classification System
NATA National Air Toxics Assessment
NESHAP national emission standards for hazardous air pollutants
NOCS Notification of Compliance Status
NSPS New Source Performance Standards
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PEL permissible exposure limit
ppm parts per million
ppmv parts per million by volume
ppmw parts per million by weight
PRA Paperwork Reduction Act
PV present value
REL reference exposure level
RFA Regulatory Flexibility Act
RTR residual risk and technology review
SSM startup, shutdown, and malfunction
SSP startup and shutdown plan
STEL short term exposure limit
TOSHI target organ-specific hazard index
tpy tons per year

Background information. On January 14, 2021, the EPA proposed revisions to the Carbon Black Production NESHAP based on our RTR, and proposed no revisions to the Carbon Black Production area source rule based on our technology review. On January 15, 2021, the EPA proposed revisions to the Cyanide Chemicals Manufacturing NESHAP based on our RTR. In this action, we are finalizing decisions for, and revisions of, the NESHAP for these source categories. We summarize some of the more significant comments we timely received regarding the proposed rules and provide our responses in this preamble. A summary of all other public comments on these proposals and the EPA's responses to those comments are available in the *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air*

Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule (see Docket ID No. EPA–HQ–OAR–2020–0505) for the Carbon Black Production source category, and *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review Proposed Rule* (see Docket ID No. EPA–HQ–OAR–2020–0532) for the Cyanide Chemicals Manufacturing source category. ''Track changes'' versions of the regulatory language that incorporates the changes in this action are available in the dockets.

Organization of this document. The information in this preamble is organized as follows:

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- H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act (NTTAA)
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations K. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Regulated entities. The source categories that are the subject of this final action are cyanide chemicals manufacturing and carbon black production major sources regulated under 40 CFR part 63, subpart YY and carbon black production area sources regulated under 40 CFR part 63, subpart MMMMMM. The North American Industry Classification System (NAICS) codes for the cyanide chemicals manufacturing industry are 325188 and 325199. The NAICS code for the carbon black production industry is 325182.

This list of categories and NAICS codes is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source categories listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of these NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the dockets for these source categories, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/acetal-resins-acrylic-modacrylic-fibers-carbon-black-hydrogen.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website.

Additional information is available on the RTR website at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.* This information includes an overview of the RTR program, links to project websites for the RTR source categories, and detailed emissions and other data we used as inputs to the risk assessments.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by January 18, 2022. Under CAA section 307(b)(2), the requirements established by these final rules may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the

Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of HAP from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category. *Louisiana Environmental Action Network (LEAN)* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this action, see 86 FR 3054, for the Carbon Black Production NESHAP and 86 FR 3906, for the Cyanide Chemicals Manufacturing NESHAP.

B. What are the source categories and how do the current NESHAP regulate HAP emissions from the source categories?

The MACT standards for both the Carbon Black Production and Cyanide Chemicals Manufacturing source categories are contained in the Generic Maximum Achievable Control Technology (GMACT) NESHAP, which also includes MACT standards for several other source categories. Section II.B.1 of this preamble discusses the current Carbon Black Production major and area source rules and section II.B.2 discusses the Cyanide Chemicals Manufacturing source category standards.

1. Carbon Black Production

The EPA promulgated the Carbon Black Production NESHAP for major sources on July 12, 2002 (67 FR 46258). The major source standards are codified at 40 CFR part 63, subpart YY. Additionally, the Carbon Black Production area source NESHAP was promulgated on July 16, 2007 (72 FR 38864). The area source standards are codified at 40 CFR part 63, subpart MMMMMM. Subpart MMMMMM was subsequently amended by a direct final rule on March 26, 2008 (73 FR 15923). As promulgated, the Carbon Black Production major source and area source NESHAP apply to carbon black production facilities that are, respectively, major sources and area sources of HAP. The affected source covered by the major and area source subparts is each new, reconstructed, or existing facility that produces carbon black by either the furnace, thermal, acetylene decomposition, or lampblack processes. The source category covered by this MACT standard currently includes 15 major source facilities; no area source facilities were identified.

Emissions limits in the 2002 major source NESHAP for the Carbon Black Production source category were set for process vents associated with the main unit filter (MUF). Process vents at the MUF that have a HAP concentration of equal to or greater than 260 parts per million by volume (ppmv) are required to reduce emissions of HAP by the use of a flare meeting the requirements of 40 CFR part 63, subpart SS, or reduce emissions of total HAP by 98 weight-

[1] The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA*, 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

percent or to a concentration of 20 ppmv, whichever is less stringent. The Carbon Black Production area source NESHAP requires area source facilities to meet the requirements of the Carbon Black Production major source NESHAP found at 40 CFR 63.1103(f) of subpart YY.

2. Cyanide Chemicals Manufacturing

The EPA promulgated the Cyanide Chemicals Manufacturing NESHAP on July 12, 2002 (67 FR 46258). The standards are codified at 40 CFR part 63, subpart YY. The cyanide chemicals manufacturing industry consists of facilities producing hydrogen cyanide or sodium cyanide. The source category covered by this MACT standard currently includes 13 facilities. As promulgated in 2002, the cyanide chemicals manufacturing standards regulate HAP emissions from cyanide chemicals manufacturing units located at major sources. The HAP emitted from the source category include cyanide compounds (hydrogen cyanide and sodium cyanide), acetonitrile, and acrylonitrile.

The NESHAP defines the affected source as each cyanide chemicals manufacturing process unit (CCMPU). The rule states that the CCMPU is the equipment assembled and connected by hard-piping or duct work to process raw materials to manufacture, store, and transport a cyanide chemicals product. Section II.B of the proposed cyanide chemicals manufacturing RTR provides more information about the source category (86 FR 3906, 3910).

The 2002 NESHAP established emissions standards for process vents, storage vessels, transfer racks, equipment leaks, and some wastewater sources. Cyanide process vents are subject to either a 98 weight-percent reduction of total HAP [2] performance standard or a 20 ppmv total HAP outlet exit concentration limit. For storage vessels in the Cyanide Chemicals Manufacturing source category, sources may either choose to comply with a 98 weight-percent reduction of hydrogen cyanide performance standard, a 20 ppmv hydrogen cyanide exit outlet concentration limit, or equipment standards (*e.g.,* use of a flare). Transfer racks are subject to either equipment standards or the same performance standard or concentration limit [3] as cyanide process vents. Equipment leaks are subject to work practice standards required by either 40 CFR part 63, subpart TT or subpart UU.

During development of the initial MACT standards, we identified process wastewater at existing sources as a potential source of emissions of hydrogen cyanide, acetonitrile, and acrylonitrile. See 65 FR 76408, 76411, and 76413, December 6, 2000, for a discussion of the HAP emitted from cyanide chemicals manufacturing. The 2002 NESHAP established requirements that HAP emissions from applicable process wastewater streams be controlled while the wastewater is being conveyed to treatment and specified requirements for the controls to reduce the hydrogen cyanide and acetonitrile concentration in the process wastewater. For a new CCMPU that generates process wastewater, the NESHAP requires a combined 93 weight-percent removal and control of HAP from process wastewater generated from hydrogen cyanide purification, ammonia purification, or flare blowdown. At the time the initial MACT standards were developed, we identified measures undertaken at cyanide chemicals manufacturing facilities to comply with other NESHAP as the ''MACT floor'' for process wastewater at existing sources, but we did not include these measures in subpart YY for existing CCMPUs. For a cyanide chemicals manufacturing process unit that generates maintenance wastewater, the NESHAP requires that an owner or operator comply with Hazardous Organic NESHAP (HON) maintenance wastewater requirements.

C. What changes did we propose for the Carbon Black Production source category in our January 14, 2021, RTR proposal?

On January 14, 2021, the EPA published a proposed rule in the **Federal Register** for the Carbon Black Production NESHAP, 40 CFR part 63, subpart YY, that took into consideration the RTR analyses. In the proposed rule, we proposed to find that the risk from the source category is acceptable, the current standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect. Based on the technology review, we proposed that it is not necessary to revise the existing standards because we did not identify developments in practices, processes, or control technologies that would result in cost-effective emission reductions for the Carbon Black Production source category.

The EPA did, however, propose to broaden the scope of the original NESHAP, which applied to process vents associated with the MUF only, to include previously unregulated process vents associated with the carbon black production unit. The EPA proposed to require all process vents that have a HAP concentration of the emission stream equal to or greater than 260 ppmv, including those located after the MUF, to reduce emissions of HAP by using a flare meeting the requirements of 40 CFR part 63, subpart SS, or to reduce emissions of total HAP by 98 weight-percent or to a concentration of 20 ppmv, whichever is less stringent. The EPA also proposed to require facilities to conduct performance testing on the additional process vents located after the MUF.

The proposal preamble also stated that the EPA did not identify any currently operating area sources in the carbon black production source category. The EPA is not proposing to change the existing area source standards. However, the area source standard requires all facilities to meet all the requirements in 40 CFR 63.1103(f) of subpart YY (major source standard). The provisions in 40 CFR 63.1103(f) include carbon black production applicability, definitions, and requirements. Therefore, all changes discussed below, which impact the requirements laid out in 40 CFR 63.1103(f), also impact the requirements of the area source rule for carbon black production.

The EPA proposed the following amendments to the Carbon Black Production major source NESHAP:

- Expansion of the process vent emission standards to cover all applicable (based on an applicability threshold) carbon black production process vents;
- A requirement for boilers/process heaters that receive tail gas for use as fuel gas to comply with annual tune-up requirements specified in 40 CFR 63.1103(f)(3)(iii);
- Addition of a work practice standard for periods of startup, as specified in 40 CFR 63.1103(f)(5);
- Revision of the MACT standard compliance provisions for the Carbon Black Production source category to require owners and operators of carbon black production process vent affected sources to conduct periodic performance tests every 5 years;

[2] ''Dry end'' process vents at sodium cyanide units must meet a 98 percent reduction performance standard for emissions of sodium cyanide since this is the form of cyanide compounds emitted from these emission points. The HAP emitted from other process vents that make up the ''total HAP'' emitted from these sources are hydrogen cyanide, acetonitrile, and acrylonitrile.

[3] Transfer racks emissions limits are expressed in terms of hydrogen cyanide as this is the only HAP emitted from these sources.

- Elimination of the startup, shutdown, malfunction (SSM) exemption, which currently appears at 40 CFR 63.1108, and any references to SSM requirements in subpart YY that apply to Carbon Black Production source category affected sources;
- Requirements for submission of electronic copies of required performance test reports, Notification of Compliance Status (NOCS), and periodic reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI); and
- Minor editorial and technical changes in the subpart.

D. What changes did we propose for the Cyanide Chemicals Manufacturing source category in our January 15, 2021, RTR proposal?

On January 15, 2021, the EPA published a proposed rule in the **Federal Register** for the Cyanide Chemicals Manufacturing NESHAP (86 FR 3906) that took into consideration the RTR analyses. In the proposed rule, we proposed to find that the risk from the source category is acceptable, the current standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect. Based on the technology review, we proposed that it is not necessary to revise the existing standards because we did not identify developments in practices, processes, or control technologies that would result in cost-effective emission reductions for the Cyanide Chemicals Manufacturing source category.

However, the EPA proposed standards pursuant to CAA section 112(d)(2) for process wastewater from existing CCMPUs, which was previously unregulated.[4] We proposed that process wastewater sources at existing sources comply with HON wastewater requirements. Specifically, for an existing cyanide chemicals manufacturing process unit that generates process wastewater from hydrogen cyanide purification, ammonia purification, or flare blowdown, we proposed that owners or operators comply with the requirements of 40 CFR 63.138(a)(1) of the HON if the total annual average concentration of Table 9 of 40 CFR part 63, subpart G compounds and cyanide compounds[5] is greater than or equal to 10,000 parts per million by weight (ppmw) at any flow rate, or the total annual average concentration of Table 9 compounds and cyanide compounds is greater than or equal to 1,000 ppmw, and the annual average flow rate is greater than or equal to 10 liters per minute (according to the procedures in 40 CFR 63.144(a)). We also proposed revising the new source standard to add the HON requirements for waste management units upstream of an open or closed biological treatment process to ensure demonstrable compliance measures are in place for these sources.

The EPA also proposed the following amendments:

- Revisions to the MACT rule at 40 CFR 63.1108 through 40 CFR 63.1112 to eliminate references to SSM requirements in subpart YY to reduce confusion that may result from referenced subparts associated with the GMACT that may contain SSM exemptions for other source categories;
- Requirements for submission of electronic copies of required performance test reports, NOCS, and periodic reports through the EPA's CDX using CEDRI; and
- Minor editorial and technical changes in the subpart.

III. What is included in these final rules?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Carbon Black Production and Cyanide Chemicals Manufacturing source categories.

For the Carbon Black Production source category, this action finalizes changes to the major source NESHAP, including elimination of the SSM exemption and any reference to SSM requirements for carbon black production facilities, inclusion of a work practice standard for startup and shutdown periods, inclusion of boiler and process heater annual tune-up requirements, expansion of process vent standard applicability, addition of periodic process vent performance testing requirements, inclusion of electronic reporting requirements, and editorial and technical changes. This final action also reflects several changes to the RTR proposal in consideration of comments received during the public comment period. Section IV presents our rationale for our final decisions and changes to the proposed amendments based on comments received on the proposal.

For the Cyanide Chemicals Manufacturing source category, this action finalizes changes to the NESHAP, including: Eliminating any reference to SSM exemptions for cyanide chemicals manufacturing facilities, adding electronic reporting requirements, adding HON requirements for process wastewater from existing cyanide chemical manufacturing process units, adding HON requirements for waste management units upstream of an open or closed biological treatment process to the new source standard, and making editorial/technical changes. This action also reflects several changes to the RTR proposal in consideration of comments received during the public comment period as described in section V of this preamble.

A. What are the final rule amendments based on the risk reviews for the Carbon Black Production and Cyanide Chemicals Manufacturing source categories?

This section introduces the final determinations for the Carbon Black Production and Cyanide Chemicals Manufacturing NESHAP pursuant to CAA section 112(f). Section III.A.1 presents the final decisions based on the risk review for the Carbon Black Production source category. Section III.A.2 presents the final decisions based on the risk review for the Cyanide Chemicals Manufacturing source category.

1. Carbon Black Production

The EPA is not amending the major source Carbon Black Production NESHAP based on the risk reviews conducted pursuant to CAA section 112(f). In this action, we are finalizing our proposed determination that the risk from HAP emissions from the Carbon Black Production source category is acceptable, and that the standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect.

2. Cyanide Chemicals Manufacturing

The EPA is not amending the Cyanide Chemicals Manufacturing NESHAP based on the risk review conducted pursuant to CAA section 112(f). In this action, we are finalizing our proposed determination that the risk from HAP emissions from the Cyanide Chemicals Manufacturing source category is acceptable, and that the standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect.

[4] The EPA not only has authority under CAA sections 112(d)(2) and (3) to set MACT standards for previously unregulated HAP emissions at any time but is required to address any previously unregulated HAP emissions as part of its periodic review of MACT standards under CAA section 112(d)(6). *LEAN* v. *EPA,* 955 F3d at 1091–1099.

[5] In the final rule, we have clarified that this requirement applies to ''free cyanide'' rather than ''cyanide compounds'' in response to public comments.

B. What are the final rule amendments based on the technology reviews for the Carbon Black Production and Cyanide Chemicals Manufacturing source categories?

This section summarizes the results of the technology reviews for the Carbon Black Production and Cyanide Chemicals Manufacturing NESHAP. Section III.B.1 presents the final decisions based on the technology review for the Carbon Black Production source category. Section III.B.2 presents the final decisions based on the technology review for the Cyanide Chemicals Manufacturing source category.

1. Carbon Black Production

We determined that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. Therefore, we are not finalizing revisions to the MACT standards for this source category under CAA section 112(d)(6). However, as part of the technology review, we identified regulatory gaps (previously unregulated processes or pollutants), and are establishing new standards to fill those gaps as described in section III.C of this preamble.

As discussed in the Carbon Black Production source category proposal preamble, we also performed a technology review of the Carbon Black Production area source NESHAP. As part of that review, the EPA did not identify any currently operating area source facilities. We are finalizing our conclusion that it is not necessary to make changes to the existing area source standards as a result of this review.

2. Cyanide Chemicals Manufacturing

We determined that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. Therefore, we are not finalizing revisions to the MACT standards for this source category under CAA section 112(d)(6). However, as part of the technology review, we identified regulatory gaps (previously unregulated processes or pollutants), and are establishing new standards to fill those gaps as described in section III.C of this preamble.

C. What are the final rule amendments pursuant to CAA sections 112(d)(2) and (3) for the Carbon Black Production and Cyanide Chemicals Manufacturing source categories?

This section describes the final rule amendments to the Carbon Black Production and Cyanide Chemicals Manufacturing NESHAP pursuant to CAA sections 112(d)(2) and (3). Section III.C.1 presents the final rule amendments for the Carbon Black Production source category. Section III.C.2 presents the final rule amendments for the Cyanide Chemicals Manufacturing source category.

1. Carbon Black Production

Pursuant to CAA sections 112(d)(2) and (3), the EPA is finalizing its proposal to broaden the scope of the current emission limits for new and existing sources in the major source NESHAP, which applies to process vents associated with the MUF, to include all process vents associated with the carbon black production unit. This amendment requires all process vents, including those located after the MUF that meet the applicability threshold, to reduce emissions of total HAP by 98 weight-percent or to a concentration of 20 ppmv, whichever is less stringent, by venting emissions through a closed vent system to any combination of control devices meeting the requirements of 40 CFR 63.982(a)(2). Additionally, these final amendments require facilities to conduct an applicability determination test on the additional process vents located after the MUF.

2. Cyanide Chemicals Manufacturing

Pursuant to CAA sections 112(d)(2) and (3), the EPA is finalizing its proposal to add standards for process wastewater at existing CCMPUs with minor applicability-related clarifications (see section V.D.3.d (Request for Clarification)). The final standards require that individual wastewater streams from CCMPU HCN purification, ammonia purification, or flare blowdown, comply with the requirements of 40 CFR 63.138(a)(1) of the HON if the total annual average concentration of Table 9 of 40 CFR part 63, subpart G compounds and free cyanide from each process wastewater stream is greater than or equal to 10,000 ppmw at any flow rate, or the total annual average concentration of Table 9 compounds and free cyanide from each process wastewater stream is greater than or equal to 1,000 ppmw and the annual average flow rate is greater than or equal to 10 liters per minute (according to the procedures in 40 CFR 63.144(a)). The EPA is also finalizing its proposal to add the HON requirements for waste management units upstream of an open or closed biological treatment process for process wastewater at new sources.

D. What are the final rule amendments addressing emissions during periods of SSM for the Carbon Black Production and Cyanide Chemicals Manufacturing source categories?

This section describes the final rule amendments to the Carbon Black Production and Cyanide Chemicals Manufacturing NESHAP that address emissions during periods of SSM. Section III.D.1 presents the final rule amendments for the Carbon Black Production source category. Section III.D.2 presents the final rule amendments for the Cyanide Chemicals Manufacturing source category.

1. Carbon Black Production

The EPA is finalizing the proposed SSM provision amendments for the Carbon Black Production major source NESHAP in subpart YY in order to ensure consistency with the decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008). As noted in the proposal for the Carbon Black Production source category, under this decision, the Court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We proposed and are finalizing revisions to the MACT rule at 40 CFR 63.1108 through 40 CFR 63.1112 that remove the SSM exemption under the Carbon Black Production NESHAP and any references to SSM-related requirements.

The EPA is also finalizing startup and shutdown work practice standards to address safety and combustibility concerns in the absence of the SSM exemption. The work practice standard, as amended under the final rule, is discussed in greater detail in section IV.C of this preamble.

2. Cyanide Chemicals Manufacturing

The EPA is finalizing the proposed SSM provision amendments for the Cyanide Chemicals Manufacturing NESHAP in order to ensure consistency with the decision in *Sierra Club* v. *EPA*, 551 F. 3d 1019 (D.C. Cir. 2008). The Cyanide Chemicals Manufacturing NESHAP promulgated in 2002 is consistent with the Court decision mentioned above. However, we proposed and are finalizing revisions to the NESHAP at 40 CFR 63.1108 through 40 CFR 63.1112 to ensure that no confusion results from referenced subparts in subpart YY that may contain SSM exemptions for other source categories. See section V.C of this preamble for more information regarding SSM provisions under subpart YY.

E. What other changes have been made to the NESHAP?

This section describes other amendments to the final Carbon Black Production and Cyanide Chemicals Manufacturing NESHAP. Section III.E.1 presents the other final rule amendments for the Carbon Black Production source category. Section III.E.2 presents the other final rule amendments for the Cyanide Chemicals Manufacturing source category.

1. Carbon Black Production

Other final amendments to the Carbon Black Production NESHAP include boiler and process heater annual tune-up requirements, electronic reporting requirements, and periodic performance testing requirements for process vents to demonstrate initial and continued compliance with the standards, as discussed below.

a. Boiler and Process Heater Annual Tune-Up Provisions

The EPA is finalizing annual tune-up requirements for boilers and process heaters that utilize tail gas for use as fuel. These provisions are specified in 40 CFR 63.1103(f)(3)(iii) of the final rule. To better reflect boilers and process heaters used in the carbon black production source category, the final annual boiler and process heater tune-up requirements were revised from the proposal, based on comments received (see section IV.D of this preamble for detail related to comments received, as well as the EPA's revisions and rationale).

b. Electronic Reporting Requirements

The EPA is finalizing its proposal that owners and operators of carbon black production facilities submit electronic copies of required performance test reports, NOCS, and periodic reports through the EPA's CDX using CEDRI. A description of the electronic data submission process is provided in the memorandum, ''*Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules*'', available in the docket for the Carbon Black Production NESHAP (see Docket ID No. EPA–HQ–OAR–2020–0505–0018).

c. Periodic Performance Testing

The EPA is finalizing rule amendments, as proposed, that require owners and operators of carbon black production process vents subject to the rule, in addition to the already required initial performance test, to conduct performance tests every 5 years to demonstrate continued compliance with the NESHAP.

2. Cyanide Chemicals Manufacturing

The EPA is finalizing its proposal that owners and operators of cyanide chemicals manufacturing facilities submit electronic copies of required performance test reports, NOCS, and periodic reports through the EPA's CDX using CEDRI. A description of the electronic data submission process is provided in the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in the docket for the Cyanide Chemicals Manufacturing NESHAP action (see Docket ID No. EPA–HQ–OAR–2020–0532–0003). Specific comments received on the proposed periodic report electronic data template and the EPA's response to those comments are provided in a memorandum to the docket, *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review Proposed Rule,* available in the Cyanide Chemicals Manufacturing NESHAP docket (see EPA HQ–OAR–2020–0532).

F. What are the effective and compliance dates of the standards?

This section describes the effective dates and compliance dates for the final amendments to the Carbon Black Production and Cyanide Chemicals Manufacturing NESHAP. Section III.F.1 presents the effective dates and compliance dates for the Carbon Black Production NESHAP amendments. Section III.F.2 presents the effective dates and compliance dates for the Cyanide Chemicals Manufacturing NESHAP amendments.

1. Carbon Black Production

a. Effective Date of the Final Rule

The revisions to the Carbon Black Production MACT standards being promulgated in this action are effective on November 19, 2021.

b. Compliance Dates

For new sources (affected sources that commenced construction or reconstruction after January 14, 2021), the EPA is finalizing, as proposed, that affected sources must comply with all of the final rule requirements immediately upon the effective date of the rule, November 19, 2021, or upon startup, whichever is later.

The EPA is finalizing, as proposed, that existing Carbon Black Production affected sources that commenced construction or reconstruction on or before January 14, 2021 (existing sources), must comply with the following requirements of the rule no later than November 20, 2022: (1) Process vent emission standards applicability testing for carbon black production process vents; (2) the requirement to conduct performance tests no more than 60 months after the preceding test when demonstrating compliance with process vent emission control requirements; and (3) boiler and process heater annual tune-up requirements.

The EPA is finalizing a requirement that previously unregulated process vents from Carbon Black Production sources that commenced construction or reconstruction on or before January 14, 2021, will have until November 19, 2024 to comply with final rule requirements for process vents. This represents a change from the proposal. The EPA determined that changing the proposed compliance period is necessary, in the event that the applicability test indicates that previously unregulated process vents are required to route emissions to an existing control device or to a newly constructed control device. Based on comments received, the EPA believes providing a 3-year compliance period for newly subject process vents, instead of 1 year, is necessary and appropriate in order to ensure sufficient time for facilities to conduct the necessary process design planning, purchases, construction, and changes to come into compliance and then perform the initial performance test.

For requirements related to SSM-related amendments and electronic reporting, the EPA is finalizing, as proposed, that all existing sources must be in compliance with the: (1) SSM-related amendments (changes proposed as a result of removing the SSM exemption from the requirements); (2) the alternative work practice standard specified in 40 CFR 63.1103(f)(5) related to the requirement that a closed vent system route the collected vapors to a control device when demonstrating compliance; and (3) the addition of requirements to submit reports electronically by May 18, 2022. Based on our assessment for existing sources, 180 days is the most expeditious compliance period practicable for complying with SSM-related and electronic reporting requirements.

The EPA considers 180 days to be sufficient for owners and operators of affected sources to comply with the

alternative work practice standard for startup and shutdown.[6] Many of the work practice standard requirements included in the final rule are already implemented by industry.

Our experience with similar industries that are required to convert reporting mechanisms, to install necessary hardware and software, become familiar with the process of submitting performance test results electronically through the EPA's CEDRI, test these new electronic submission capabilities, and reliably employ electronic reporting, shows that a time period of a minimum of 90 days, and, more typically, 180 days is generally necessary to successfully accomplish these revisions.

Our experience with similar industries further shows that owners and operators generally require a time period of 180 days to read and understand the amended rule requirements; to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; and to update their operation, maintenance, and monitoring plan to reflect the revised requirements.

2. Cyanide Chemicals Manufacturing

a. Effective Date of the Final Rule

The revisions to the Cyanide Chemicals Manufacturing standards being promulgated in this action are effective on November 19, 2021.

b. Compliance Dates

New sources (affected sources that commenced construction or reconstruction after January 15, 2021) must comply with all of the standards immediately upon the effective date of the standard, November 19, 2021, or upon startup, whichever is later.

The compliance date for existing Cyanide Chemicals Manufacturing affected sources (affected sources that commenced construction or reconstruction on or before January 15, 2021) to comply with the final process wastewater standards is November 20, 2022. The EPA determined that affected sources are already complying with similar or substantially equivalent process wastewater requirements. The EPA is allowing one year to comply with the final process wastewater requirements in order to provide owners and operators the time to evaluate process wastewater rule requirements and applicability to their operations, perform compliance calculations, and adjust plans and reports, as necessary.

For requirements related to SSM-related amendments (removing references to SSM-related exemptions in other subparts) and electronic reporting, the compliance date is May 18, 2022. Based on our assessment for existing sources, 180 days is the most expeditious compliance period practicable for complying with SSM-related and electronic reporting requirements.

For SSM-related amendments, our experience with similar industries indicates that regulated facilities generally require a time period of 180 days to read and understand the amended rule requirements; to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; and to update their operations to reflect the revised requirements.

For electronic reporting changes, our experience with similar industries that are required to convert reporting mechanisms, to install necessary hardware and software, become familiar with the process of submitting performance test results electronically through the EPA's CEDRI, test these new electronic submission capabilities, and reliably employ electronic reporting indicates that a time period of a minimum of 90 days, and, more typically, 180 days is generally necessary to successfully accomplish these revisions.

IV. What is the rationale for our final decisions and amendments for the Carbon Black Production source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket for this source category.

A. Residual Risk Review for the Carbon Black Production Source Category

1. What did we propose pursuant to CAA section 112(f) for the Carbon Black Production source category?

On January 14, 2020 (86 FR 3056), the EPA proposed that risk posed by major sources in the Carbon Black Production source category is acceptable, that the current NESHAP provides an ample margin of safety to protect public health, and that additional standards are not necessary to prevent an adverse environmental effect. The estimated cancer risks were below the presumptive limit of acceptability and the noncancer risk results indicate there is minimal likelihood of adverse noncancer health effects due to HAP emissions from this source category. The proposed decision on ample margin of safety was based on weighing factors relevant to this particular source category, including the risk posed by point sources and the costs and cost-effectiveness of additional controls to reduce risk further, as well as uncertainties in the baseline emissions estimates used in estimating risk, the costs and effectiveness of the work practices we considered to reduce these emissions, and the amount of risk reduction that could be achieved with the work practices. The EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual risk (MIR) of approximately 1-in-10 thousand.'' (54 FR 38045, September 14, 1989). In the proposal, the EPA estimated risks based on actual and allowable emissions from carbon black production sources, and we considered these in determining acceptability. A more thorough discussion of the risk assessment is included in the *Residual Risk Assessment for the Carbon Black Production Source Category in Support of the Risk and Technology Review 2021 Final Rule document,* available in the docket for this final rule (Docket–EPA–HQ–OAR–2020–0505).

In the proposed rule, as presented in Table 1 below, based on modeling actual emissions from the Carbon Black Production source category for all 15 facilities, we estimated inhalation cancer risk to the individual most exposed was less than 1-in-1 million. The estimated incidence of cancer due to inhalation exposures resulting from emissions from the source category was 0.00004 excess cancer cases per year, or one excess case every 25,000 years with no-one exposed to an excess cancer risk greater than or equal to 1-in-1 million due to inhalation exposure to HAP emissions from this source category. The Agency estimated that the maximum chronic noncancer target

[6] Section 63.983(a)(1) of 40 CFR part 63, subpart SS requires that each closed vent system be designed and operated to collect the regulated material vapors from the emission point, and to route the collected vapors to a control device, apply at all times.

organ-specific hazard index (TOSHI) from inhalation exposure from this source category was 0.06. In the screening assessment of worst-case acute inhalation impacts, we estimated a maximum hazard quotient (HQ) of 0.09 (due to hydrogen cyanide) based on the reference exposure level (REL). As shown in Table 1, the chronic cancer and non-cancer risks are the same for allowable and facility-wide emissions as they are for actuals.

TABLE 1—INHALATION RISK ASSESSMENT SUMMARY FOR CARBON BLACK PRODUCTION [1] SOURCE CATEGORY

Risk assessment	Number of facilities [2]	Maximum individual cancer risk (1-in-1 million) [3]	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated population at increased risk of cancer ≥10-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [4]	Maximum screening acute noncancer HQ [5]
Baseline Actual Emissions							
Source Category.	15	0.06	0	0	0.00004	<1 (neurological)	0.09 (REL)
Facility-wide	15	0.06	0	0	0.00004	<1 (neurological).	
Baseline Allowable Emissions							
Source Category.	15	0.06	0	0	0.00004	<1 (neurological).	

[1] Based on actual and allowable emissions.
[2] Number of facilities evaluated in the risk assessment. Includes 15 operating facilities subject to 40 CFR part 63, subpart YY.
[3] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[4] Maximum TOSHI. The target organ with the highest TOSHI for the Carbon Black Production source category is the neurological system.
[5] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. The acute HQ shown was based upon the lowest acute 1-hour dose-response value, the REL for hydrogen cyanide. When an HQ exceeds 1, we also show the HQ using the next lowest available acute dose-response value.

We also conducted a multipathway screening assessment for the source category, and the results of the screening assessment are presented in the risk report titled *Residual Risk Assessment for the Carbon Black Production Source Category in Support of the 2021 Risk and Technology Review Final Rule,* and section IV of the proposal preamble (86 FR 3054), January 14, 2021) available in the docket for this action.

A screening value is not an estimate of the cancer risk or a noncancer HQ (or HI). Rather, a screening value represents a high-end estimate of what the risk or HQ may be. For the Carbon Black Production source category, the highest cancer screening value was from arsenic emissions, with a Tier 2 cancer screening value of 9, and the highest non-cancer screening value was from mercury emissions, with a Tier 3 non-cancer screening value of 2. We are confident that if a refined multipathway risk assessment was conducted, the HQ for mercury would be lower than 2. Further details on the Tier 3 screening assessment can be found in Appendix 11 of the *Residual Risk Assessment for the Carbon Black Production Source Category in Support of the Risk and Technology Review 2021 Final Rule.* Arsenic emissions resulted in a Tier 2 cancer screening value of 9, which means that we are confident that the multipathway cancer risk is lower than 9-in-1 million. The EPA has determined that it is not necessary to go beyond the Tier 3 assessment for mercury (to a site-specific assessment) or beyond the Tier 2 cancer screening assessment. As explained above, the mercury screening value of 2 is a high-end estimate of what the risk or hazard may be and can be interpreted to mean that we are confident that the HQ would be lower than 2. Similarly, we are confident that the excess cancer risk is less than 9-in-1 million, and evaluation under Tier 3 or a site-specific assessment would further reduce the estimated risk. Further, risk results from five site-specific mercury assessments the EPA has conducted for five RTR source categories resulted in noncancer HQs that range from 50 times to 800 times lower than the respective Tier 2 mercury screening value for those facilities (refer to the identified Docket ID No. EPA–HQ–OAR–2017–0015 for a copy of these reports).[7] Based on our review of these analyses, we expect if we were to perform a site-specific assessment for the Carbon Black Production source category, the mercury HQ would be at least a one order of magnitude less than the modeled Tier 3 non-cancer screening value of 2 for mercury. Thus, the EPA is confident that the mercury HQ would be less than 1, if further refined to incorporate enhanced site-specific analyses such as improved model boundary identification with improved soil/water run-off calculations and AERMOD deposition outputs used in the TRIM.FaTE model.

In evaluating the potential for multipathway effects from emissions of lead for the Carbon Black Production source category, the EPA compared modeled annual lead concentrations to the secondary National Ambient Air Quality Standards (NAAQS) level for lead (0.15 micrograms per cubic meter ($\mu g/m^3$), arithmetic mean concentration over a 3-month period). The highest annual average lead concentration, 0.000099 $\mu g/m^3$, is far below the NAAQS level for lead, indicating a low potential for multipathway impacts from lead.

In determining whether risk is acceptable for this source category, the EPA considered all available health information and risk estimation

[7] EPA Docket records: EPA–HQ–OAR–2017–0015, Appendix 11 of the *Residual Risk Assessment for the Taconite Manufacturing Source Category in Support of the Risk and Technology Review 2019 Proposed Rule,* Appendix 11 of the *Residual Risk Assessment for the Integrated Iron and Steel Source Category in Support of the Risk and Technology Review 2019 Proposed Rule,* Appendix 11 of the *Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the 2018 Risk and Technology Review Final Rule,* and Appendix 11 of the *Residual Risk Assessment for the Coal and Oil-Fired EGU Source Category in Support of the 2018 Risk and Technology Review Proposed Rule* and EPA Docket record: EPA–HQ–OAR–2019–0373, Appendix 11 of the *Residual Risk Assessment for the Iron and Steel Foundries Source Category in Support of the Risk and Technology Review 2019 Proposed Rule.*

uncertainty that includes the uncertainty in the data (See proposal at 86 FR 3054, section III.C.7, *How do we consider uncertainties in risk assessment?*). The maximum cancer risk for all facilities was below 1-in-1 million; in addition, there were no facilities with an estimated maximum chronic noncancer HI or maximum HQ greater than or equal to 1. The EPA weighed all health risk factors in our risk acceptability determination, and we proposed that the risk from this source category is acceptable. We then considered whether the NESHAP provides an ample margin of safety to protect public health, and whether more stringent standards were necessary to prevent an adverse environmental effect, by taking into consideration costs, energy, safety, and other relevant factors. Based upon these considerations, we proposed and are finalizing the determination that the 2002 Carbon Black Production NESHAP requirements provide an ample margin of safety to protect public health. Based on the results of our environmental risk screening assessment, we also proposed and are finalizing the determination that more stringent standards are not necessary to prevent an adverse environmental effect.

2. How did the risk review change for the Carbon Black Production source category?

We did not receive any information that changed our determination concerning risk and we are finalizing our proposed conclusion on the risk review.

3. What key comments did we receive on the risk review, and what are our responses?

We received several comments regarding the proposed risk review and our proposed determination that no revisions to the standard were warranted under CAA section 112(f)(2). One commenter supported the proposed determination, while another, stated that EPA underestimated risks. After review of these comments, we disagreed with the commenter's assertion that risks were underestimated and determined no changes to the standard were necessary. The comments and our specific responses can be found in the document, *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule,* which is available in docket: EPA–HQ–OAR–2020–0505.

4. What is the rationale for our final approach and final decisions for the risk review?

We evaluated all the comments on the EPA's risk review and determined that no changes are needed. For the reasons explained in the proposed rule, we determined that the risk from the Carbon Black Production source category is acceptable, the current standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect. Therefore, pursuant to CAA section 112(f)(2), we are finalizing our residual risk determination as proposed.

B. Technology Review for the Carbon Black Production Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Carbon Black Production source category?

We proposed a determination that it is not necessary to revise the existing standards because we did not identify developments in practices, processes, or control technologies that would result in cost-effective emission reductions for the Carbon Black Production source category. However, we did identify a potential gap in the regulation, and proposed to broaden the scope of the standards under the CAA sections 112(d)(2) and (3). The final approach related to that issue is discussed in section IV.C of this preamble. Additional information on our technology review can be found in the memorandum, *Technology Review for Carbon Black Production Source Category,* which is available in docket: EPA–HQ–OAR–2020–0505.

We also performed a technology review of the Carbon Black Production area source NESHAP. As part of that review, the EPA did not identify any currently operating sources in the Carbon Black Production area source category, and therefore, we proposed no changes. In this action, we are finalizing our proposed determination. For more information on the review of potential area source facilities see the memorandum, *Identification of Area Sources for the Carbon Black Production NESHAP,* which is available in docket: EPA–HQ–OAR–2020–0505.

2. How did the technology review change for the Carbon Black Production source category?

The technology review did not change from proposal. Therefore, we are finalizing our determination that no revisions to the NESHAP are necessary pursuant to CAA section 112(d)(6) for both the major and area source categories.

3. What key comments did we receive on the technology review, and what are our responses?

We received two comments regarding the major source proposed technology review and our proposed determination that no revisions were warranted under CAA section 112(d)(6). Comments suggested changes to our technology review to include additional technologies mentioned in consent decrees, including incinerators, wet or dry gas scrubbers, and selective catalytic reduction technologies. After review of these comments, we determined that no changes to the standards were necessary. Specifically, we determined that these technologies were not cost-effective for controlling HAP from carbon black facilities. The comments and our specific responses can be found in the document, *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule,* which is available in docket: EPA–HQ–OAR–2020–0505. We did not receive any comments on the area source category proposed technology review.

4. What is the rationale for our final approach and final decisions for the technology review?

Our technology review sought to identify add-on control technology that was not identified during the original NESHAP development and improvements to existing add-on controls. We also sought to identify new work practices, operational procedures, process changes, pollution prevention alternatives, or techniques that have the potential to reduce emissions. Based on our review, we did not identify any technologies, that would result in cost-effective emission reductions for the Carbon Black Production source category. Since proposal, no information has been presented to cause us to change the proposed determination. Consequently, we are finalizing our CAA section 112(d)(6) determination as proposed.

C. What are the final rule amendments pursuant to 112(d)(2) and (3) for the Carbon Black Production source category?

1. What did we propose pursuant to CAA sections 112(d)(2) and (3) for the Carbon Black Production source category?

Under CAA sections 112(d)(2) and (3) we proposed to broaden the scope of the existing emission limit in the major source NESHAP, which applies to process vents associated with the MUF, to include all process vents associated with the carbon black production unit. The expansion to cover all process vents under the Carbon Black Production MACT standard is in accordance with *LEAN* v. *EPA,* 955 F. 3d. 1088 (D.C. Cir. 2020), in which the Court held that the EPA has an obligation to set standards for unregulated pollutants which the EPA is required to regulate as part of technology reviews under CAA section 112(d)(6).

We proposed to require all process vents that have a HAP concentration of the emission stream equal to or greater than 260 ppmv, including those located after the MUF, to reduce emissions of total HAP by 98 weight-percent or to a concentration of 20 ppmv, whichever is less stringent. We also proposed to require applicability testing of process vents located after the MUF and compliance with process vent standards (where applicability threshold was exceeded) within 1 year after the effective date of the final rule.

2. What changed since proposal?

We are finalizing a longer timeframe for previously unregulated process vents to come into compliance with the requirements, since this may require the addition of add-on controls. The extension changes the proposed compliance date of 1 year from the effective date of the final rule to 3 years from the effective date of the final rule.

3. What are the key comments and responses?

The EPA received comments generally supporting the proposal to broaden the emission limit to apply to all process vents that have a HAP concentration of the emission stream equal to or greater than 260 ppmv, associated with the carbon black production unit. One commenter requested an extension to the compliance date.

a. Compliance Date Extension

Comment: The commenter stated that they do not believe carbon black facilities will be able to implement the carbon black process vent requirements for any previously unregulated process vents within 1 year of the effective date. In support of their comment, the commenter stated that the EPA has addressed similar situations in final rules by allowing up to 3 years from the effective date of the final rule for facilities to complete any necessary capital projects as allowed for by CAA section 112(i). For a detailed summary of the comment, see the document *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule,* available in the docket for this source category.

Response: The EPA agrees with the commentor that, in the event that the applicability test indicates that any newly identified process vents are subject and require re-routing to an existing control device or the construction of a new control device, the 1-year time period that the EPA proposed to allow for carbon black facilities to bring the process vents into compliance may be insufficient. As noted by the commenter, while the 1-year time frame is sufficient for conducting the applicability test, it may not provide enough time to complete the process of safely designing and constructing the ductwork necessary to either re-route the vent to an existing control device or design and construct ductwork for re-routing the vent and a new control device. To address this concern, the EPA is extending this time period in the final rule and allowing up to 3 years from the effective date of the final rule for facilities to complete any necessary capital projects as allowed for by CAA section 112(i). The language at 40 CFR 63.1102(e) has been amended in the final rule to reflect this change.

D. Amendments Addressing Emissions During Periods of SSM for the Carbon Black Production Source Category

1. What amendments did we propose to address emissions during periods of SSM?

The EPA proposed to remove the exemption for periods of startup and shutdown. Additionally, we proposed a work practice standard during periods of startup that would have allowed carbon black manufacturing facilities to vent tail gas upon startup for a period not to exceed 13 minutes, and to begin running control devices thereafter. The proposed work practice standard sought to address safety concerns surrounding startup processes at carbon black manufacturing facilities. The EPA proposed the work practice standard to mitigate the risk of explosion at carbon black manufacturing facilities upon startup due to the characteristics of the tail gas. The proposed work practice standard addressed combustibility concerns by allowing tail gas to be vented through the MUF vent for a short, time-limited period in order to prevent excess oxygen from mixing with tail gas. The EPA time-limited the proposed work practice standard to ensure sources would begin routing tail gas to control devices as soon as practicable, while accounting for variability across facilities that impact startup procedures.

2. How did the proposed amendments to address emissions during periods of SSM requirements change in the final rule?

The EPA initially proposed that the work practice standard would apply for 13 minutes upon startup. Due to comments received on the proposal, the EPA is finalizing a work practice standard that applies to both startup and shutdown of the reactor. The work practice standard allows the closed vent system to the control device to be bypassed, during both startup and shutdown of a reactor, when the excess oxygen concentration in the closed vent system is greater than or equal to 3 percent. Additionally, the maximum bypass period for the work practice standard is extended from 13 minutes to 15 minutes. To determine when the oxygen concentration of the closed vent system falls below 3 percent, each facility must use the calculated purge duration method or oxygen sensors. The language at 40 CFR 63.1003(f)(5) has been amended in the final rule to reflect these changes.

3. What key comments did we receive on the SSM revisions and what are our responses?

The EPA received comments on several aspects of the proposed work practice standard. Comments received include requests for (1) site-specific procedures, (2) expansion of the standard to shutdown periods (in addition to startup periods), (3) an increase in the time period allowed under the work practice standard, and (4) specific regulatory language changes. We are only revising requirements where credible technical and/or safety issues were identified, while maintaining the goal of minimizing emissions during periods of startup and shutdown to the maximum extent practicable. These comments and the

EPA's response to these comments are provided below.

a. Site-Specific Startup and Shutdown Procedures

Comment: The commenter stated that factors affecting the time needed for startup and shutdown procedures are specific to each facility because the time needed to purge the closed vent system and/or open and close valves depends on the configuration of the facility, common tail gas header, and the production line; the volume of the production line; the size of the valves; the production rate; and the facility-specific operating procedures and provides an example. To allow for this source-specific variability, the commenter suggested that instead of relying solely on oxygen concentration, the regulation should allow bypass of the control device during startup and shutdown of a reactor in accordance with the maximum duration calculated using the calculated purge duration method located in the startup and shutdown plan (SSP) and that the startup and shutdown occur ''as expeditiously as possible.'' The commenter stated that the use of oxygen sensors in the MUF is not current industry practices, and that of the current 15 major source facilities, only two of them have oxygen sensors. The commenter also stated that the calculated purge duration method in the SSP would include a calculation of the amount of time it takes to purge the production line, as well as a safety factor that accounts for the physical and technological constraints of the facility; the maximum duration could not be more than 15 minutes. The commenter stated that the SSP would provide the amount of time needed when completing startup and shutdown ''as expeditiously as possible.'' For a more detailed summary of the comment, see the document *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule,* which is available in docket: EPA–HQ–OAR–2020–0505.

Response: The EPA agrees that the bypass time allowed for a reactor to startup or shutdown should be source specific. The EPA acknowledges that most facilities currently do not operate oxygen sensors and relying solely on oxygen sensors to detect oxygen content in the ductwork upon startup and shutdown could lead to undetected pockets of high-oxygen concentration gases escaping the sensors, creating an explosion risk within the ductwork at a facility.

Additionally, the EPA agrees that during startup the MUF vent must be open and the common tail gas header closed when initially burning feedstock oil to purge the line of excess oxygen. If the common tail gas header is opened while the oxygen level was above 3 percent, there is a risk of explosion due to the combustible nature of the tail gas. Once the oxygen level falls below 3 percent (determined by using the calculated purge duration method discussed below), the MUF vent must gradually close while the common tail gas header is gradually opened. This gradual change helps to ensure that constant pressure is maintained within the closed vent system and common tail gas header. The EPA acknowledges that maintaining constant pressure is important. A sudden surge or interruption in tail gas flow could extinguish the flame on the control device located downstream of the common tail gas header. If the flame is extinguished, there is a risk that combustible gases will build up in the common tail gas header; if combustible gases build up in the common tail gas header, then these gases could cause an explosion when the flame is relit.

The EPA found that all facilities currently use the calculated purge duration method to predict when the oxygen level in the ductwork drops below 3 percent. The calculated purge duration method estimates the total time a facility needs to safely startup or shutdown a carbon black production line by taking into account several factors, including the volume of tail gas in the closed vent system, the flowrate within the closed vent system, a safety factor, and the time needed to balance pressure by opening and closing the necessary valves. Using the calculated purge duration method is industry practice for facilities to determine when oxygen levels are below 3 percent.

Since all facilities currently utilize the calculated purge duration method, the EPA finds this practice to be representative of the best performing facilities within the industry. The EPA is declining to require SSPs in the final rule; instead, the EPA is finalizing a change from proposal at 40 CFR 63.1103(f) to require facilities to utilize the calculated purge duration method to determine a site-specific maximum bypass duration upon startup and shutdown. The EPA determined that including site-specific requirements at 40 CFR 63.1103(f) would accomplish the same goal as SSPs without adding additional reporting burden.

b. Work Practice Standard Should Apply During Startup and Shutdown

Comment: The commenter requested that the proposed work practice standard be revised to apply during shutdown as well as during startup. In support of their comment, the commenter provided a comprehensive discussion of the carbon black production startup and shutdown processes and the reasoning for their request for modifications to the proposed work practice standard requirements. Reasons for expanding the work practice to shutdown as well as startup include the similarities in the need to maintain constant pressure and to reduce the oxygen content in the closed vent system to under 3 percent due to the risk of explosion for both startup and shutdown. For a summary of their detailed comments regarding startup and shutdown, see the document *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule,* available in the docket for this rulemaking.

Response: Based on the information provided by the commenter, EPA agrees that shutdown operations present safety concerns similar to those associated with startup. Accordingly, the EPA is finalizing a revision to the proposed work practice standard so that it applies to both startup and shutdown operations.

The EPA agrees that the shutdown process presents combustibility concerns similar to startup. When facilities stop burning feedstock oil, higher oxygen content is created in the closed vent system. This creates an explosion risk if the oxygen level rises above 3 percent. Therefore, prior to removing feedstock oil from the reactor, the common tail gas header vent must be closed completely, diverting closed vent system emissions from the common tail gas header to the MUF, before the oxygen content begins to increase.

Similar to startup, constant pressure must be maintained within the closed vent system during shutdown operations to reduce the risk of explosion. To achieve constant pressure within the closed vent system, the MUF vent must be slowly opened while the tail gas header vent is slowly closed. Once the tail gas header has been completely closed and the MUF vent is completely open, the burning of feedstock oil in the reactor ceases. The

EPA acknowledges that maintaining constant pressure is important. A sudden surge or interruption in tail gas flow could extinguish the flame on the CCD or other combustion device located downstream of the common tail gas header. If the flame is extinguished, there is a risk that combustible gases will build up in the common tail gas header; if combustible gases build up in the common tail gas header, then these gases create an explosion risk when the flame is relit.

c. Work Practice Standard Time Allotment

Comment: The commenter requested that the maximum time allowed to bypass the control device during startup and shutdown of a reactor be increased from 13 minutes to 15 minutes. The commenter explained that their request for this increase in time is based on the minimum time necessary to completely purge the ductwork and MUF of certain facilities. The commenter provided that this was previously agreed to by the EPA in the consent decrees below.

In 2007, the EPA began a National Enforcement Initiative to investigate the carbon black manufacturing sector. As a result of this initiative, each of the International Carbon Black Association (ICBA) member companies in the United States entered into a settlement with the EPA and the Department of Justice regarding CAA claims (hereinafter, the ''Consent Decrees''). The implementation of the terms of these Consent Decrees has and will result in substantial changes to the facilities as flares are removed and different control technologies are installed at a significant cost. Many facilities have already implemented the agreed upon technologies and others are in the procurement stages.

The commenter stated that, in the preamble, the EPA explains that ''the 13-minute allotment to bypass the control device, corresponds with the minimum time necessary to completely purge the ductwork and primary bag filter of the facility representing the lowest production rate.'' However, the commenter suggested that when setting the 13-minute limit, it appears that the EPA did not fully consider the agreed-upon time limit in all of the consent decrees or all of the factors which affect how long it takes a facility to purge excess oxygen and introduce tail gas to the common tail gas header while balancing pressure. The commenter stated that the consent decree for Sid Richardson Carbon, Ltd. allowed a 15-minute bypass.[8] [9]

Response: The EPA acknowledges that the consent decree cited by the commenter allows a 15-minute control device bypass upon startup for the facility subject to the consent decree allotment to bypass the control device. In their comment, the commenter provided information to the EPA concerning the source-specific nature of startup and shutdown operations at carbon black manufacturing facilities, including technical support demonstrating that one source subject to this rulemaking may need up to 15 minutes to purge the excess oxygen content in the MUF vent during startup and shutdown operations in order to mitigate combustibility concerns. To address this comment, in the final rule, the EPA is extending the proposed 13-minute bypass period to a maximum 15-minute bypass period. However, this time period is further constrained by the calculated purge duration method. The EPA is also finalizing a requirement that facilities subject to this rule use the calculated purge duration method to determine the length of the startup and/or shutdown bypass period required for a specific facility before that specific facility may begin to safely operate control devices, and the facility must begin operating control devices as soon as the facility may safely do so. In no case do the finalized requirements allow the startup or shutdown bypass period to exceed 15 minutes for any facility. The EPA is also amending the work practice standard to apply to periods of shutdown as well as startup.

As previously mentioned, carbon black production facilities currently use the calculated purge duration method to predict when the oxygen level in the closed vent system drops below 3 percent. The calculated purge duration method considers the volume of tail gas in the closed vent system, with an appropriate safety factor, and the time needed to balance pressure and close or open the necessary valves. Using the calculated purge duration method is common industry practice for facilities to determine when oxygen levels are below 3 percent.

Since all facilities currently utilize the calculated purge duration method, the EPA finds this practice to be representative of the best performing facilities within the industry. As previously discussed, the EPA is declining to require SSPs. Instead, the EPA is modifying the proposed standard at 40 CFR 63.1103(f)(5) to require facilities to utilize the calculated purge duration method or oxygen sensors to determine a site-specific maximum bypass duration upon startup and shutdown. In no case shall the maximum bypass duration period exceed 15 minutes for any facility. The calculated purge duration method is the same approach underlying the control device bypass timeframes included in the enforcement-related consent decrees for the carbon black industry.

4. What is the rationale for our changes to the proposed amendments to address emissions during periods of SSM in the final rule?

Based on the consideration of comments received concerning technical and safety concerns with the proposed work practice standard, the EPA revised the work practice standard provisions in the final rule. As discussed in our responses to comments in section IV.C.3 of this preamble, we are only revising requirements where credible technical and/or safety issues were identified, while maintaining the goal of minimizing emissions during periods of startup and shutdown to the maximum extent practicable.

E. Other Technical Amendments to the Carbon Black Production NESHAP

1. Boiler and Process Heater Annual Tune-Up Requirements

a. What amendments did we propose for boiler and process heater annual tune-up requirements?

As a result of the EPA's assessment of the MACT standards that currently apply to the Carbon Black Production source category under subpart YY, the EPA received a comment that there may be instances where carbon black production process vents at affected sources route emissions to a boiler or process heater for use as fuel gas and may not be subject to any requirements. Under the existing standards, although emission streams may be subject to the Carbon Black Production MACT, these streams are exempt from any requirements under the rule when emissions are routed to a boiler or process heater for use as fuel gas. Under the Boiler MACT, process heaters and boilers covered under another standard (as with the Carbon Black Production MACT) are not subject to the Boiler MACT.

The EPA proposed to revise subpart YY to include boiler and process heater annual tune-up requirements for those boilers and process heaters that receive

[8] *United States* v. *Sid Richardson Carbon, Ltd.,* 3:17–cv–01792–SDD–RLB (M.D. La.), Consent Decree, filed Dec. 22, 2017, at § III.8.oo.

[9] *United States* v. *Sid Richardson Carbon, Ltd.,* 3:17–cv–01792–SDD–RLB (M.D. La.), Consent Decree, filed Dec. 22, 2017, at § III.8.oo.

tail gas for use as fuel gas. These provisions were proposed in 40 CFR 63.1103(f)(3)(iii) of the final rule. The annual tune-up provisions paralleled those specified under the Boiler MACT.

b. How did the proposed boiler and process heater tune-up requirements change in the final rule?

The final rule revises the definition for ''process vent'' to remove the fuel gas exemption for the Carbon Black Production source category. This revised change ensures that the annual tune-up requirements apply to process heaters and boilers, as intended.

The final rule also revises the text at 40 CFR 63.1103(f)(3)(iii)(A) (first sentence) to require inspection to be of the ''combustion device'' instead of the ''burner,'' and at 40 CFR 63.1103(f)(iii)(B), (C), (D) and (E) to provide industry-specific clarification on tune-up requirements.

c. What key comments did we receive on the proposed annual boiler and process heater tune-up requirements and what are our responses?

The EPA received comments on the proposed boiler and process heater tune-up requirements related to the applicability language and specified tune-up procedures. These comments and the EPA's responses and subsequent changes to the proposed boiler and process heater tune-up provisions are provided below.

i. Applicability

Comment: The commenter suggested that the proposed language for the annual tune-up requirement be changed so that it applies to the process heaters and boilers that the EPA intended. The commenter noted that the EPA explained that it added the annual tune-up requirement to close a perceived loophole. The commenter stated that they are unsure whether the proposed modifications in the proposal achieved the EPA's goal. The commenter noted that while the preamble to the proposed rule identifies the target of the annual tune-up requirements to be boilers and process heaters receiving emissions to use as fuel gas, the language in the proposed rule may not apply to the intended boilers or process heaters.

The commenter explained that, in the current regulations, emission streams that are routed to a boiler or process heater for fuel gas are not regulated as a process vent, because ''[g]as streams transferred for fuel value (*i.e.,* net positive heating value), use reuse, or sale for fuel value, use, or reuse,'' are excluded from the definition of process vent. 40 CFR 63.1101. Therefore, the commenter noted that when emissions are routed to a boiler or process heater for use as fuel gas at a carbon black production facility, those points of discharge are not process vents. The proposed rule does not alter the definition of process vent, and the commenter was uncertain what effect the changes to Table 8 of the proposed regulatory text would have on the current standards. The commenter stated that changes in Table 8 of the proposed regulatory text apply only to ''process vents'' and under the definition of process vents, this would necessarily mean that it could not include gas streams routed to boilers or process heaters for fuel value. For a more detailed summary of the comment, see *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule,* which is available in docket: EPA–HQ–OAR–2020–0505.

Response: The EPA acknowledges that the proposed regulatory text was unclear and could lead to subject facilities not complying with the added boiler and process heater requirements. To resolve this issue, the EPA is revising the definition for process vent to remove the fuel gas exemption for the Carbon Black Production source category. Specifically, the EPA is finalizing an amended definition of ''process vent'' to remove the exemption for gas streams transferred for fuel value, use, reuse, or sale for fuel value, use, or reuse for the carbon black production source category.

ii. Annual Tune-Up Requirements

Comment: Commenters also requested tailored modifications to the tune-up requirements to better reflect the specifications of combustion devices typically used in the carbon black production process. The commenter noted that carbon black combustion devices differ significantly from natural gas combustion devices such that not all of the proposed tune-up requirements apply In support of their comment, the commenter states that additional optimization outside of inspection and cleaning may not be possible for all facilities. For a more detailed summary of the comment, see *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants Carbon Black Production Residual Risk and Technology Review and Carbon Black Production Area Sources Technology Review Proposed Rule,* which is available in docket: EPA–HQ–OAR–2020–0505.

Response: The EPA agrees with the commenter that, as a result of the nature of the burner configuration and design of tail gas fired boilers and process heaters in the Carbon Black Production source category, the tune-up requirements of the proposed rule may not be able to be performed as written. As the commenter noted, due to the lack of an inspection port for the ''typical'' burner configuration used in the carbon black production process, it may not be possible to perform a direct inspection of the burner in operation, as described in 40 CFR 63.1103(f)(3)(iii)(A). Thus, the EPA is finalizing the suggested revision to the regulatory text at 40 CFR 63.1103(f)(3)(iii)(A) to read ''[i]nspect the combustion device for damage, wear, and buildup of material that could impact effectiveness'' rather than ''inspect the burner.'' The EPA disagrees in part with the other changes suggested by the commenter. As noted by the commenter, a ''typical'' burner configuration may not be amenable to inspection of the flame pattern and adjustment of the burner, but it is possible in some configurations. The regulatory text at 40 CFR 63.1103(f)(iii)(B) has been amended to require the inspection and adjustment only when possible based upon the physical configuration of the burner. Similarly, the requirements of 40 CFR 63.1103(f)(iii)(C) state to ''[i]nspect the system controlling the air-to-fuel ratio, as applicable, and ensure that it is correctly calibrated and functioning properly.'' The EPA agrees that not all configurations of systems controlling air-to-fuel ratio have calibrated components, but some systems may have components that are calibrated and would need that calibration verified. However, if a burner system does not have anything to be calibrated, then ensuring proper calibration is not necessary; the inspection of the fuel to air ratio controlling mechanism in that case could be as simple as verifying that there are no obstructions to the air intake in a natural draft system and verifying proper fan operation for a fixed air flow fan. For these reasons, the EPA also agrees that 40 CFR 63.1103(f)(iii)(C) should not be finalized as proposed and is amending the final language to reflect that ensuring proper calibration is only necessary for calibrated components of the air-to-fuel system.

The EPA disagrees with the commenter that 40 CFR 63.1103(f)(iii)(D) and (E) should not be finalized and disagrees that measurement of carbon monoxide (CO)

is a poor indicator of optimized performance. As CO is a primary component of tail gas, any tail gas not combusted by the boiler or process heater will result in CO emissions. Additionally, CO is produced from the incomplete combustion of hydrocarbons in the tail gas. During proper operation of the combustion device, the output of CO from either uncombusted tail gas or from incomplete combustion is minimized. The EPA agrees that optimization beyond the inspection and cleaning required in 40 CFR 63.1103(f)(iii)(A) may not be possible for the configuration of some carbon black facility combustion devices. In such a scenario, the proposed language of 40 CFR 63.1103(f)(iii)(D) was clear that ''[t]his optimization should be consistent with the manufacturer's specifications, if available.'' In instances where there are no manufacturer's recommendations for optimization, the cleaning of the combustion device constitutes the optimization procedure, and CO measurement should be taken before and after cleaning the combustion device. The regulatory text at 40 CFR 63.1103(f)(iii)(D) has been amended from that proposed to more clearly reflect that, in the cases where no manufacturer's specification for optimization are available, the inspection and cleaning procedures of 40 CFR 63.1103(f)(iii)(A) fulfill the requirements of optimization and that when available, manufacturer's specification should be used for the optimization procedure. The regulatory text at 40 CFR 63.1103(f)(iii)(E) has been amended from that proposed to reflect that if adjustments are not or cannot be made, the measurements of CO are performed after the inspection and cleaning procedures of 40 CFR 63.1103(f)(iii)(A) are performed.

d. What is the rationale for our final changes to the proposed boiler and process heater annual tune-up provisions?

Based on the consideration of comments received on the combustion devices typically used in the carbon black production process, we clarified and revised the applicability and requirements of the annual boiler and process heater tune-up requirements to better reflect the combustion devices typically used. See our comment response directly above in subsection ii, for our rationale for revisions based on our evaluation of comments.

V. What is the rationale for our final decisions and amendments for the Cyanide Chemicals Manufacturing source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses (when applicable). For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket for this source category.

A. Residual Risk Review for the Cyanide Chemicals Manufacturing Source Category

1. What did we propose pursuant to CAA section 112(f) for the Cyanide Chemicals Manufacturing source category?

On January 15, 2021 (86 FR 3906), the EPA proposed that risk posed by emissions from the source category is acceptable, that the current NESHAP provides an ample margin of safety to protect public health, and that additional standards are not necessary to prevent an adverse environmental effect. The EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of approximately 1-in-10 thousand.'' (54 FR 38045, September 14, 1989). The maximum estimated cancer risk was below the presumptive limit of acceptability and the noncancer risk results indicate there is minimal likelihood of adverse noncancer health effects due to HAP emissions from this source category. The proposed decision on ample margin of safety was based on weighing factors relevant to this particular source category, including the risk posed by emissions from the category and the costs and cost-effectiveness of additional controls to reduce risk further, as well as uncertainties in the baseline emissions estimates used in estimating risk, the costs and effectiveness of the work practices we considered to reduce these emissions, and the amount of risk reduction that could be achieved with the work practices. A more thorough discussion of the risk assessment is included in the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2021 Final Rule* document, available in the docket for cyanide chemicals manufacturing (Docket–EPA–HQ–OAR–2020–0532). In the proposed rule, as presented in Table 2 below, based on modeling actual emissions from the source category for all 13 facilities, we estimated inhalation cancer risk to the individual most exposed was equal to 5-in-1 million. The estimated incidence of cancer due to inhalation exposures resulting from emissions from the source category was 0.004 excess cancer cases per year, or one excess case every 250 years with 61,653 people exposed to an excess cancer risk greater than or equal to 1-in-1 million due to inhalation exposure to HAP emissions from the source category. Emissions of acrylonitrile from process vents account for 95 percent of the cancer incidence. The Agency estimated that the maximum chronic noncancer TOSHI from inhalation exposure for this source category was equal to 1. In the screening assessment of worst-case acute inhalation impacts, we estimated a maximum HQ of 1 (due to hydrogen cyanide) based on the REL. In the proposal, the EPA estimated risks based on actual and allowable emissions from cyanide chemicals manufacturing sources, and we considered these in determining acceptability. As shown in Table 2, the chronic cancer and non-cancer risks are the same for allowable emissions as they are for actual emissions.

TABLE 2—INHALATION RISK ASSESSMENT SUMMARY FOR CYANIDE CHEMICALS MANUFACTURING [1] SOURCE CATEGORY

Risk assessment	Number of facilities [2]	Maximum individual cancer risk (1-in-1 million) [3]	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated population at increased risk of cancer ≥10-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [4]	Maximum screening acute noncancer HQ [5]
Baseline Actual Emissions							
Source Category	13	5	61,653	0	0.004	1 (neurological)	1 (REL).
Facility-wide	13	200	266,532	58,000	0.04	1 (neurological).	

TABLE 2—INHALATION RISK ASSESSMENT SUMMARY FOR CYANIDE CHEMICALS MANUFACTURING [1] SOURCE CATEGORY—Continued

Risk assessment	Number of facilities [2]	Maximum individual cancer risk (1-in-1 million) [3]	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated population at increased risk of cancer ≥10-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [4]	Maximum screening acute noncancer HQ [5]
Baseline Allowable Emissions							
Source Category	13	5	61,653	0	0.004	1 (neurological).	

[1] Based on actual and allowable emissions.
[2] Number of facilities evaluated in the risk assessment. Includes 13 operating cyanide chemicals manufacturing facilities subject to 40 CFR part 63, subpart YY.
[3] Maximum individual excess lifetime cancer risk due to HAP emissions.
[4] Maximum TOSHI. The target organ with the highest TOSHI for the Cyanide Chemical Manufacturing source category is the neurological system.
[5] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. The acute HQ shown was based upon the lowest acute 1-hour dose-response value, the REL for hydrogen cyanide. When an HQ exceeds 1, we also show the HQ using the next lowest available acute dose-response value.

The EPA also estimated inhalation risk based on facility-wide emissions. The estimated maximum individual excess lifetime cancer risk based on facility-wide emissions was 200-in-1 million, with 0.04 excess cancer cases per year, or one case every 25 years. This cancer risk is driven by emissions sources that are not in the Cyanide Chemicals Manufacturing source category; specifically, emissions of ethylene oxide and polycyclic organic matter from non-category sources account for 95 percent of the cancer incidence. Approximately 150 people are exposed to an excess cancer risk greater than or equal to 100-in-1 million, with 266,532 people exposed to an excess cancer risk above 1-in-1 million. The estimated maximum chronic noncancer TOSHI values for the facility-wide assessment was the same as estimated based on actual and allowable emissions from the source category. The TOSHI value was equal to 1 for neurological effects driven by hydrogen cyanide emissions from process vents, wastewater, and equipment leaks.

Regarding the facility-wide risks due to ethylene oxide emissions, which are emitted by sources that are not part of the Cyanide Chemicals Manufacturing source category, we intend to continue to evaluate those facility-wide estimated emissions and risks further and may address these in separate actions, as appropriate. In particular, the EPA is addressing ethylene oxide in response to the results of the latest National Air Toxics Assessment (NATA) released in August 2018, which identified the chemical as a potential concern in several areas across the country.[10] The latest NATA estimates that ethylene oxide significantly contributes to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). These elevated risks are largely driven by an EPA risk value that was updated in late 2016. The EPA is taking steps to address ethylene oxide emissions by: (1) Reviewing and, as appropriate, revising CAA regulations for facilities that emit ethylene oxide—starting with air toxics emissions standards for miscellaneous organic chemical manufacturing facilities (85 FR 49084, August 12, 2020) and commercial sterilizers; and (2) working with industry and state, local, and tribal air agencies to achieve near-term emission reductions. The EPA posts updates on its work to address ethylene oxide at: *https://www.epa.gov/ethylene-oxide.*

We also conducted a multipathway screening assessment for the source category, and the results of the screening assessment are presented in the risk report titled *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the 2021 Risk and Technology Review Final Rule,* and section IV of the proposal preamble (86 FR 3906, January 15, 2021) available in the docket for this action. A screening value is not an estimate of the cancer risk or a noncancer HQ (or HI). Rather, a screening value represents a high-end estimate of what the risk or HQ may be. For this source category the highest cancer screening value was a Tier 2 cancer screening value less than 1 for arsenic emissions, which means that we are confident that the multipathway cancer risk is lower than 1-in-1 million. The highest Tier 2 non-cancer screening value for the category was less than 1 for mercury emissions, which can be interpreted to mean that we are confident that the chronic HQ for mercury is less than 1.

In evaluating the potential for multipathway effects from emissions of lead, the EPA compared modeled annual lead concentrations to the secondary NAAQS level for lead (0.15 micrograms per cubic meter (ug/m^3), arithmetic mean concentration over a 3-month period). The highest annual average lead concentration, 0.000004 ug/m^3, is far below the NAAQS level for lead, indicating a low potential for multipathway impacts from lead.

Based on the results of the environmental risk screening analysis, we do not expect an adverse environmental effect as a result of HAP emissions from this source category. For further additional detail on the environmental risk screening assessment, refer to the *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2021 Final Rule.*

In determining whether risk is acceptable for this source category, the EPA considered all available health information and risk estimation uncertainty, including the uncertainty in the emissions data. Further discussion of the uncertainties in our risk assessment can be found in section III.C.7 of the preamble to the proposed rule at 86 FR 3918. Under the ample margin of safety analysis, we evaluated the cost and feasibility of available control technologies and other measures (including the controls, measures, and costs reviewed under the technology review) that could be applied to this source category to further reduce the risks (or potential risks) due to emissions of HAP from the source category. At proposal, we determined that the risk from Cyanide Chemicals Manufacturing emissions is acceptable and that the standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect. In this action, we are finalizing our proposed determination. See section IV.C of the proposal preamble (86 FR 3906, 3923–3924) for a discussion of the results of our risk assessment and analyses and our proposed decisions

[10] NATA is the Agency's nationwide air toxics screening tool, designed to help the EPA and state, local, and tribal air agencies identify areas, pollutants, or types of sources for further examination.

regarding risk acceptability, ample margin of safety, and adverse environmental effects. The EPA is not amending the Cyanide Chemicals Manufacturing NESHAP based on the risk review conducted pursuant to CAA section 112(f). The maximum cancer risk for all facilities was 5-in-1 million, which is 20 times below 100-in-1 million, the presumptive upper limit of acceptable risk. In addition, there were no facilities with an estimated maximum chronic noncancer HI or maximum HQ greater than 1. Based upon these considerations and the lack of additional cost-effective control technologies to reduce risk further, we proposed and are finalizing a determination that the 2002 Cyanide Chemicals Manufacturing NESHAP requirements provide an ample margin of safety to protect public health. Based on the results of our environmental risk screening assessment, we also proposed and are finalizing a determination that more stringent standards are not necessary to prevent an adverse environmental effect.

2. How did the risk review change for the Cyanide Chemicals Manufacturing source category?

We did not receive any information that changed our determination concerning risk and we are finalizing our proposed conclusion on the risk review.

3. What key comments did we receive on the risk review, and what are our responses?

We received several comments regarding the proposed risk review and our proposed determination that no revisions to the standard were warranted under CAA section 112(f)(2). Comments both supported and suggested changes to our risk review. Commenters opposed our proposed decisions regarding risk acceptability and certain aspects of our risk assessment methodology. After review of these comments, we determined that no changes to the standard were necessary because the current standards provide an ample margin of safety to protect public health. The comments and our specific responses can be found in the document, *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review Proposed Rule,* which is available in docket: EPA–HQ–OAR–2020–0532.

4. What is the rationale for our final approach and final decisions for the risk review?

We evaluated all the comments on the EPA's risk review and determined that no changes are needed. For the reasons explained in the proposed rule, we determined that the risk from the Cyanide Chemicals Manufacturing source category is acceptable, the current standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect. Therefore, pursuant to CAA section 112(f)(2), we are finalizing our residual risk determination as proposed.

B. Technology Review for the Cyanide Chemicals Manufacturing Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Cyanide Chemicals Manufacturing source category?

At proposal, we proposed to determine that it is not necessary to revise the existing standards pursuant to CAA section 112(d)(6) because we did not identify developments in practices, processes, or control technologies that would result in cost-effective emission reductions for the Cyanide Chemicals Manufacturing source category. Additional information on our technology review can be found in the memorandum, *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal,* which is available in the docket for this action (see Docket ID No. EPA–HQ–OAR–2020–0532–0025) and section IV.D of the proposal preamble (86 FR 3924). The EPA is not amending the Cyanide Chemicals Manufacturing NESHAP based on our technology review. However, we did identify a potential gap in the regulation, and proposed standards for process wastewater at existing sources and upstream suppression of process wastewater at new sources under CAA sections 112(d)(2) and (3). The final approach related to that issue is discussed in section V.C of this preamble.

2. How did the technology review change for the Cyanide Chemicals Manufacturing source category?

The technology review did not change from proposal. Therefore, we are finalizing our determination that no revisions to the NESHAP are necessary pursuant to CAA section 112(d)(6).

3. What key comments did we receive on the technology review, and what are our responses?

We received two comments regarding the proposed technology review and our proposed determination that no revisions were warranted under CAA section 112(d)(6). One commenter suggested changes to our technology review to include additional technologies related to flares and equipment leaks. After review of these comments, we determined that no changes to the standards were necessary because these technologies would not result in cost-effective emission reductions for the cyanide chemicals manufacturing source category. The comments and our specific responses can be found in the document, *Summary of Comments and EPA's Responses on the National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review Proposed Rule,* which is available in docket: EPA–HQ–OAR–2020–0532.

4. What is the rationale for our final approach and final decisions for the technology review?

Our technology review sought to identify add-on control technology that was not identified during the original NESHAP development and improvements to existing add-on controls. We also sought to identify new work practices, operational procedures, process changes, pollution prevention alternatives, or techniques that have the potential to reduce emissions. Based on our review, we did not identify any such developments that would result in cost-effective emission reductions for the Cyanide Chemicals Manufacturing source category. Since proposal, no information has been presented to cause us to change the proposed determination. Consequently, we are finalizing our CAA section 112(d)(6) determination as proposed.

C. Amendments Addressing Emissions During Periods of SSM for the Cyanide Chemicals Manufacturing Source Category

1. What amendments did we propose to address emissions during periods of SSM?

Consistent with the 2008 decision in *Sierra Club* v. *EPA,* the EPA evaluated the Cyanide Chemicals Manufacturing NESHAP requirements to identify the need to eliminate any SSM exemptions in the rule to ensure that standards that apply during normal operations apply at all times. As noted at proposal (86 FR 3906, 3924), the Cyanide Chemicals

Manufacturing source category NESHAP did not include an exemption for SSM events, and already included standards that apply at all times, including periods of SSM. Therefore, we determined that the NESHAP was already consistent with *Sierra Club* v. *EPA,* in which the Court vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. However, we proposed revisions to subpart YY at 40 CFR 63.1108 through 40 CFR 63.1112 to remove any references associated with the GMACT that contained SSM exemptions for other source categories and from referenced subparts to reduce confusion. The EPA did not propose any other amendments addressing emissions during SSM periods because of our determination that the NESHAP already included standards that apply at all times, including periods of SSM.

2. How did the proposed SSM-related amendments change in the final rule?

We are finalizing our proposal to remove SSM exemption language included in 40 CFR 63.1108 through 40 CFR 63.1112 and GMACT referenced subparts.

3. What key comments did we receive on SSM-related emissions and what are our responses?

While one commenter provided support for the EPA's removal of references to provisions that contained SSM exemptions for other source categories and from referenced subparts to reduce confusion, the commenter expressed concern that the EPA had not removed references to SSM exemptions in HON-referenced provisions and that the EPA must assure full removal of SSM exemptions in the final rule to assure compliance with the CAA.

Other commenters expressed concern that the EPA had not established work practice standards to cover situations that they contend had been covered under their SSM plan included under the SSM exemption requirements that were proposed to be removed. The commenter requested that the EPA include provisions for specified circumstances that were previously covered under their SSM plan similar to what was included for the ethylene production source category in subpart YY.

These comments and the EPA's responses to these comments are provided below.

a. Elimination of the SSM Exemption

Comment: One commenter noted that SSM events play a considerable role in the issue of pollution and environmental contamination as these processes increase an industrial plant's pollution and noted concern that the EPA would continue to maintain SSM exemptions in this rule. Another commenter supported the removal of the SSM exemptions, stating that removal of these provisions is required to assure compliance with the CAA because this is a 'necessary' revision under CAA section 112(d)(6).

Response: As discussed in section V.C.1 of this preamble, we are finalizing revisions (as proposed) to subpart YY at 40 CFR 63.1108 through 40 CFR 63.1112 to remove any references associated with the GMACT that contained SSM exemptions for other source categories and referenced subparts.

Comment: One commenter stated that the EPA's proposed standards are illegal because the HON standard the EPA is proposing to incorporate for wastewater requirements includes the illegal SSM exemption that the EPA admits it must remove from the cyanide chemical manufacturing rules here under CAA section 112(d)(6). The commenter stated that the EPA may not lawfully remove the exemption and then immediately reinstate it by incorporation of an equally illegal SSM exemption in the HON.

Response: The EPA assessed the specific HON wastewater provisions referenced in the proposed Cyanide Chemicals Manufacturing MACT rule and did not identify any language containing exemptions for periods of SSM. The commenter made a general allegation about exemptions and did not identify any specific provisions that contained exemptions. The EPA has therefore not made changes to the final rule based on this comment.

b. Pressure Relief Devices (PRD) in HAP Service

Comment: One commenter stated, ''[p]ressure relief discharges to the atmosphere from cyanide chemicals manufacturing covered processes are rare. However, if a discharge from a [PRD] occurs, it would currently be addressed under the SSM plan and the emissions would be reported to the appropriate regulatory entities if the amount is greater than an applicable Reportable Quantity (RQ) for any air contaminant.'' The commenter contended that, because the SSM plan will be proposed to be withdrawn 180 days after the rule is amended, ''any modifications to the process or additions of emissions control equipment are not feasible in this timeframe.'' Therefore, the commenter suggested including in this rule the same work practice requirements for PRDs that are in the subpart YY regulation for the ethylene production source category, which the commenter alleges also has a small number of PRDs venting to the atmosphere.

Specifically, the commenter recommended that the EPA incorporate the work practice standards of 40 CFR 63.1107(h)(3) through (8) within the Cyanide Chemicals manufacturing rule in order to ''address any potential discharge from a [PRD] that is on fixed equipment and to exempt any [PRD] from infeasible monitoring for portable containers and mobile equipment.'' The commenter requested that any referenced citations in the aforementioned section be aligned with the Cyanide Chemicals Manufacturing MACT rule and noted that certain ethylene flare provisions are not applicable to this source category.

Additionally, the commenter suggested that the associated recordkeeping and reporting requirements in 40 CFR 63.1109(i) and 63.1110(e)(8) may also be appropriate to add to the rule in support of the PRD work practice standards.

Response: The EPA has not added the provisions requested by the commenter. While these or similar provisions exist in NESHAP for some source categories, the EPA does not have data (nor was sufficient data provided) to demonstrate that such provisions are warranted for the cyanide chemicals manufacturing NESHAP. The commenter requested these provisions be added to the Cyanide Chemicals Manufacturing NESHAP because they exist in the Ethylene Production NESHAP. The commenter did not definitively assert that any PRDs exist that would be subject to this action, nor whether they are controlled or atmospheric PRDs.

The commenter stated that there is insufficient time to implement process modifications/add emissions control equipment within 180 days after the rule is amended. This statement acknowledged that the process can be modified and emissions control equipment can be used to meet standards at all times. Without data to support the need for specific work practice provisions for PRDs, including the prevalence of PRDs, whether they are routed to control devices, the frequency of releases, magnitude of emissions during releases, and costs of further controls, we have insufficient basis to add these requirements for the

cyanide chemicals manufacturing source category.

c. Maintenance Vents

Comment: One commenter requested that, since the SSM plan and various exceptions are proposed to be removed within 180 days after the rule is amended, the same work practice requirements for maintenance vents that are in the subpart YY regulation for the ethylene production source category be included ''so that it is clear that equipment can be cleared and opened for maintenance or other similar work.''

The commenter provided that some covered facilities include similar work practice provisions in Texas New Source Review air permits for routine maintenance activities. According to the commenter, ''[i]ncluding provisions for maintenance vents in the final rule will clarify the requirements when these maintenance activities occur.''

The commenter suggested the following requirements and options when incorporating the subpart YY regulation for the ethylene production source category maintenance vents language:

- Limit the lower explosive limit (LEL) to 10 percent; and
- Limit the concentration of hydrocarbons or hydrogen cyanide to 500 ppmv measured using one of the following options:
  - The use of an instrument that complies with EPA Method 21 in 40 CFR part 60, appendix A (measures total hydrocarbon concentration)
  - The use of colorimetric gas detector tubes provided the tube is used in accordance with manufacturer's guidelines (measures hydrogen cyanide concentration); or
  - The use of an electrochemical sensor for hydrogen cyanide (measures hydrogen cyanide concentration).

Furthermore, the commenter suggested that the recordkeeping and reporting requirements in 40 CFR 63.1109(f) and 63.1110(e)(5) may also be appropriate to add to the rule in support of the maintenance venting provisions.

Response: The EPA has not made the commenter's suggested revisions. The commenter did not provide sufficient information regarding why they could not meet the standards or why their suggested requirements should be included.

Additionally, neither limiting the LEL to 10 percent nor limiting the concentration to 500 ppmv when considering hydrogen cyanide are defensible. The 10 percent LEL for hydrogen cyanide in air is 5,600 ppm. Hydrogen cyanide is highly toxic by all routes of exposure and may cause central nervous system, cardiovascular, and respiratory effects that could lead to death. The Occupational and Safety and Health Administration (OSHA) has concluded that a variety of symptoms are associated with exposure to hydrogen cyanide at levels less than 10 ppm and has established a 4.7-ppm 15-minute short term exposure limit (STEL) as the permissible exposure limit (PEL).[11]

d. Storage Vessel Degassing—Fixed Roof Storage Tanks

Comment: One commenter requested that the EPA include the same requirements for storage vessel degassing for fixed roof tanks that are in the subpart YY regulation for the ethylene production source category. The commenter suggested the following requirements and options when incorporating the subpart YY regulation for ethylene production storage vessel degassing language:

- Limit the LEL to 10 percent; and
- Limit the concentration of hydrocarbons or hydrogen cyanide to 500 ppmv measured using one of the following options:
  - The use of an instrument that complies with EPA Method 21 in 40 CFR part 60, appendix A (measures total hydrocarbon concentration)
  - The use of colorimetric gas detector tubes provided the tube is used in accordance with manufacturer's guidelines (measures hydrogen cyanide concentration); or
  - The use of an electrochemical sensor for hydrogen cyanide (measures hydrogen cyanide concentration).

Response: The EPA has not made the commenter's requested revisions. However, insufficient information was provided to support their contention that they could not meet the standards during storage vessel degassing or why their suggested requirements should be included.

As discussed in section V.C.3.c above for Maintenance Vents, neither limiting the LEL to 10 percent or limiting the concentration to 500 ppmv when considering hydrogen cyanide are defensible. The 10 percent LEL for hydrogen cyanide in air is 5,600 ppm. Hydrogen cyanide is highly toxic by all routes of exposure and may cause central nervous system, cardiovascular, and respiratory effects that could lead to death. The OSHA has concluded that a variety of symptoms are associated with exposure to hydrogen cyanide at levels less than 10 ppm and has established a 4.7-ppm 15-minute STEL as the PEL.[12]

4. What is the rationale for our final changes to the SSM-related amendments?

We evaluated all of the comments on the EPA's proposed amendments to the SSM provisions. For the reasons explained in the proposed rule (86 FR 3906, 3924), we determined that these amendments, which remove and revise provisions related to SSM, are necessary to ensure there is no confusion that standards are required to apply at all times, consistent with *Sierra Club* v. *EPA.* More information concerning the amendments we are finalizing for SSM is in the preamble to the proposed rule and in our specific responses to the comments above (section V.C.3). Therefore, we are finalizing our amendments for the SSM provisions as proposed.

D. Other Technical Amendments to the Cyanide Chemicals Manufacturing NESHAP

1. What wastewater provision amendments did we propose?

As discussed in section II.D of this preamble and in the proposal preamble for the Cyanide Chemicals Manufacturing NESHAP (see 86 FR 3906, 3920–3921), the EPA proposed standards pursuant to CAA sections 112(d)(2) and (d)(3) for process wastewater from existing cyanide chemical manufacturing process units, which was previously unregulated. We proposed that process wastewater sources at existing sources comply with HON wastewater requirements. We proposed the HON requirements for cyanide chemicals manufacturing existing sources because the HON requirements represented: (1) The measures employed by the best performing sources in the category; and (2) an acceptable means of compliance for wastewater emissions at sources subject to subpart YY. We also proposed adding the HON requirements for waste management units upstream of an open or closed biological treatment process to the new source standard to ensure demonstrable compliance measures are in place for these sources.

[11] *https://www.cdc.gov/niosh/idlh/74908.html,* 1988 OSHA PEL Project—Hydrogen Cyanide | NIOSH | CDC.

[12] *https://www.cdc.gov/niosh/idlh/74908.html,* 1988 OSHA PEL Project—Hydrogen Cyanide | NIOSH | CDC.

2. How did the proposed wastewater provision amendments change in the final rule?

We are finalizing the proposed wastewater provision amendments with minor clarifications (see section V.D.3.d).

3. What key comments did we receive on the proposed wastewater provision amendments and what are our responses?

Environmental groups provided comments on the basis for the EPA's selected standards and contended that the proposed limits were not sufficient to satisfy CAA sections 112(d)(2)-(3), which requires the maximum achievable degree of emission limitation.

Industry commenters requested that clarifications of the applicability of the wastewater requirements be included in the final rule and that the EPA provide additional compliance options to what was proposed in the final rule. These commenters also requested that the EPA include a test method for hydrogen cyanide or cyanide compounds in the final rule.

These comments and the EPA's responses are provided below.

a. Basis-Support for Wastewater Provisions

Comment: One commenter supported the EPA's recognition that it must set limits on uncontrolled HAP emissions from process wastewater under CAA section 112(d)(6)—including hydrogen cyanide, acetonitrile, and acrylonitrile,[13] but contended that the limits are not strong enough to satisfy CAA sections 112(d)(2)–(3), which requires the maximum achievable degree of emission limitation.

The commenter stated that the EPA proposes ''to just require compliance with the [HON] wastewater requirements for process wastewater and upstream waste management units at existing sources—and to add HON requirements for waste management units.'' [14] The commenter claimed that the EPA does not discuss what the proposed requirements are in the preamble other than referencing the outdated standard.

According to the commenter, the EPA's proposed wastewater standards are ''illegally and arbitrarily weak and must be strengthened before finalizing.'' The commenter stated that the EPA has not performed any floor analysis as required by CAA section 112(d)(3) and instead appears to rely on the outdated 2008 HON rule and old and unreliable data, not included here, as its justification for not requiring stronger wastewater standards. The commenter noted that there is no assessment of what the best-performing standards have achieved, or what the average emission limitation achieved is. The commenter added that the EPA also does not demonstrate that the 2008 HON standards satisfy the CAA sections 112(d)(2)–(3) test for cyanide chemical manufacturing wastewater process sources.

Lastly, the commenter asserted that the EPA's proposed wastewater standards are illegal and arbitrary because the EPA has given only a conclusory statement to attempt to satisfy the beyond-the-floor requirement of CAA section 112(d)(2). According to the commenter, the EPA has failed to show how its proposal reflects the ''maximum achievable'' degree of emission limitation for these sources. The commenter stated that citing to data not in the record from 2004, without discussion or any rational explanation, does not meet the EPA's statutory obligation. The commenter contended that the EPA should collect current data, review more recent wastewater control methods, and perform a lawful beyond-the-floor analysis to ensure that it requires the ''maximum achievable'' degree of emission reduction in the final standards.

Response: The EPA evaluated the data available to the Agency at the time the proposed MACT standards for process wastewater at existing cyanide chemicals manufacturing sources were developed. We also reviewed title V permits for all cyanide chemicals manufacturing facilities and determined that all existing facilities subject to the cyanide NESHAP are also subject to the HON wastewater requirements or other NESHAP that also incorporate those requirements. We concluded that these requirements constitute the performance of the best performing facilities in the source category. These standards represent the best measures that we identified for minimizing wastewater emissions from the category, and we did not identify additional measures that could further reduce emissions ''beyond the floor''. The commenter did not provide any data to support their conclusion that these requirements are not representative of the best performers.

Our conclusion at proposal that the HON process wastewater requirements represent the MACT floor has not changed and we are finalizing those requirements with minor clarifications (see section V.D.3.d of this preamble for minor clarification changes made in the final rule).

b. Fraction Measured (Fm)/Fraction Removal (Fr) Values for Hydrogen Cyanide/Cyanide Compounds

Comment: One commenter recommended that the EPA provide a Fm value for hydrogen cyanide or cyanide compounds so that the regulated entity can comply with the applicability option described in 40 CFR 63.144(b)(1) of subpart G. Similarly, the commenter also requested that the EPA provide a Fr value for hydrogen cyanide or cyanide compounds so that the regulated entity can comply with the option available in 40 CFR 63.138(e)(2) of subpart G. The commenter recommended that this value would be no greater than 0.93, as it is the removal requirement for new cyanide chemicals manufacturing process units, but also noted it could be less based on the physical properties of hydrogen cyanide or cyanide compounds.

Response: 40 CFR 63.144(b)(1) allows several options for determining how to calculate the annual average concentration, including knowledge of the wastewater, bench-scale or pilot scale test data, or test data from sampling at the point of determination or at a location downstream of the point of determination. For free cyanide, the final rule adds specific procedures for determining the annual average concentration of free cyanide (see 40 CFR 63.1103(g)(5)(vi) of the final rule). For compliance with the wastewater free cyanide analysis provisions of Table 9 to 40 CFR 63.1103(g), free cyanide is to be measured according to ASTM D4282–15 (Standard Test Method for Determination of Free Cyanide in Water and Wastewater by Microdiffusion) or ASTM D7237 (Standard Test Method for Free Cyanide and Aquatic Free Cyanide with Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection). Under 40 CFR 63.144(b)(1) of subpart G, Fm adjustment factors are allowed under specified circumstances (*e.g.,* when concentration is determined by Method 305 as specified in 40 CFR 63.144(b)(5)(i)(B), concentration may be adjusted by dividing by the compound-specific Fm). For free cyanide measured according to ASTM D4282–15 or ASTM D7237 (as required under the final rule), the EPA is not including an Fm adjustment factor option.

In addition to the compliance option available under 40 CFR 63.138(e)(2) of the rule that requires an Fr value to demonstrate compliance, an owner or operator has other compliance options that do not require an Fr value.

[13] 86 FR at 3920 & n.23, 3921.

[14] 86 FR at 3921.

However, the EPA acknowledges that existing sources complying with 40 CFR part 63 subpart G wastewater provisions may already be complying with wastewater requirements under the 40 CFR part 63 subpart G wastewater provisions that require an Fr value for individual HAP in order to demonstrate compliance. To allow flexibility to owners and operators in complying with the process wastewater options that we proposed for cyanide chemicals manufacturing existing sources under 40 CFR 63.138(a)(1), the final rule has added that, for compliance options and calculations requiring an Fr value under 40 CFR 63.138(a)(1), an owner or operator may use a value of 0.93 for free cyanide (see Table 9 to 40 CFR 63.1103(g), line entry (g) of the final rule). This value is based on the requirement that new sources meet an emissions control level of 93 percent for process wastewater streams.

c. Hydrogen Cyanide/Cyanide Compound Test Methods To Measure Wastewater Stream Concentration

Comment: One commenter stated that the HON regulation includes a number of options for determining the concentration of the regulated organic HAP compounds in a process wastewater stream. The commenter provided that the existing 40 CFR 63.144(b)(5)(i) of the HON regulation does not have a listed test method for hydrogen cyanide or cyanide compounds. The commenter recommended that the EPA include any approved test methods in Table 1B of 40 CFR 136.3 in the final Cyanide Chemicals manufacturing rule (subpart YY) for these measurements that the regulated entity can use if they opt to make measurements.

The commenter also requested that EPA include any updates to the test method(s) automatically in the rule as an option for the regulated entities to use. The commenter suggested that, if EPA Method 335.4 is updated in the future, the regulated entity should be able to use either EPA Method 335.4 or the updated method.

Response: The EPA has added 40 CFR 63.1103(g)(5)(vi) to include two test methods for measuring the concentration of cyanide in water (ASTM 4282–15 and ASTM 7237–18). The test methods in the table submitted by the commenter were not included because they corresponded to parameters that were irrelevant (total cyanide concentration and available cyanide concentration) or were, subsequent to the submission of the comment, supplanted by a new version of the method in Table 1B. Available cyanide refers to cyanide that is loosely bound in metal-ion complexes, and total cyanide refers to the sum of available and free cyanide. Free cyanide is toxic and bioavailable cyanide, and this is the form of cyanide that the EPA intends to limit. Table 1B of 40 CFR 136.3 was updated July 19, 2021 (86 FR 27226) to incorporate updated versions of the free cyanide methods. The updated versions of the two ASTM methods for free cyanide are included in the final rule, but the OI Analytical method was excluded, as the method text actually describes how to measure available cyanide and does not include information on the modifications necessary to test for free cyanide. EPA Method 335.4 was not included as this method is only available in draft and has not yet been finalized.

d. Request for Clarifications

Comment: One commenter requested that the EPA clarify the text in the proposed paragraph (g) of Table 9 of the proposed 40 CFR part 63 subpart YY regulation to confirm that the provisions apply to each individual wastewater stream.

Response: The EPA has revised line entries (g)(1) and (g)(2) (for existing sources) of Table 9 to 63.1103(g) in the final rule as recommended by the commenter to clarify the EPA's intent that the wastewater requirements apply to each individual wastewater stream.

Comment: One commenter recommended that the EPA clarify that the term ''cyanide compounds'' is the same as ''cyanide chemicals product''.

Response: The EPA has added a definition for the term ''free cyanide'' in 40 CFR 63.1103(g)(2) to clarify the EPA's intent that hydrogen cyanide and cyanide ion (both of which may be present in wastewater due to dissolution of cyanide salts) are the cyanide chemical compounds subject to the Cyanide Chemicals Manufacturing source category wastewater provisions.

4. What is the rationale for our final changes to proposed wastewater provision amendments?

We evaluated the comments on the EPA's proposed process wastewater amendments for existing and new sources. For the reasons explained in the proposed rule (86 FR 3906, 3920–3921), we determined that the process wastewater amendments for existing and new sources are necessary to ensure all affected sources in the cyanide chemicals manufacturing source category are subject to MACT standards, and that the requirements for waste management units upstream of an open or closed biological treatment process for new sources are necessary to ensure demonstrable compliance measures are in place for these sources. More information concerning the amendments we are finalizing is in the preamble to the proposed rule and in our specific responses to the comments above (section V.D.3). Therefore, we are finalizing the wastewater amendments as proposed, with minor clarifications (see section V.D.3.b–e).

VI. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A summary of cost, environmental, and economic impacts is presented in section VI.A for the Carbon Black Production NESHAP and section VI.B for Cyanide Chemicals Manufacturing NESHAP final rule amendments.

A. Carbon Black Production

1. What are the affected facilities?

The EPA estimates that there are 15 production facilities in the Carbon Black Production major source category that are subject to the Carbon Black Production NESHAP and affected by the final amendments to 40 CFR part 63, subpart YY. The basis of our estimates of affected facilities is provided in the memorandum, *Identification of Major Sources for the Carbon Black Production NESHAP,* which is available in the docket for this action (see Docket ID No. EPA–HQ–OAR–2020–0505–0022). We are not currently aware of any planned or potential new or reconstructed carbon black production facilities in the source category. No carbon black production area sources were identified; therefore, there are no area sources subject to this rulemaking.

2. What are the air quality impacts?

While we are broadening the scope of the current Carbon Black Production standard, setting annual tune-up requirements for process heaters and boilers, removing the SSM exemption, and establishing a work practice standard for periods of startup and shutdown, we do not have data to determine quantitatively the reduction in HAP emissions resulting from this action. Through discussions with industry members, it is our understanding that process vents located after the MUF are likely already below the applicability threshold where additional controls will be required. The other requirements we are adding are based on current industry practices. For this reason, we do not anticipate that this action will result in significant HAP emission reductions.

3. What are the cost impacts?

Costs were developed on a per facility basis for Carbon Black Production facilities, and all facilities were determined to have similar costs. Costs are presented in 2019 dollars. Costs were broken into three separate categories based on final requirements: Initial Applicability Test, Performance Test, and Boiler/Process Heater Maintenance Costs.

Initial applicability testing costs include costs associated with the final requirements for process vents located after the MUF to meet the standard, which will require facilities to determine whether emissions control is needed for process vents after the MUF process vent. We estimate this to be a one-time cost of $21,350 per facility, due to the assumption that the majority of HAP is removed and controlled at the MUF, which likely results in the vent stream concentration located after the MUF falling below the HAP applicability concentration threshold (260 ppmv).

Performance test costs include costs associated with the requirement to conduct emissions tests at the subject process vents every 5 years starting in the first year after promulgation. Based on our understanding of industry practices and emissions profiles, we do not expect any process vents located after the MUF to exceed the applicability threshold, which would require them to conduct performance tests. Facilities must conduct performance tests no more than 60 months after the preceding test when demonstrating compliance with process vent emission control requirements. We estimate that 20 percent of subject facilities will conduct a performance test each year resulting in an annual cost of $15,241 per facility.

Boiler/process heater maintenance costs include costs associated with the final requirement to ensure that boilers and process heaters are operating at peak efficiency and not creating excess emissions through inefficient operation. Initial tune-up costs are assumed to be higher to get the units back to peak efficiency. We assume that subsequent year costs would be lower because less maintenance would be needed. As such, we estimate the initial tune-up cost to be $6,750 per facility and subsequent annual tune-ups to cost $1,350 per facility.

Costs were based primarily on labor, equipment, and travel costs. Labor costs are based on Bureau of Labor Statistics data for relevant employees necessary to perform the tests and maintenance. A detailed cost analysis can be found in the memorandum, *Carbon Black Cost Memorandum,* available in the docket for this action (see Docket ID No. EPA–HQ–OAR–2020–0505–0007).

4. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other markets may also be examined. Both the magnitude of costs associated with the final requirements and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a final rule. Economic costs to carbon black producers were measured in Present Value (PV) total costs and Equivalent Annual Value (EAV) costs. All producer facilities were estimated to have similar costs. All costs are presented in 2019 dollars. Refer to the memorandum, *Carbon Black Economic Impact Analysis,* in the docket for this rulemaking for more information (see Docket ID No. EPA–HQ–OAR–2020–0505–0008). PV total costs and EAV costs were measured at the 3-percent and 7-percent discount rate. The duration of analysis was 10 years which represented two full cycles of cost analysis for the final requirements. Per facility PV total costs were estimated to be $70,000 and $63,000 at the 3-percent and 7-percent discount rates, respectively. EAV costs per facility were estimated to be $8,000 and $9,000 at the 3-percent and 7-percent discount rates, respectively. The combined PV total cost of the final requirements for all facilities was estimated to be $1,005,000 and $945,000 at the 3-percent and 7-percent discount rates, respectively. The combined EAV cost of the final requirements for all facilities was estimated to be $118,000 and $135,000 at the 3-percent and 7- percent discount rates, respectively. No carbon black production facilities subject to this rule are small businesses based on Small Business Administration standards. Because the PV and EAV costs associated with the final revisions are minimal, no significant economic impacts from the final amendments are anticipated. Refer to the *Carbon Black Economic Impact Memorandum,* available in the docket (see Docket ID No. EPA–HQ–OAR–2020–0505–0008), for more information.

5. What are the benefits?

As discussed in section VI.A.2 of this preamble, we do not anticipate the finalized amendments to the Carbon Black Production source category to significantly impact air quality. The electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in those reports; is in keeping with current trends in data availability and transparency; will further assist in the protection of public health and the environment; will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements; will improve compliance by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance; and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public.

Although the EPA does not anticipate any significant reductions in HAP emissions as a result of the final amendments to the Carbon Black Production NESHAP, we believe that the final action will result in improvements to the rule by broadening the current emission limit, requiring an annual tune-up for boilers and process heaters, and revising the SSM standards such that a standard applies at all times, including periods covered by the final work practice standard. Additionally, the final amendments requiring electronic submittal of NOCS reports, performance test results, and periodic reports will increase the usefulness of the data, are in keeping with current trends of data availability, will further assist in the protection of public health and the environment, and will ultimately result in reduced reporting burden on the regulated community.

6. What analysis of environmental justice did we conduct?

Executive Order 12898 directs the EPA staff to identify the populations of concern who are most likely to experience unequal burdens from environmental harms; specifically, minority populations, low-income populations, and indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 13985 was signed to advance racial equity and support underserved communities through federal government actions (86 FR 7009, January 20, 2021). The EPA defines environmental justice (EJ) as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income

with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies'' (*https://www.epa.gov/environmentaljustice*). In recognizing that minority and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution.

To examine the potential for any EJ issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we also evaluated the distribution of HAP-related cancer and noncancer risks from the Carbon Black Production major source category across different demographic groups within the populations living near facilities. The demographic analysis and the risk analysis are contained in the docket and were summarized in the proposed rule preamble.

When examining the risk levels of those exposed to emissions from carbon black production facilities, we find that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1.

Results of the demographic analysis indicate that, of the total population residing within 5km of facilities in the source category, the percentages of people who are African American, age greater than or equal to 65, age greater than or equal to 25 years of age without a high school diploma, and below the poverty level are greater than the national average percentages of people in those demographic groups. The EPA also provided demographic results for populations residing within 50km.

Based on analyses of exposed populations, the EPA determined that this action is unlikely to pose a disproportionately high adverse health impact on minority populations and/or low-income populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994) and referenced in Executive Order 13985 (86 FR 7009, January 20, 2021).

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Carbon Black Production Source Category Operations,* available in the docket for the Carbon Black Production source category NESHAP (see Docket Item No. EPA–HQ–OAR–2020–0505–0014).

7. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessment are documented in the risk report, *Residual Risk Assessment for the Carbon Black Production Source Category in Support of the Risk and Technology Review 2021 Final Rule,* available in the docket for the Carbon Black Production source category NESHAP (see Docket No. EPA–HQ–OAR–2020–0505).

B. Cyanide Chemicals Manufacturing

1. What are the affected facilities?

There are 13 cyanide chemicals manufacturing facilities currently operating as major sources of HAP subject to the final amendments. A list of facilities that are currently subject to the MACT standards is available in the memorandum titled *Technical Support Document for the Cyanide Chemicals Manufacturing NESHAP Residual Risk and Technology Review Proposal,* available in the docket for this action (see Docket ID No. EPA–HQ–OAR–2020–0532–0025).

2. What are the air quality impacts?

The final amendments add wastewater requirements to the Cyanide Chemicals Manufacturing NESHAP, however the EPA does not anticipate that the amendments to the cyanide chemicals manufacturing NESHAP will impact air quality. We are not proposing changes to the standard that will result in additional emission reductions beyond the levels already achieved by the NESHAP.

3. What are the cost impacts?

The final amendments will have a limited cost impact on affected cyanide chemicals manufacturing facilities. Total estimated costs are $47,527, based on a $3,656 per facility cost for all 13 facilities. The costs result from reading and understanding rule requirements and adjusting compliance plans based on the rule proposal. All costs other than wastewater testing are one-time expenses expected to occur in the first year after the rule is finalized. Costs are based on Agency knowledge and experience with the NESHAP program, related Information Collection Requests (ICRs), and Bureau of Labor Statistics data.

4. What are the economic impacts for Cyanide Chemicals Manufacturing?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other markets may also be examined. Both the magnitude of costs associated with the final requirements and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a rule.

Economic costs to owners of Cyanide Chemicals Manufacturing facilities were measured in PV total costs and EAV costs. All Cyanide Chemicals Manufacturing facilities were estimated to have similar costs. All costs are presented in 2019 dollars.

PV total costs and EAV costs were measured at the 3 percent and 7 percent discount rates. The duration of analysis was 8 years. Per facility PV total cost estimate is $3,968 at 3 percent and $3,925 at 7 percent discount rates. EAV costs per facility are measured to be $565 and $657 at the 3 percent and 7 percent discount rates, respectively. Combined total PV cost of the final requirements for all facilities is measured to be $51,577 at 3 percent and $51,030 at 7 percent discount rates. Combined EAV costs of the final requirements for all facilities are measured to be $7,346 and $8,546 at the 3 percent and 7 percent discount rates, respectively.

As required by the Regulatory Flexibility Act (RFA), we performed an analysis to determine if any small entities would be unduly burdened by the final amendments. No cyanide chemicals manufacturers are small businesses based on Small Business Administration standards. No significant economic impacts from the final amendments are anticipated because the PV and EAV costs associated with the final revisions are minimal.

5. What are the benefits?

As discussed in section VI.B.2 of this preamble, we do not anticipate the finalized amendments to the NESHAP for the Cyanide Chemicals Manufacturing source category to

impact air quality. The electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and, by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public.

6. What analysis of environmental justice did we conduct?

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations. Additionally, Executive Order 13985 was signed to advance racial equity and support underserved communities through federal government actions (86 FR 7009, January 20, 2021). The EPA defines EJ as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies'' (*https://www.epa.gov/environmentaljustice*). In recognizing that minority and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution.

To examine the potential for any EJ issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we also evaluated the distribution of HAP-related cancer and noncancer risks from the Cyanide Chemicals Manufacturing major source category across different demographic groups within the populations living near facilities. The demographic analysis and the risk analysis are contained in the docket and were summarized in the proposed rule preamble.

When examining the risk levels of those exposed to emissions from cyanide chemical manufacturing facilities, we find that 61,653 people nationwide are exposed to an incremental cancer risk at or above 1-in-1 million with no one exposed to an excess cancer risk greater than 5-in-1 million based upon actual or allowable emissions. Also, no people are exposed to a chronic noncancer TOSHI greater than 1.

Results of the demographic analysis indicate that of the 61,653 people residing within 50 km of facilities in the source category whose risk is at or above 1-in-1 million (but less than 5-in-1 million) as a result of emissions from the source category, the percent of individuals in three demographic groups, African American, below poverty level, and greater than or equal to 25 years of age without a high school diploma, are greater than the corresponding national average percentage of people in those demographic groups. Specifically, the population with risks greater than 1-in-1 million live in areas where 19 percent of the population is African American compared to 12 percent nationally, 23 percent are below the poverty level [15] compared to 14 percent nationally, and 16 percent are greater than or equal to 25 years of age without a high school diploma compared to 14 percent nationally. Because the final amendments to the rule are not anticipated to result in emissions reductions, implementation of the final rule will not result in a significant increase or decrease in any existing risk disparities for the demographic groups.

Based on the analyses of exposed populations described above, the EPA determined that this action is unlikely to pose a disproportionately high and adverse health impact on minority populations and/or low-income populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994) and referenced in Executive Order 13985 (86 FR 7009, January 20, 2021).

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Cyanide Chemicals Manufacturing Source Category Operations,* available in the docket for this action; (see Docket Item No. EPA–HQ–OAR–2020–0532–0006).

7. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessment are documented in the risk report, *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2021 Final Rule,* available in the docket for the Cyanide Chemicals Manufacturing source category rule (see Docket No. EPA–HQ–OAR–2020–0532).

VII. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Paperwork Reduction Act (PRA)

Section VII.B.1 presents PRA considerations related to the Carbon Black Production NESHAP, and section VII.B.2 presents the PRA considerations related to the Cyanide Chemicals Manufacturing NESHAP.

1. Carbon Black Production

The information collection activities in the final rule for the Carbon Black Production source category have been submitted for approval to the OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 2677.02. A copy of the ICR is available in the docket for the

[15] Table 2 of the proposed rule preamble erroneously listed this percentage as 16 percent rather than 23 percent.

Carbon Black Production source category NESHAP (see Docket No. EPA–HQ–OAR–2020–0505), and is briefly summarized here. We are finalizing changes to the recordkeeping and reporting requirements associated with 40 CFR part 63, subpart YY, in the form of eliminating the SSM plan and reporting requirements; broadening the initial emission limit to include process vents located after the MUF; and including the requirement for electronic submittal of reports. In addition, the number of facilities subject to the standards changed. The number of respondents was reduced from 18 to 15 based on consultation with industry representatives and state and local agencies.

Respondents/affected entities: The respondents to the recordkeeping and reporting requirements are owners and operators of carbon black production facilities subject to 40 CFR part 63, subpart YY.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart YY).

Estimated number of respondents: 15 facilities.

Frequency of response: The frequency of responses varies depending on the burden item. Responses include one-time review of rule amendments, reports of periodic performance tests, and semiannual compliance reports.

Total estimated burden: The annual recordkeeping and reporting burden for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be 289 hours (per year). The average annual burden to the Agency over the 3 years after the amendments are final is estimated to be 213 hours (per year) for the Agency. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting cost for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be $180,928 (per year). There are no estimated capital and operation and maintenance costs. The total average annual Agency cost over the first 3 years after the amendments are final is estimated to be $10,247. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities in this final rule.

2. Cyanide Chemicals Manufacturing

The information collection activities in the final rule have been submitted to the OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 2678.02. A copy of the ICR is available in the docket for the Cyanide Chemicals Manufacturing source category NESHAP (see Docket No. EPA–HQ–OAR–2020–0532), and is briefly summarized here.

The EPA is finalizing amendments that revise provisions pertaining to emissions during periods of SSM, add requirements for electronic reporting of NOCS, periodic reports, and performance test results, and make other minor clarifications and corrections. This information will be collected to assure compliance with the Cyanide Chemicals Manufacturing NESHAP. The ICR burdens for these final amendments are summarized below.

Respondents/affected entities: Owners or operators of cyanide chemicals manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart YY).

Estimated number of respondents: 13 (assumes no new respondents over the next 3 years).

Frequency of response: Initially, occasionally, and annually.

Total estimated burden: 169 hours (per year) to comply with all of the requirements in the NESHAP. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $17,108 (per year). Includes total capital costs of $1,300 incurred in the first year ($433 per year over 3 years) for process wastewater stream sampling to determine applicability and compliance with the final rule amendments. There are no annualized operation and maintenance costs to comply with under the final amendments to the NESHAP.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities, since there are no small entities in the affected source categories.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. None of the carbon black production or cyanide chemicals manufacturing production facilities that have been identified as being affected by this proposed action are owned or operated by tribal governments. However, we determined that one carbon black facility and two cyanide facilities are located within 50 miles of tribal lands. Consistent with the EPA Policy on Coordination and Consultation with Indian Tribes, the EPA offered tribal leadership the opportunity for government-to-government consultation with no response. In addition, the EPA held multiple outreach activities that included a webinar and participation on tribal partnership calls.

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

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action

present a disproportionate risk to children.

The health and risk assessments for the Carbon Black Production and Cyanide Chemicals Manufacturing source categories are discussed in sections IV.A and V.A of this preamble. The document, *Residual Risk Assessment for the Carbon Black Production Source Category in Support of the Risk and Technology Review 2021 Final Rule,* is available in the docket for the Carbon Black Production source category (see Docket ID No. EPA–HQ–OAR–2020–0505). The document, *Residual Risk Assessment for the Cyanide Chemicals Manufacturing Source Category in Support of the Risk and Technology Review 2021 Final Rule,* is available in the docket for the Cyanide Chemicals Manufacturing source category (see Docket ID No. EPA–HQ–OAR–2020–0532).

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

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

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action does not involve technical standards for the Carbon Black Production source category.

This action does involve technical standards for the Cyanide Chemicals Manufacturing source category. Therefore, the EPA conducted a search to identify potentially applicable voluntary consensus standards (VCS). However, the Agency identified no such standards. A thorough summary of the search and results are included in the memorandum titled *Voluntary Consensus Standard Results for Cyanide Chemicals Manufacturing Residual Risk and Technology Review,* which is available in the docket for this action/source category (see Docket ID No. EPA–HQ–OAR–2020–0532–0004).

In the final rule, the EPA is incorporating by reference the VCS ASTM D4282–15, Standard Test Method for Determination of Free Cyanide in Water and Wastewater by Microdiffusion and ASTM D7237–18, Standard Test Method for Free Cyanide and Aquatic Free Cyanide with Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection. Both methods are water and wastewater methods for the determination of free cyanide. In ASTM D4282–15, the reactions are carried out in a microdiffusion cell. The sample is treated with cadmium ion to precipitate hexacyanoferrates and buffered to pH 6. The HCN then diffuses into a sodium hydroxide solution which is subsequently treated, and the concentration of free cyanide determined by spectrophotometric analysis. In ASTM–7237–18, the sample is introduced into the carrier solution of the flow injection analysis system with a phosphate buffer solution at pH 6. The released hydrogen cyanide gas diffuses through a hydrophobic gas diffusion membrane into an alkaline receptor stream where the cyanide ion is captured and sent to an amperometric flowcell detector with a silver-working electrode. In the presence of cyanide, silver in the working electrode is oxidized at the applied potential. The anodic current measured if proportional to the concentration of cyanide in the sample. These methods are reasonably available from ASTM at *https://www.astm.org* or 1100 Barr Harbor Drive, West Conshohocken, PA 19428–2959, telephone number: (610) 832–9500, fax number: (610) 832–9555 email: *service@astm.org.*

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

The EPA believes that this final action for both the Carbon Black Production source category and the Cyanide Chemicals Manufacturing source category does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898.

The documentation for this decision for the Carbon Black Production source category is contained in the technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Carbon Black Production Facilities,* available in the docket for this action (see Docket ID No. EPA–HQ–OAR–2020–0505–0014) and discussed in Section VI.A.6 of this final rule.

The documentation for this decision for the Cyanide Chemicals Manufacturing is contained in the technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Cyanide Chemicals Manufacturing Facilities,* available in the docket for this action (see Docket ID No. EPA–HQ–OAR–2020–0532–0006) and discussed in Section VI.B.6 of this final rule.

The EPA provided opportunities to engage with the EPA on these proposals. The Agency offered a public hearing and also reached out to communities in other ways, including a webinar held on February 10, 2021, to exchange information with stakeholders about these proposals. We did not receive any requests for a public hearing and we did not receive feedback regarding EJ during the webinar. The EPA remains committed to engaging with communities and stakeholders throughout the development of air pollution regulations.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report for this action to each House of the Congress and to the Comptroller General of the United States. Neither of the NESHAP amended by this action constitute a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency is amending part 63 of title 40, chapter I, of the Code of Federal Regulations as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

Subpart A—General Provisions

■ 2. Section 63.14 is amended by:

■ a. Redesignating paragraphs (h)(105) through (h)(117) as (h)(107) through (h)(119);

■ b. Redesignating paragraphs (h)(63) through (h)(104) as (h)(64) through (h)(105);

■ c. Adding new paragraphs (h)(63) and (h)(106);

The additions read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(h) * * *

(63) ASTM D4282–15, Standard Test Method for Determination of Free Cyanide in Water and Wastewater by

Microdiffusion, Approved July 15, 2015, IBR approved for § 63.1103(g).

* * * * *

(106) ASTM D7237–18, Standard Test Method for Free Cyanide and Aquatic Free Cyanide with Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection, Approved December 1, 2018, IBR approved for § 63.1103(g).

* * * * *

Subpart YY—National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards

■ 3. Section 63.1101 is amended by revising the definition for ''Process vent'' to read as follows:

§ 63.1101 Definitions.

* * * * *

Process vent means the point of discharge to the atmosphere (or the point of entry into a control device, if any) of a gas stream from a unit operation within a source category subject to this subpart. Process vent excludes the following gas stream discharges:

(1) Relief valve discharges;

(2) Leaks from equipment subject to this subpart;

(3) Gas streams exiting a control device complying with this subpart;

(4) Gas streams transferred to other processes (on-site or off-site) for reaction or other use in another process (*i.e.,* for chemical value as a product, isolated intermediate, byproduct, or co-product for heat value);

(5) Gas streams transferred for fuel value (*i.e.,* net positive heating value), use, reuse, or sale for fuel value, use, or reuse. On or after November 19, 2021 this exclusion no longer applies to the Carbon Black Production source category;

(6) Gas streams from storage vessels or transfer racks subject to this subpart;

(7) Gas streams from waste management units subject to this subpart;

(8) Gas streams from wastewater streams subject to this subpart;

(9) Gas streams exiting process analyzers; and

(10) Gas stream discharges that contain less than or equal to 0.005 weight-percent total organic HAP.

* * * * *

■ 4. Section 63.1102 is amended by revising paragraph (a) introductory text and adding paragraphs (d) and (e) to read as follows:

§ 63.1102 Compliance schedule.

(a) *General requirements.* Affected sources, as defined in § 63.1103(a)(1)(i) for acetyl resins production, § 63.1103(b)(1)(i) for acrylic and modacrylic fiber production, § 63.1103(c)(1)(i) for hydrogen fluoride production, § 63.1103(d)(1)(i) for polycarbonate production, § 63.1103(e)(1)(i) for ethylene production, § 63.1103(f)(1)(i) for carbon black production, § 63.1103(g)(1)(i) for cyanide chemicals manufacturing, or § 63.1103(h)(1)(i) for spandex production shall comply with the appropriate provisions of this subpart and the subparts referenced by this subpart YY according to the schedule in paragraph (a)(1) or (2) of this section, as appropriate, except as provided in paragraph (b) of this section. Affected sources in ethylene production also must comply according to paragraph (c) of this section. Affected sources in cyanide chemicals manufacturing also must comply according to paragraph (d) of this section. Affected sources in carbon black production also must comply according to paragraph (e) of this section. Proposal and effective dates are specified in table 1 to this section and in paragraph (d) for cyanide chemicals manufacturing affected sources and paragraph (e) for carbon black production affected sources of this section.

* * * * *

(d) *Cyanide chemicals manufacturing.* (1) If applicable, all cyanide chemicals manufacturing affected sources that commenced construction or reconstruction on or before January 15, 2021, must be in compliance with the requirements listed in paragraphs (d)(1)(i) and (ii) of this section upon initial startup or November 20, 2022, whichever is later. If applicable, all cyanide chemicals manufacturing affected sources that commenced construction or reconstruction after January 15, 2021, must be in compliance with the requirements listed in paragraphs (d)(1)(i) and (ii) of this section upon initial startup, or November 19, 2021, whichever is later.

(i) Requirements specified in Table 9 to § 63.1103(g), table entry (f)(1)(ii), for new cyanide chemicals manufacturing process units that generate process wastewater.

(ii) Requirements specified in Table 9 to § 63.1103(g), table entry (g), for existing cyanide chemicals manufacturing process units that generate process wastewater.

(2) All cyanide chemicals manufacturing affected sources that commenced construction or reconstruction on or before January 15, 2021, must be in compliance with the requirements listed in paragraphs (d)(2)(i) through (iii) of this section upon initial startup or May 18, 2022, whichever is later. All cyanide chemicals manufacturing affected sources that commenced construction or reconstruction after January 15, 2021, must be in compliance with the requirements listed in paragraphs (d)(2)(i) through (iii) of this section upon initial startup, or November 19, 2021, whichever is later.

(i) The exceptions specified in § 63.1103(g)(6) related to 40 part 63, subparts SS, TT, and UU startup, shutdown, and malfunction requirements.

(ii) The compliance requirements specified in § 63.1108(a)(4)(i), (b)(1)(ii), (b)(2), and (b)(4)(ii)(B).

(iii) The electronic reporting requirements specified in § 63.1110(a)(10).

(e) *Carbon black production.* (1) If applicable, all carbon black production affected sources that commenced construction or reconstruction on or before January 14, 2021, must be in compliance with the requirements listed in paragraphs (e)(1)(i) through (iii) of this section upon initial startup or November 20, 2022, whichever is later. If applicable, all carbon black production affected sources that commenced construction or reconstruction after January 14, 2021, must be in compliance with the requirements listed in paragraphs (e)(1)(i) through (iii) of this section upon initial startup, or November 19, 2021, whichever is later.

(i) The process vent applicability determination requirements specified in § 63.1103(f)(3)(iv).

(ii) The performance test frequency requirements specified in § 63.1108(b)(4)(ii).

(iii) The boiler and process heater tune up requirements specified in § 63.1103(f)(3)(iii).

(2) All carbon black production affected sources that commenced construction or reconstruction on or before January 14, 2021, must be in compliance with the requirements listed in paragraphs (e)(2)(i) through (iv) of this section upon initial startup or May 18, 2022, whichever is later. All carbon black production affected sources that commenced construction or reconstruction after January 14, 2021, must be in compliance with the requirements listed in paragraphs (e)(2)(i) through (iv) of this section upon initial startup, or November 19, 2021, whichever is later.

(i) The exceptions specified in § 63.1103(f)(4) related to 40 part 63, subpart SS, startup, shutdown, and malfunction requirements.

(ii) The exception specified in § 63.1103(f)(5) related to the requirement that a closed vent system route the collected vapors to a control device when demonstrating compliance.

(iii) The compliance requirements specified in § 63.1108(a)(4)(i), (b)(1)(ii), (b)(2), and (b)(4)(ii)(B).

(iv) The electronic reporting requirements specified in § 63.1110(a)(10).

(3) All carbon black production affected sources that commenced construction or reconstruction on or before January 14, 2021, must be in compliance with the requirements specified in line entry (b) in Table 8 to § 63.1103(f) on or before November 19, 2024. All carbon black production affected sources that commenced construction or reconstruction after January 14, 2021, must be in compliance with the requirements specified in line entries (b) and (c) in Table 8 to § 63.1103(f) upon initial startup or November 19, 2021, whichever is later.

■ 5. Section 63.1103 is amended by:
■ a. Revising paragraph (f)(3)(i) and adding paragraphs (f)(3)(iii) through (v).
■ b. Adding entries (b) and (c) to table 8 to § 63.1103(f).
■ c. Adding paragraphs (f)(4) and (5).
■ d. Revising paragraph (g)(1)(ii).
■ e. In paragraph (g)(2) adding the definition for ''free cyanide'' in alphabetical order.
■ f. Revising paragraph (g)(3).
■ g. Adding paragraph (g)(5)(vi).
■ h. Adding paragraph (g)(6).
■ i. In table 9 to § 63.1103(g), revising entries (f) through (i) and adding entry (j).

The additions and revisions read as follows:

§ 63.1103 Source category-specific applicability, definitions, and requirements.

* * * * *

(f) * * *

(3) * * *

(i) Table 8 to this section specifies the carbon black production standards applicability for existing and new sources. Applicability assessment procedures and methods are specified in § 63.1104. An owner or operator of an affected source is not required to perform applicability tests or other applicability assessment procedures if they opt to comply with the most stringent requirements for an applicable emission point pursuant to this subpart. General compliance, recordkeeping, and reporting requirements are specified in §§ 63.1108 through 63.1112. Before May 18, 2022, minimization of emissions from startup, shutdown, and malfunctions must be addressed in the startup, shutdown, and malfunction plan required by § 63.1111; the plan must also establish reporting and recordkeeping of such events. A startup, shutdown, and malfunction plan is not required on and after May 18, 2022 and the requirements specified in § 63.1111 no longer apply; however, for historical compliance purposes, a copy of the plan must be retained and available on-site for 5 years after May 18, 2022. Procedures for approval of alternative means of emission limitations are specified in § 63.1113.

* * * * *

(iii) The boiler and process heater tune up requirements of paragraphs (f)(3)(iii)(A) through (F) of this section apply beginning no later than the compliance dates specified in § 63.1102(e) for carbon black production affected sources and as specified in Table 8 to § 63.1103(f), line entry (c).

(A) Inspect the combustion device for damage, wear, and buildup of material that could impact effectiveness, and clean or replace any components of the burner as necessary. Units that produce electricity for sale may delay the combustion device inspection until the first outage after the annual inspection is required, not to exceed 36 months from the previous inspection. At units where entry into a piece of process equipment or into a storage vessel is required to complete the tune-up inspections, inspections are required only during planned entries into the storage vessel or process equipment;

(B) When possible based upon the configuration of the burner, inspect the flame pattern and adjust the burner if needed to optimize the flame pattern. If manufacturer's specifications for an optimized flame pattern are available, the adjustment should be consistent with the manufacturer's specifications;

(C) Inspect the system controlling the air-to-fuel ratio, and ensure that it is functioning properly. For any calibrated components ensure that it is correctly calibrated The annual inspection may be delayed until the next scheduled unit shutdown. Units that produce electricity for sale may delay the inspection until the first outage after the annual inspection is required, not to exceed 36 months from the previous inspection;

(D) Optimize total emissions of CO. If manufacturer's specifications for optimization are available, this optimization should be consistent with the manufacturer's specifications and with any NO_X requirement to which the unit is subject. If no manufacturer's specifications are available, the inspection and cleaning procedures of paragraph (f)(3)(iii)(A) fulfill the obligations of this paragraph;

(E) Measure the concentrations in the effluent stream of CO in parts per million, by volume, and oxygen in volume percent, before and after the adjustments are made. Measurements may be taken using a portable CO analyzer and may be either on a dry or wet basis, as long as it is the same basis before and after the adjustments are made. If adjustments are not or cannot be made, make the measurements before and after the inspection and cleaning procedures specified in paragraph (f)(3)(iii)(A); and

(F) Maintain on-site and submit, if requested by the Administrator, a report containing the information in paragraphs (f)(3)(iii)(F)(*1*) through (*3*) of this section,

(*1*) The concentrations of CO in the effluent stream in parts per million by volume, and oxygen in volume percent, measured at high fire or typical operating load, before and after the tune-up of the boiler or process heater;

(*2*) A description of any corrective actions taken as a part of the tune-up; and

(*3*) The type and amount of fuel used over the 12 months prior to the tune-up, but only if the unit was physically and legally capable of using more than one type of fuel during that period. Units sharing a fuel meter may estimate the fuel used by each unit.

(iv) When determining the applicability of the carbon black production process vent requirements specified in line entry (b) to Table 8 to § 63.1103(f), an owner or operator is required to determine the HAP concentration of the process vent streams, at a minimum, as specified in paragraphs (f)(3)(iv)(A) through (D) of this section.

(A) As an alternative to testing all carbon black production process carbon black or product vent streams after the main unit filter to determine applicability, an owner or operator has the option of testing the first carbon black production process or product vent stream after the main unit filter. If the concentration of the emission stream is less than 260 parts per million by volume as determined by the process vent applicability determination requirements specified in § 63.1103(f)(3)(iv), then all process vents after the main unit filter and before the dryer are deemed to be in compliance and are not subject to the emission limits in Table 8 below.

(B) As an alternative to testing all carbon black production process carbon

black or product vent streams after the dryer to determine applicability, an owner or operator has the option of testing the first carbon black production process carbon black or product vent stream after the dryer. If the concentration of the emission stream is less than 260 parts per million by volume as determined by the process vent applicability determination requirements specified in § 63.1103(f)(3)(iv), then all process vents after the dryer are deemed to be in compliance and are not subject to the emission limits in Table 8 below.

(C) Report the results of the applicability assessment according to paragraph § 63.1110(a)(10)(i).

(D) A test meeting the requirements of § 63.1104(e) conducted after November 18, 2016 and where no process changes have occurred since the test that may affect emissions, may be submitted according to § 63.1110(a)(10)(i)(A) through (C) in lieu of performing a new applicability determination.

(v) When determining the applicability of the carbon black production main unit filter process vent requirements specified in line entry (a) to Table 8 to § 63.1103(f), an owner or operator is required to determine the HAP concentration of the main unit filter process vent streams. Beginning November 19, 2021, report the results of any applicability assessment conducted after November 19, 2021, the applicability assessment according to paragraph § 63.1110(a)(10)(i).

TABLE 8 TO § 63.1103(f)—WHAT ARE MY REQUIREMENTS IF I OWN OR OPERATE A CARBON BLACK PRODUCTION EXISTING OR NEW AFFECTED SOURCE?

If you own or operate . . .	And if . . .	Then you must . . .
* *	* *	* * *
(b) A carbon black production process vent not subject to line entry (a) of this table.	(1) The HAP concentration of the emission stream is equal to or greater than 260 parts per million by volume [a] as determined by the process vent applicability determination requirements specified in § 63.1103(f)(3)(iv).	Beginning no later than the compliance dates specified in § 63.1102(e): (i) Reduce emissions of HAP by using a flare meeting the requirements of subpart SS of this part; or (ii) Reduce emissions of total HAP by 98 weight-percent or to a concentration of 20 parts per million by volume, whichever is less stringent, by venting emissions through a closed vent system to any combination of control devices meeting the requirements of § 63.982(a)(2).
(c) A carbon black production process vent subject to (a) or (b) above.	(1) The process vent complies by routing emissions to a boiler/process heater for use as fuel gas.	(i) Beginning no later than the compliance dates specified in § 63.1102(e), conduct annual tune up requirements as specified in § 63.1103(f)(3)(iii) of this subpart.

[a] The weight-percent organic HAP is determined according to the procedures specified in § 63.1104(e).

* * * * *

(4) Beginning no later than the compliance dates specified in § 63.1102(e), the referenced provisions specified in paragraphs (f)(4)(i) through (xiii) of this section do not apply when demonstrating compliance with paragraph (f)(3) of this section.

(i) The phrase ''except during periods of start-up, shutdown and malfunction as specified in the referencing subpart'' in § 63.984(a) of subpart SS(equipment and operating requirements for fuel gas systems and processes requirements).

(ii) The phrase ''except during periods of start-up, shutdown and malfunction as specified in the referencing subpart'' in § 63.985(a) of subpart SS (nonflare control device equipment and operating requirements).

(iii) The phrase ''other than start-ups, shutdowns, or malfunctions'' in § 63.994(c)(1)(ii)(D) of subpart SS (halogen scrubber and other halogen reduction device monitoring requirements).

(iv) Section 63.996(c)(2)(ii) of subpart SS (operation and maintenance of continuous parameter monitoring systems) ''(ii) If under the referencing subpart, an owner or operator has developed a start-up, shutdown, and malfunction plan, the plan is followed, and the CPMS is repaired immediately, this action shall be recorded as specified in § 63.998(c)(1)(ii)(E).''

(v) The last sentence of § 63.997(e)(1)(i) (performance test procedures) of subpart SS (general procedures for continuous unit operations): ''Operations during periods of start-up, shutdown, and malfunction shall not constitute representative conditions for the purpose of a performance test.''

(vi) Section 63.998(b)(2)(iii) (excluded data) of subpart SS: ''(iii) Startups, shutdowns, and malfunctions, if the owner or operator operates the source during such periods in accordance with § 63.1111(a) and maintains the records specified in paragraph (d)(3) of this section.''

(vii) The phrase ''other than periods of startups, shutdowns, and malfunctions'' from § 63.998(b)(5)(i)(A) (alternative recordkeeping) of subpart SS.

(viii) The phrase ''other than a start-up, shutdown, or malfunction'' from § 63.998(b)(5)(i)(B)(3) (alternate recordkeeping) of subpart SS.

(ix) The phrase ''other than periods of startups, shutdowns, and malfunctions'' from § 63.998(b)(5)(i)(C) (alternate recordkeeping) of subpart SS.

(x) The phrase ''other than a start-up, shutdown, or malfunction'' from § 63.998(b)(5)(ii)(C) (alternate recordkeeping) of subpart SS.

(xi) The phrase ''except as provided in paragraphs (b)(6)(i)(A) and (B) of this section'' from § 63.998(b)(6)(i) (alternative recordkeeping) of subpart SS.

(xii) The second sentence of § 63.998(b)(6)(ii) (alternative recordkeeping) of subpart SS. ''If a source has developed a startup, shutdown and malfunction plan, and a monitored parameter is outside its established range or monitoring data are not collected during periods of start-up, shutdown, or malfunction (and the source is operated during such periods in accordance with § 63.1111(a)) or during periods of nonoperation of the process unit or portion thereof (resulting in cessation of the emissions to which monitoring applies), then the excursion is not a violation and, in cases where continuous monitoring is required, the excursion does not count as the excused excursion for determining compliance.''

(xiii) Section 63.998(c)(1)(ii)(D) through (G) (nonflare control and

recovery device regulated source monitoring records) of subpart SS.

(xiv) Section 63.998(d)(3) (regulated source and control equipment start-up, shutdown, and malfunction records) of subpart SS.

(5) Beginning no later than the compliance dates specified in § 63.1102(e), the provisions specified in § 63.983(a)(1) of subpart SS that each closed vent system shall be designed and operated to collect the regulated material vapors from the emission point shall apply at all times, with the following exception: The closed vent system to the control device may be bypassed during startup or shutdown of a reactor when the excess oxygen concentration in the closed vent system is greater than or equal to 3 percent. Startup and shutdown of a reactor must be completed as expeditiously as possible, and in fewer than 15 minutes whenever possible. In no case shall the time period allowed be permitted to exceed 15 minutes. The bypass of the control device must use one of the methods specified in paragraphs (f)(5)(i) through (ii):

(i) *Calculated Purge Duration Method:* Each facility must calculate the purge duration of their closed vent system by evaluating the volume of the closed vent system and the flowrate of the contents of the closed vent system from the reactor to the common tail gas header. Additionally, each facility must calculate the amount of time it takes to open and/or close the common tail gas header and open and/or close the main unit filter vent to maintain constant pressure. The time required to completely purge the closed vent system is added to the time required to open and close the associated vents along with a safety factor that accounts for the physical and technological constraints of the facility, to determine the total calculated purge duration in minutes.

(ii) *Oxygen Sensors:* Facilities may use oxygen sensors located within the closed vent system to determine when the oxygen level falls below 3 percent.

* * * * *

(g) * * *

(1) * * *

(ii) *Compliance schedule.* The compliance schedule for the affected source, as defined in paragraph (*g*)(1)(i) of this section, is specified in § 63.1102.

(2) * * *

Free cyanide means chemical species of cyanide that are dissolved in water and are bioavailable and known for their toxic effects on living organisms. This refers to the sum of molecular hydrogen cyanide (HCN) and cyanide ion (CN^-) dissolved in water. Included in this definition are the dissolved products of cyanide salts (including potassium cyanide [KCN] and sodium cyanide [NaCN]), as these salts dissociate to cyanide ion and hydrogen cyanide when added to water.

* * * * *

(3) *Requirements.* Table 9 to this section specifies the cyanide chemicals manufacturing standards applicable to existing and new sources. Applicability assessment procedures and methods are specified in § 63.1104. An owner or operator of an affected source is not required to perform applicability tests or other applicability assessment procedures if they opt to comply with the most stringent requirements for an applicable emission point pursuant to this subpart. General compliance, recordkeeping, and reporting requirements are specified in §§ 63.1108 through 63.1112. Before May 18, 2022, minimization of emissions from startup, shutdown, and malfunctions must be addressed in the startup, shutdown, and malfunction plan required by § 63.1111; the plan must also establish reporting and recordkeeping of such events. A startup, shutdown, and malfunction plan is not required on and after May 18, 2022 and the requirements specified in § 63.1111 no longer apply; however, for historical compliance purposes, a copy of the plan must be retained and available on-site for 5 years after May 18, 2022. Procedures for approval of alternative means of emission limitations are specified in § 63.1113.

* * * * *

(5) * * *

(vi) For compliance with the wastewater free cyanide analysis provisions of table 9 to § 63.1103(g), free cyanide is to be measured according to ASTM D4282–15 or ASTM D7237–18 (both incorporated by reference, see § 63.14).

(6) *Startup, shutdown, and malfunction referenced provisions.* Beginning no later than the compliance dates specified in § 63.1102(d), the referenced provisions specified in paragraphs (g)(6)(i) through (xxiii) of this section do not apply when demonstrating compliance with paragraph (g)(3) of this section.

(i) The second/last sentence of § 63.983(a)(5) (requirements for pressure relief devices in a transfer rack's closed vent system requirements) of subpart SS: ''Pressure relief devices needed for safety purposes are not subject to this paragraph.''

(ii) The phrase ''except during periods of start-up, shutdown and malfunction as specified in the referencing subpart'' in § 63.984(a) of subpart SS (equipment and operating requirements for fuel gas systems and processes requirements).

(iii) The phrase ''except during periods of start-up, shutdown and malfunction as specified in the referencing subpart'' in § 63.985(a) of subpart SS (nonflare control device equipment and operating requirements).

(iv) The phrase ''other than start-ups, shutdowns, or malfunctions'' in § 63.994(c)(1)(ii)(D) of subpart SS (halogen scrubber and other halogen reduction device monitoring requirements).

(v) Section 63.996(c)(2)(ii) of subpart SS (operation and maintenance of continuous parameter monitoring systems) ''(ii) If under the referencing subpart, an owner or operator has developed a start-up, shutdown, and malfunction plan, the plan is followed, and the CPMS is repaired immediately, this action shall be recorded as specified in § 63.998(c)(1)(ii)(E).''

(vi) The last sentence of § 63.997(e)(1)(i) (performance test procedures) of subpart SS (general procedures for continuous unit operations): ''Operations during periods of start-up, shutdown, and malfunction shall not constitute representative conditions for the purpose of a performance test.''

(vii) Section 63.998(b)(2)(iii) (excluded data) of subpart SS: ''(iii) Startups, shutdowns, and malfunctions, if the owner or operator operates the source during such periods in accordance with § 63.1111(a) and maintains the records specified in paragraph (d)(3) of this section.''

(viii) The phrase ''other than periods of startups, shutdowns, and malfunctions'' from § 63.998(b)(5)(i)(A) (alternative recordkeeping) of subpart SS.

(ix) The phrase ''other than a start-up, shutdown, or malfunction'' from § 63.998(b)(5)(i)(B)(3) (alternate recordkeeping) of subpart SS.

(x) The phrase ''other than periods of startups, shutdowns, and malfunctions'' from § 63.998(b)(5)(i)(C) (alternate recordkeeping) of subpart SS.

(xi) The phrase ''other than a start-up, shutdown, or malfunction'' from § 63.998(b)(5)(ii)(C) (alternate recordkeeping) of subpart SS.

(xii) The phrase ''except as provided in paragraphs (b)(6)(i)(A) and (B) of this section'' from § 63.998(b)(6)(i) (alternative recordkeeping) of subpart SS.

(xiii) The second sentence of § 63.998(b)(6)(ii) (alternative recordkeeping) of subpart SS. ''If a source has developed a startup, shutdown and malfunction plan, and a monitored parameter is outside its

established range or monitoring data are not collected during periods of startup, shutdown, or malfunction (and the source is operated during such periods in accordance with § 63.1111(a)) or during periods of nonoperation of the process unit or portion thereof (resulting in cessation of the emissions to which monitoring applies), then the excursion is not a violation and, in cases where continuous monitoring is required, the excursion does not count as the excused excursion for determining compliance.''

(xiv) Section 63.998(c)(1)(ii)(D) through (G) (nonflare control and recovery device regulated source monitoring records) of subpart SS.

(xv) Section 63.998(d)(3) (regulated source and control equipment start-up, shutdown and malfunction records) of subpart SS.

(xvi) The phrase ''may be included as part of the startup, shutdown, and malfunction plan, as required by the referencing subpart for the source, or'' from § 63.1005(e)(4)(i) (leak repair records written procedures) of subpart TT.

(xvii) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1007(e)(1)(ii)(A) (dual mechanical seal system special provisions for pumps) of subpart TT.

(xviii) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1009(e)(1)(i)(A) (dual mechanical seal system special provisions for agitators) of subpart TT.

(xix) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1012(b)(1) (compressor seal system standard) of subpart TT.

(xx) The phrase ''may be included as part of the startup, shutdown, and malfunction plan, as required by the referencing subpart for the source, or'' from § 63.1024(f)(4)(i) (leak repair records written procedures) of subpart UU.

(xxi) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1026(e)(1)(ii)(A) (dual mechanical seal system special provisions for pumps) of subpart UU.

(xxii) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1028(e)(1)(i)(A) (dual mechanical seal system special provisions for agitators of subpart UU.

(xxiii) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1031(b)(1) (compressor seal system standard) of subpart UU.

TABLE 9 TO § 63.1103(g)—WHAT ARE MY REQUIREMENTS IF I OWN OR OPERATE A CYANIDE CHEMICALS MANUFACTURING EXISTING OR NEW AFFECTED SOURCE?

If you own or operate . . .	And if . . .	Then you must . . .
* *	* *	* * *
(f) A new cyanide chemicals manufacturing process unit that generates process wastewater.	(1) The process wastewater is from HCN purification, ammonia purification, or flare blowdown.	(i) Achieve a combined removal and control of HAP from wastewater of 93 weight-percent; and (ii) Beginning no later than the compliance dates specified in § 63.1102(d), waste management units upstream of an open or closed biological treatment process shall meet the requirements of § 63.133 through § 63.137 of subpart G of this part, as applicable.
(g) An existing cyanide chemicals manufacturing process unit that generates process wastewater.	(1) The process wastewater stream is from HCN purification, ammonia purification, or flare blowdown; and. (2) the total annual average concentration of Table 9 of 40 CFR part 63, subpart G compounds (Table 9 compounds) and free cyanide measured according to § 63.1103(g)(5)(vi) from each process wastewater stream are greater or equal to 10,000 ppmw at any flow rate, or the total annual average concentration of Table 9 compounds and free cyanide from each process wastewater stream are greater or equal to 1,000 ppmw, and the annual average flow rate is greater or equal to 10 liters per minute, according to the procedures in § 63.144(a).	(i) Beginning no later than the compliance dates specified in § 63.1102(d), comply with the requirements of § 63.138(a)(1). (ii) For compliance options and calculations requiring an Fr value under § 63.138(a)(1); owners and operators may use a value of 0.93 for free cyanide.
(h) A cyanide chemicals manufacturing process unit that generates maintenance wastewater.	(1) The maintenance wastewater contains hydrogen cyanide or acetonitrile.	(i) Comply with the requirements of § 63.1106(b).
(i) An item of equipment listed in § 63.1106(c)(1) that transports or contains wastewater liquid streams from a cyanide chemicals manufacturing process unit.	(1) The item of equipment meets the criteria specified in § 63.1106(c)(1) through (3) and either (c)(4)(i) or (ii).	(i) Comply with the requirements in Table 35 of subpart G of this part.
(j) Equipment, as defined under § 63.1101.	(1) The equipment contains or contacts hydrogen cyanide and operates equal to or greater than 300 hours per year.	(i) Comply with either subpart TT or UU of this part, and paragraph (g)(5) of this section, with the exception that open-ended lines that contain or contact hydrogen cyanide are exempt from any requirements to install a cap, plug, blind flange, or second valve to be capped.

■ 6. Section 63.1104 is amended by revising paragraph (c) to read as follows:

§ 63.1104 Process vents from continuous unit operations: applicability assessment procedures and methods.

* * * * *

(c) *Applicability assessment requirements.* The TOC or organic HAP concentrations, process vent volumetric flow rates, process vent heating values,

process vent TOC or organic HAP emission rates, halogenated process vent determinations, process vent TRE index values, and engineering assessments for process vent control applicability assessment requirements are to be determined during maximum representative operating conditions for the process, except as provided in paragraph (d) of this section, or unless the Administrator specifies or approves alternate operating conditions. For acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, polycarbonate production affected sources, and ethylene production affected sources, operations during periods of malfunction shall not constitute representative conditions for the purpose of an applicability test. For all other affected sources, operations during periods of startup, shutdown, and malfunction shall not constitute representative conditions for the purpose of an applicability test.

* * * * *

■ 7. Section 63.1108 is amended by:
■ a. Revising paragraphs (a) introductory text and paragraph (a)(4)(i).
■ b. Revising paragraphs (b)(1)(ii), (b)(2) introductory text, and paragraphs (b)(4)(ii)(A) and (B).

The revisions read as follows:

§ 63.1108 Compliance with standards and operation and maintenance requirements.

(a) *Requirements.* The requirements of paragraphs (a)(1), (2), and (5) of this section apply to all affected sources except acrylic and modacrylic fiber production affected sources and polycarbonate production affected sources, and beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing affected sources, and specified in § 63.1102(e) for carbon black production affected sources. The requirements of paragraph (a)(4) of this section apply only to acrylic and modacrylic fiber production affected sources, polycarbonate production affected sources and beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing affected sources, and specified in § 63.1102(e) for carbon black production affected sources. The requirements of paragraphs (a)(3), (6), and (7) of this section apply to all affected sources.

* * * * *

(4) * * *

(i) For acrylic and modacrylic fiber production affected sources and polycarbonate production affected sources, and beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing, and specified in § 63.1102(e) for carbon black production affected sources, the emission limitations and established parameter ranges of this part shall apply at all times except during periods of non-operation of the affected source (or specific portion thereof) resulting in cessation of the emissions to which this subpart applies. Equipment leak requirements shall apply at all times except during periods of non-operation of the affected source (or specific portion thereof) in which the lines are drained and depressurized resulting in cessation of the emissions to which the equipment leak requirements apply.

* * * * *

(b) * * *

(1) * * *

(ii) Excused excursions are not allowed for acrylic and modacrylic fiber production affected sources, polycarbonate production affected sources, and beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing affected sources, and specified in § 63.1102(e) for carbon black production affected sources. For all other affected sources, including ethylene production, cyanide chemicals manufacturing, and carbon black production affected sources, prior to the compliance dates specified in § 63.1102(c) through (e), an excused excursion, as described in § 63.998(b)(6)(ii), is not a violation.

(2)*Parameter monitoring: Excursions.* An excursion is not a violation in cases where continuous monitoring is required and the excursion does not count toward the number of excused excursions (as described in § 63.998(b)(6)(ii)), if the conditions of paragraph (b)(2)(i) or (ii) of this section are met, except that the conditions of paragraph (b)(2)(i) of this section do not apply for acrylic and modacrylic fiber production affected sources, polycarbonate production affected sources, and beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing affected sources, and specified in § 63.1102(e) for carbon black production affected sources. Nothing in this paragraph shall be construed to allow or excuse a monitoring parameter excursion caused by any activity that violates other applicable provisions of this subpart or a subpart referenced by this subpart.

* * * * *

(4) * * *

(ii) * * *

(A) The Administrator may determine compliance with emission limitations of this subpart based on, but not limited to, the results of performance tests conducted according to the procedures specified in § 63.997, unless otherwise specified in this subpart or a subpart referenced by this subpart. For carbon black production affected sources, beginning no later than the compliance dates specified in § 63.1102(e), in addition to initial performance test requirements to demonstrate compliance with process vent requirements, subsequent performance tests are required no later than 60 months after the preceding performance test in accordance with the procedures specified in § 63.997(e) for initial performance tests.

(B) For acrylic and modacrylic fiber production affected sources, polycarbonate production affected sources, and beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing affected sources, and specified in § 63.1102(e) for carbon black production affected sources, performance tests shall be conducted under such conditions as the Administrator specifies to the owner or operator based on representative performance of the affected source for the period being tested. Representative conditions exclude periods of startup and shutdown unless specified by the Administrator or an applicable subpart. The owner or operator may not conduct performance tests during periods of malfunction. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

■ 8. Section 63.1110 is amended by:
■ a. Revising paragraph (a) introductory text.

■ b. Revising paragraphs (a)(7), (a)(10)(i) introductory text, (a)(10)(i)(A) through (C), and (a)(10)(ii).
■ c. Revising paragraph (d)(2).
The revisions read as follows:

§ 63.1110 Reporting requirements.

(a) *Required reports.* Each owner or operator of an affected source subject to this subpart shall submit the reports listed in paragraphs (a)(1) through (8) of this section, as applicable. Each owner or operator of an acrylic and modacrylic fiber production affected source or polycarbonate production affected source subject to this subpart shall also submit the reports listed in paragraph (a)(9) of this section in addition to the reports listed in paragraphs (a)(1) through (8) of this section, as applicable. Beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing affected sources, and specified in § 63.1102(e) for carbon black production affected sources, each owner or operator of an ethylene production affected source, cyanide chemicals manufacturing affected source, and carbon black production affected source subject to this subpart shall also submit the reports listed in paragraph (a)(10) of this section in addition to the reports listed in paragraphs (a)(1) through (8) of this section, as applicable.

* * * * *

(7) Startup, Shutdown, and Malfunction Reports described in § 63.1111 (except for acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, ethylene production affected sources, and polycarbonate production affected sources).

* * * * *

(10) * * *

(i) Beginning no later than the compliance dates specified in § 63.1102(c) for ethylene production affected sources, specified in § 63.1102(d) for cyanide chemicals manufacturing affected sources, and specified in § 63.1102(e) for carbon black production affected sources, within 60 days after the date of completing each performance test required by this subpart or applicability assessment required by § 63.1103(f)(3)(iv), the owner or operator must submit the results of the performance test or applicability assessment following the procedures specified in paragraphs (a)(10)(i)(A) through (C) of this section.

(A) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test or applicability assessment to the EPA via CEDRI, which can be accessed through the EPA's CDX (*https://cdx.epa.gov/*). The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(B) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test or applicability assessment must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(C) *CBI.* Do not use CEDRI to submit information you claim as CBI. Anything submitted to CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if an owner or operator wishes to assert a CBI claim for some of the information submitted under paragraph (a)(10)(i)(A) or (B) of this section, then the owner or operator must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via EPA's CDX as described in paragraphs (a)(10)(i)(A) and (B) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(ii) Beginning no later than the compliance dates specified in § 63.1102(c) through (e), the owner or operator must submit all subsequent Notification of Compliance Status reports required under paragraph (a)(4) of this section in PDF format to the EPA via CEDRI, which can be accessed through EPA's CDX (*https://cdx.epa.gov/*). All subsequent Periodic Reports required under paragraph (a)(5) of this section must be submitted to the EPA via CEDRI using the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*) for this subpart beginning no later than the compliance dates specified in § 63.1102(c) through (e) or once the report template has been available on the CEDRI website for 1 year, whichever date is later. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim, then submit a complete report, including information claimed to be CBI, to the EPA. Periodic Reports must be generated using the appropriate template on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, MD C404–02, 4930 Old Page Road, Durham NC 27703 to the attention of the applicable person specified in paragraphs (A) through (C) of this section. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(A) Ethylene Production Sector Lead
(B) Cyanide Chemicals Manufacturing Sector Lead
(C) Carbon Black Production Sector Lead

* * * * *

(d) * * *

(2) *Due date.*The owner or operator shall submit the Notification of Compliance Status for each affected source 240 days after the compliance date specified for the affected source under this subpart, or 60 days after completion of the initial performance

test or initial compliance assessment/ subsequent required performance test or subsequent compliance assessment, whichever is earlier. Notification of Compliance Status reports may be combined for multiple affected sources as long as the due date requirements for all sources covered in the combined report are met.

* * * * *

■ 9. Section 63.1111 is amended by revising paragraphs (a) introductory text, (b) introductory text, and (c) introductory text to read as follows:

§ 63.1111 Startup, shutdown, and malfunction.

(a) *Startup, shutdown, and malfunction plan.* Before May 18, 2022, the requirements of this paragraph (a) apply to all affected sources except for acrylic and modacrylic fiber production affected sources and polycarbonate production affected sources. On and after May 18, 2022, the requirements of this paragraph (a) apply to all affected sources except for acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, and polycarbonate production affected sources. On and after July 6, 2023, the requirements of this paragraph (a) apply to all affected sources except for acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, ethylene production affected sources, and polycarbonate production affected sources.

* * * * *

(b) *Startup, shutdown, and malfunction reporting requirements.* Before May 18, 2022, the requirements of this paragraph (b) apply to all affected sources except for acrylic and modacrylic fiber production affected sources and polycarbonate production affected sources. On and after May 18, 2022, the requirements of this paragraph (b) apply to all affected sources except for acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, and polycarbonate production affected sources. On and after July 6, 2023, the requirements of this paragraph (b) apply to all affected sources except for acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, ethylene production affected sources, and polycarbonate production affected sources.

* * * * *

(c) *Malfunction recordkeeping and reporting.* Before May 18, 2022, the requirements of this paragraph (c) apply only to acrylic and modacrylic fiber production affected sources and polycarbonate production affected sources. On and after May 18, 2022, the requirements of this paragraph (c) apply only to acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, and polycarbonate production affected sources. On and after July 6, 2023, the requirements of this paragraph (c) apply only to acrylic and modacrylic fiber production affected sources, carbon black production affected sources, cyanide chemicals manufacturing affected sources, ethylene production affected sources, and polycarbonate production affected sources.

* * * * *

[FR Doc. 2021–24204 Filed 11–18–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2021–0016; FRL–8339–01–OAR]

RIN 2060–AV34

National Emission Standards for Hazardous Air Pollutants: Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing the results of the technology review conducted in accordance with the Clean Air Act (CAA) for the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources and proposing amendments to the NESHAP. The EPA is proposing no changes to the standards as a result of the technology review. The EPA is proposing to amend provisions regarding electronic reporting; make miscellaneous clarifying and technical corrections; simplify the petition for exemption process; and clarify requirements addressing emissions during periods of startup, shutdown, and malfunction (SSM).

DATES: Comments must be received on or before January 3, 2022. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before December 20, 2021.

Public hearing. If anyone contacts us requesting a public hearing on or before November 24, 2021, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2021–0016 for 40 Code of Federal Regulations (CFR) part 63, subpart HHHHHH, Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2021–0016 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2021–0016.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2021–0016, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the applicable Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID–19. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action contact Mr. John Feather, Sector Policies and Programs Division (D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–3052; fax number: (919) 541–4991; and email address: *feather.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that because of current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time.

To request a virtual public hearing, contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* If requested, the virtual hearing will be held on December 6, 2021. The hearing will convene at 11:00 a.m. Eastern Time (ET) and will conclude at 9:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/paint-stripping-and-miscellaneous-surface-coating-operations.*

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/paint-stripping-and-miscellaneous-surface-coating-operations* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be December 1, 2021. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/paint-stripping-and-miscellaneous-surface-coating-operations.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *feather.john@epa.gov.* The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/paint-stripping-and-miscellaneous-surface-coating-operations.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by November 26, 2021. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking: Docket ID No. EPA–HQ–OAR–2021–0016. All documents in the docket are listed in *https://www.regulations.gov.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov*.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2021–0016. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Due to public health concerns related to COVID–19, the EPA Docket Center and Reading Room are open to the public by appointment only. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2021–0016. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Preamble acronyms and abbreviations. Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ACA American Coatings Association
BACT best available control technology
CAA Clean Air Act
CBI Confidential Business Information
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CFR Code of Federal Regulations
ECHO Enforcement and Compliance History Online
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
GACT generally available control technology
HAP hazardous air pollutant(s)
HVLP high volume, low pressure
kg kilogram
km kilometer
LAER lowest achievable emission rate
MACT maximum achievable control technology
MeCL methylene chloride
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NSR New Source Review
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
OSHA Occupational Safety and Health Administration
PDF portable document format
PRA Paperwork Reduction Act
PTE permanent total enclosure

RACT reasonably available control technology
RBLC RACT/BACT/LAER Clearinghouse
RFA Regulatory Flexibility Act
RTO regenerative thermal oxidizer
SSM startup, shutdown, and malfunction
tpy tons per year
UMRA Unfunded Mandates Reform Act
VOC volatile organic compounds

Organization of this document. The information in this preamble is organized as follows:

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A. What are the results and proposed decisions based on our technology review, and what is the rationale for those decisions?
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G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and associated regulated industrial source categories that are the subject of this proposal. Table 1 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed amendments to 40 CFR part 63, subpart HHHHHH, once promulgated, will be directly applicable to the affected sources. These three area source categories, Paint Stripping, Miscellaneous Surface Coating, and Motor Vehicle and Mobile Equipment Surface Coating, were listed as part of the Urban Air Toxics Strategy and include methylene chloride (MeCl)-containing paint stripping operations and certain surface coating operations located at area sources. The NESHAP's title of Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources refers to a single set of emission standards that addresses all three source categories. Paint stripping is often used as preparation for surface coating operations, so was included along with the other two source categories in this NESHAP but is treated separately within this NESHAP due to differences in practices and standards. The Miscellaneous Surface Coating and Motor Vehicle and Mobile Equipment Surface Coating source categories are subject to similar standards for the same HAP, so they are grouped together as ''surface coating'' operations for most purposes within this action. However, as explained in this section and section II.B of this preamble, there are some differences in applicability and standards between the two source categories. An area source is defined in CAA section 112(a) as any stationary source of HAP that is not a major source, and a major source is defined as any stationary source or group of stationary sources located within a contiguous area and under common control that emits, or has the potential to emit, considering controls, in the aggregate, 10 tons per year (tpy) or more of any single HAP or 25 tpy or more of any combination of HAP. Paint stripping operations are those that perform paint stripping using MeCl for the removal of dried paint (including, but not limited to, paint, enamel, varnish, shellac, and lacquer) from wood, metal, plastic, and other substrates at area sources as either (1) an independent activity where paint stripping is the principal activity at the source or (2) an activity incidental to the principal activity (*e.g.,* surface coating, inspection, maintenance, etc.) at the source. Co-located paint stripping activities that use one ton or less per year are considered to be incidental to the principal activity and those using more than one ton to be performing paint stripping as a principal activity. Motor vehicle and mobile equipment surface coating operations are those that spray apply coatings at area sources to automobiles, light trucks, heavy duty trucks, buses, construction equipment, self-propelled vehicles and equipment that may be drawn and/or driven on a roadway. Miscellaneous surface coating operations are those that involve the spray application of coatings that contain compounds of chromium, lead, manganese, nickel, or cadmium, herein after referred to as target HAP, to miscellaneous parts and/or products made of metal or plastic, or combinations of metal and plastic. In general, the facilities and entities potentially affected by the proposed amendments to 40 CFR part 63, subpart HHHHHH are covered under the North American Industrial Classification System (NAICS) Codes listed in the following table. However, facilities classified under other NAICS codes may be subject to the proposed amendments if they meet the applicability criteria.

TABLE 1—NESHAP, INDUSTRIAL AND GOVERNMENT SOURCES AFFECTED BY THIS PROPOSED ACTION

NESHAP source category	NAICS code	Regulated entities [1]
Aerospace Equipment	336413 336414 336415 54171	Aircraft engines, aircraft parts, aerospace ground equipment.

TABLE 1—NESHAP, INDUSTRIAL AND GOVERNMENT SOURCES AFFECTED BY THIS PROPOSED ACTION—Continued

NESHAP source category	NAICS code	Regulated entities [1]
Automobiles and Automobile Parts	335312 336111 336211 336310 33632 33633 33634 33637 336390 441110 441120 811121	Engine parts, vehicle parts and accessories, brakes, axles, etc. Motor vehicle body manufacturing and automobile assembly plants. New and used car dealers. Automotive body, paint, and interior repair and maintenance.
Chemical Manufacturing and Product Preparation.	325110 325120 325130 325180 325192 325193 325199 325998	Petrochemicals, Industrial Gases, Inorganic Dyes and Pigments, Basic Inorganic and Organic Chemicals, Cyclic Crude and Intermediates, Ethyl Alcohol, Miscellaneous Chemical Production and Preparation.
Extruded Aluminum	331318 331524 332321 332323	Extruded aluminum, architectural components, coils, rod, and tubes.
Government	Not Applicable	Government entities, besides Department of Defense, that maintain vehicles, such as school buses, police and emergency vehicles, transit buses, or highway maintenance vehicles.
Heavy Equipment	33312 333611 333618	Tractors, earth moving machinery.
Job Shops	332312 332722 332813 332991 332999 334118 339999	Manufacturing industries not elsewhere classified (*e.g.,* bezels, consoles, panels, lenses).
Large Trucks and Buses	33612 336211	Large trucks and buses.
Metal Buildings	332311	Prefabricated metal buildings, carports, docks, dwellings, greenhouses, panels for buildings.
Metal Containers	33242 81131 322219 331513 332439	Drums, kegs, pails, shipping containers.
Metal Pipe and Foundry	331110 331513 33121 331221 331511	Plate, tube, rods, nails, etc.
Rail Transportation	33651 482111	Brakes, engines, freight cars, locomotives.
Recreational Vehicles and Other Transportation Equipment.	321991 3369 331318 336991 336211 336112 336212 336213 336214 336390 336999 33635 56121 8111 56211	Mobile Homes. Motorcycles, motor homes, semi-trailers, truck trailers. Miscellaneous transportation related equipment and parts. Travel trailer and camper manufacturing.
Rubber-to-Metal Products	326291 326299	Engine mounts, rubberized tank tread, harmonic balancers.

TABLE 1—NESHAP, INDUSTRIAL AND GOVERNMENT SOURCES AFFECTED BY THIS PROPOSED ACTION—Continued

NESHAP source category	NAICS code	Regulated entities [1]
Structural Steel	332311	Joists, railway bridge sections, highway bridge sections.
	332312	
	562211	
Waste Treatment, Disposal, and Materials Recovery.	562212	Hazardous Waste Treatment and Disposal, Solid Waste Landfill, Solid Waste Combustors and Incinerators, Other Nonhazardous Waste Treatment and Disposal, Materials Recovery.
	562213	
	562219	
	562920	
Other Industrial and Commercial	211130	Natural Gas Liquid Extraction.
	311942	Spices and Extracts.
	331313	Alumina Refining.
	337214	Office furniture, except wood. Reupholstery and Furniture Repair.
	811420	
	325211	Plastics Material Synthetic Resins, and Nonvulcanizable Elastomers.
	325510	Paint and Coating Manufacturing.
	32614, 32615	Plastic foam products (*e.g.,* pool floats, wrestling mats, life jackets).
	326199	Plastic products not elsewhere classified (*e.g.,* name plates, coin holders, storage boxes, license plate housings, cosmetic caps, cup holders).
	333316	Office machines.
	33422	Radio and television broadcasting and communications equipment (*e.g.,* cellular telephones).
	339112, 339113, 339114, 339115, 339116	Medical equipment and supplies.
	33992	Sporting and athletic goods.
	33995	Signs and advertising specialties.
	336611, 336612	Boat and ship building.
	713930	Marinas, including boat repair yards.

[1] Regulated entities means area source facilities that use MeCl to strip paint or apply surface coatings to these parts or products.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket for this action, an electronic copy of this proposed action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/paint-stripping-and-miscellaneous-surface-coating-operations.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website.

The proposed changes to the CFR that would be necessary to incorporate the changes proposed in this action are set out in an attachment to the memorandum titled *Proposed Regulation Edits for 40 CFR part 63, subpart HHHHHH,* available in the docket for this action (Docket ID No. EPA–HQ–OAR–2021–0016). The document includes the specific proposed amendatory language for revising the CFR and, for the convenience of interested parties, a redline version of the regulation. Following signature by the EPA Administrator, the EPA will also post a copy of this memorandum and the attachments to *https://www.epa.gov/stationary-sources-air-pollution/paint-stripping-and-miscellaneous-surface-coating-operations.*

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). Section 112(d)(6) requires the EPA to review standards promulgated under CAA section 112(d) and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years following promulgation of those standards. This is referred to as a ''technology review'' and is required for all standards established under CAA section 112(d) including generally available control technology (GACT) standards that apply to area sources.[1] This action constitutes the 112(d)(6) technology review for the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources area source NESHAP.

Several additional CAA sections are relevant to this action as they specifically address regulation of hazardous air pollutant emissions from area sources. Collectively, CAA sections 112(c)(3), (d)(5), and (k)(3) are the basis of the Area Source Program under the Urban Air Toxics Strategy, which provides the framework for regulation of area sources under CAA section 112.

Section 112(k)(3)(B) of the CAA requires the EPA to identify at least 30 HAP that pose the greatest potential health threat in urban areas with a primary goal of achieving a 75-percent reduction in cancer incidence attributable to HAP emitted from stationary sources. As discussed in the Integrated Urban Air Toxics Strategy (64 FR 38706, 38715, July 19, 1999), the EPA identified 30 HAP emitted from area sources that pose the greatest potential health threat in urban areas, and these HAP are commonly referred to as the ''30 urban HAP.''

Section 112(c)(3), in turn, requires the EPA to list sufficient categories or subcategories of area sources to ensure that area sources representing 90 percent of the emissions of the 30 urban HAP are subject to regulation. The EPA implemented these requirements through the Integrated Urban Air Toxics Strategy by identifying and setting standards for categories of area sources including the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources source categories that are addressed in this action.

CAA section 112(d)(5) provides that for area source categories, in lieu of

setting maximum achievable control technology (MACT) standards (which are generally required for major source categories), the EPA may elect to promulgate standards or requirements for area sources ''which provide for the use of generally available control technology or management practices [GACT] by such sources to reduce emissions of hazardous air pollutants.'' In developing such standards, the EPA evaluates the control technologies and management practices that reduce HAP emissions that are generally available for each area source category. Consistent with the legislative history, we can consider costs and economic impacts in determining what constitutes GACT.

GACT standards were set for the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources source categories in 2008. As noted above, this proposed action presents the required CAA 112(d)(6) technology review for those source categories.

B. What are the source categories and how does the current NESHAP regulate their HAP emissions?

1. Source Category Descriptions

The NESHAP for the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources source categories was promulgated on January 9, 2008 (73 FR 1738), and is codified at 40 CFR 63, subpart HHHHHH. Technical corrections were promulgated on February 13, 2008 (73 FR 8408).

The sources that are affected by 40 CFR part 63, subpart HHHHHH, and would be affected by the proposed amendments are area sources engaged in paint stripping using MeCl, and/or engaged in coating of miscellaneous parts and/or products made of metal or plastic, or combinations of metal and plastic, or motor vehicle or mobile equipment refinishing.

The affected source is broadly defined to include all operations associated with the removal of dried paint from a substrate using MeCl or the spray application of coatings. These paint stripping operations include the use of MeCl-containing paint strippers by immersion, brushing on, and/or spraying on to remove a coating to change the color of the item or because the life of the coating has been exceeded, or to remove paint for inspection purposes or during repair. These surface coating operations include the storage and mixing of coatings and other materials; surface preparation; coating application and flash-off; drying and curing of applied coatings; cleaning operations; and waste handling operations.

Surface coating operations are those that involve the application of coatings at area sources to (1) miscellaneous parts and/or products made of metal or plastic, or combinations of metal and plastic; or (2) motor vehicles and mobile equipment (*e.g.,* heavy duty-trucks, buses, construction equipment, self-propelled vehicles and equipment that may be drawn and/or driven on a roadway), hereinafter referred to as autobody and mobile equipment refinishing.

The NESHAP defines a ''coating'' as ''a material spray-applied to a substrate for decorative, protective, or functional purposes. For the purposes of this subpart, coating does not include the following materials: (1) Decorative, protective, or functional materials that consist only of protective oils for metal, acids, bases, or any combination of these substances. (2) Paper film or plastic film that may be pre-coated with an adhesive by the film manufacturer. (3) Adhesives, sealants, maskants, or caulking materials. (4) Temporary protective coatings, lubricants, or surface preparation materials. (5) In-mold coatings that are spray-applied in the manufacture of reinforced plastic composite parts.'' (40 CFR 63.11180).

The NESHAP does not apply to paint stripping or surface coating operations that are specifically covered under another area source NESHAP, and does not apply to paint stripping or surface coating operations that meet any of the following:

- Paint stripping or surface coating performed on-site at installations owned or operated by the Armed Forces of the United States (including the Coast Guard and the National Guard of any such state), the National Aeronautics and Space Administration, or the National Nuclear Security Administration.
- Paint stripping or surface coating of military munitions manufactured by or for the Armed Forces of the United States (including the Coast Guard and the National Guard of any such state) or equipment directly and exclusively used for the purposes of transporting military munitions.
- Paint stripping or surface coating performed by individuals on their personal vehicles, possessions, or property, either as a hobby or for maintenance of their personal vehicles, possessions, or property. The NESHAP also does not apply when these operations are performed by individuals for others without compensation. An individual who spray applies surface coating to more than two motor vehicles or pieces of mobile equipment per year is subject to the requirements in this subpart that pertain to motor vehicle and mobile equipment surface coating regardless of whether compensation is received.
- Paint stripping or surface coating for research and laboratory activities, for quality control activities, or for activities that are covered under another area source NESHAP.

Based on our search of the National Emission Inventory (NEI) (*www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei*) and the EPA's Enforcement and Compliance History Online (ECHO) database (*echo.epa.gov*), we estimate that at least 3,000 facilities are subject to the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP. A list of facilities subject to the NESHAP found in the ECHO database is included in a file, titled *Facility List for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources,* which is available in the docket for this action. However, these data are not likely to be comprehensive for these source categories because not all states submit data to ECHO for smaller sources such as these. We also observed that some states with large populations did not have as many facilities in the ECHO database as expected based on population, indicating inconsistent reporting of these facilities among states.

2. HAP Emission Sources

This section describes the emission sources for paint stripping and miscellaneous coating operations.

Paint Stripping Operations

The HAP for which the EPA listed this source category pursuant to CAA section 112(c)(3) is the MeCl contained in paint stripper formulations. The primary source of the MeCl emissions in this source category comes from evaporative losses during the use and storage of MeCl-containing paint strippers.

Surface Coating Operations

The EPA listed the area source surface coating operations categories pursuant to CAA section 112(c)(3) based on emissions of cadmium, chromium, lead, manganese, and nickel compounds. These target HAP emissions from miscellaneous coating operations are the heavy metals contained in the coatings (*e.g.,* in corrosion-resistant primers and as the pigments in topcoats). The target HAP compounds are emitted as the coatings are atomized during spray application. A substantial fraction of coating that is atomized does not reach the part and becomes what is termed

''overspray.'' The fraction that becomes overspray depends on many variables, but two of the most important are the type of spray equipment being used and the skill of the painter. Some overspray lands on surfaces of the spray booth and the masking paper that is usually placed around the surface being sprayed, but the rest of the overspray is drawn into the spray booth exhaust system. If the spray booth has filters, most of the overspray is captured by the filters; otherwise, it is exhausted to the atmosphere.

After coating application, the spray gun must be cleaned to remove the remaining coating before it cures and to prepare the spray gun for the next coating job. Spray guns are usually cleaned in a device, commonly referred to as an enclosed spray gun washer, that consists of a solvent reservoir and a covered enclosure that dispenses solvent for gun cleaning. The enclosure may hold the gun for automated gun cleaning. During gun cleaning, target HAP from the coating may be emitted if the cleaning solvent is sprayed through the gun during cleaning.

3. Current NESHAP Requirements for Control of HAP

Paint Stripping Operations

All sources conducting paint stripping involving the use of MeCl must implement management practice standards that reduce emissions of MeCl by minimizing evaporative losses of MeCl.

In addition to the management practices, sources that use more than one ton of MeCl, per year, must develop and implement a MeCl minimization plan consisting of a written plan with the criteria to evaluate the necessity of MeCl in the stripping operations and management techniques to minimize MeCl emissions when it is needed in the paint stripping operation.

The MeCl minimization plan evaluation criteria specify only using a MeCl-containing paint stripper when an alternative on-site stripping method or material is incapable of accomplishing the work as determined by the operator. Alternative methods to reduce MeCl usage may include: (1) Non- or low-MeCl-containing chemical strippers; (2) mechanical stripping; (3) abrasive blasting (including dry or wet media); or (4) thermal and cryogenic decomposition.

The management practices required to be contained in the plan include optimizing stripper application conditions, reducing exposure of stripper to the air, and practicing proper storage and disposal of materials containing MeCl. Sources are required to submit the plan to their delegated authority, keep a written copy of the plan on site and post a placard or sign outlining the evaluation criteria and management techniques in each area where MeCl-containing paint stripping operations occur. They are also required to review the plan annually and update it based on the experiences of the previous year or the availability of new methods of stripping, and to keep a record of the review and changes made to the plan on file. Sources must maintain copies of the specified records for a period of at least five years after the date of each record.

Surface Coating Operations

All motor vehicle and mobile equipment surface coating operations and those miscellaneous surface coating operations that spray-apply coatings containing the target HAP must apply the coatings with a high volume, low pressure (HVLP) spray gun, electrostatic spray gun, airless spray gun, air-assisted airless spray gun, or a gun demonstrated to be equal in transfer efficiency to an HVLP spray gun. All spray-applied coatings must be applied in a prep station or spray booth. For motor vehicle and mobile equipment surface coating, prep stations and spray booths that are large enough to hold a complete vehicle must have four complete side walls or curtains and a complete roof. For motor vehicle and mobile equipment subassemblies and for miscellaneous surface coating, coatings must be spray applied in a booth with a full roof and at least three walls or side curtains. Openings are allowed in the sidewalls and roof of booths used for miscellaneous surface coating to allow for parts conveyors, if needed. The exhaust from the prep station or spray booth must be fitted with filters demonstrated to achieve at least 98 percent capture efficiency of paint overspray.

Additionally, sources are required to demonstrate that (1) all painters that spray-apply coatings are certified as having completed operator training to improve coating transfer efficiency and minimize overspray and (2) that no spray gun cleaning is performed by spraying solvent through the gun creating an atomized mist (*i.e.,* spray guns are cleaned in an enclosed spray gun cleaner or by cleaning the disassembled gun parts by hand). Each painter must be certified as having completed classroom and hands-on training in the proper selection, mixing, and application of coatings, and must complete refresher training at least once every 5 years. The initial and refresher training must address the following topics:

- Spray gun equipment selection, set up, and operation, including measuring coating viscosity, selecting the proper fluid tip or nozzle, and achieving the proper spray pattern, air pressure and volume, and fluid delivery rate.
- Spray technique for different types of coatings to improve transfer efficiency and minimize coating usage and overspray, including maintaining the correct spray gun distance and angle to the part, using proper banding and overlap, and reducing lead and lag spraying at the beginning and end of each stroke.
- Routine spray booth and filter maintenance, including filter selection and installation.
- Environmental compliance with the requirements of this subpart.

C. What data collection activities were conducted to support this action?

For this technology review, we used information from the EPA's ECHO database to identify facilities subject to the NESHAP. The ECHO database provides integrated compliance and enforcement information for approximately 800,000 regulated facilities nationwide. We supplemented the ECHO database information with data provided by EPA Region 4. Using the feature in ECHO to search by NESHAP subpart, the EPA identified approximately 3,000 facilities as subject to this NESHAP. However, these data are not likely to be comprehensive for these source categories because not all states submit data to ECHO for smaller sources such as these, and we also observed that some states with large populations did not have as many facilities in the ECHO database as expected based on population. The compliance history data in ECHO does not contain detailed information on non-compliance and enforcement actions involving the facilities subject to 40 CFR part 63, subpart HHHHHH, that could be used to identify developments in practices, processes, and control technologies, or other rule changes that are needed.

Also, for the technology review, we collected information from the reasonably available control technology (RACT), best available control technology (BACT), and lowest achievable emission rate (LAER) determinations in the EPA's RACT/BACT/LAER Clearinghouse (RBLC).[1] This database contains case-specific information on air pollution

[1] *https://www.epa.gov/catc/ractbactlaer-clearinghouse-rblc-basic-information.*

technologies that have been required to reduce the emissions of air pollutants from stationary sources. Under the EPA's New Source Review (NSR) program, an NSR permit must be obtained if a facility is planning new construction that increases the air emissions of any regulated NSR pollutant at or above 100 or 250 tpy (or a lower threshold depending upon nonattainment severity) or a modification that results in a significant emissions increase and a significant net emissions increase of any regulated NSR pollutant (''significant'' emissions increase is defined in the NSR regulations and is pollutant-specific, ranging from less than 1 pound (lb) to 100 tpy of the applicable regulated NSR pollutant). This central database promotes the sharing of information among permitting agencies and aids in case-by-case determinations for NSR permits. We examined information contained in the RBLC to determine what technologies are currently used for these surface coating and paint stripping operations to reduce air emissions.

Additional information about these data collection activities for the technology review is contained in the memoranda titled *Technology Review for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources,* July 2021, available in the docket for this action.

The EPA also performed a literature search for information on alternatives to coatings that contain the target metal HAP and alternative processes to reduce emissions from the application of these coatings, and for alternatives to chemical paint stripping using MeCl-containing paint stripping materials.

The EPA also reviewed data collected as part of the National Small Business Environmental Assistance Program (SBEAP) (*https://nationalsbeap.org/*). This program and the data collected are used to assist companies in complying with 40 CFR part 63, subpart HHHHHH. These data include lists of coatings provided by the coating manufacturers that are commonly used in autobody and mobile equipment refinishing operations. The lists indicate whether each coating contains the target HAP, and whether substitute coatings are available that do not contain the target HAP. The EPA also contacted coatings suppliers, through state members of the SBEAP, to collect information on alternative coatings that do not contain the target HAP and current best practices to minimize emissions during coating application. The EPA also reached out to industry representatives for input regarding developments in technology and practices that have occurred since promulgation of the original rule.

D. What other relevant background information and data are available?

As part of the technology review for the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP source categories, we reviewed information available in the American Coatings Association's (ACA) *Industry Market Analysis'* 9th Edition (2014–2019).[2] The *ACA Industry Market Analysis* provided information on trends in coatings technology that can affect emissions from the source categories. Additional details regarding our review of this information source are contained in the *Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources Technology Review Memo,* available in the docket for this action.

E. How does the EPA perform the technology review?

Our technology review focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the GACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is ''necessary'' to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a ''development'':

- Any add-on control technology or other equipment that was not identified and considered during development of the original GACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original GACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original GACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original GACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original GACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls that may have not been considered during development of the NESHAP. Among the sources we reviewed were the NESHAP technology reviews for various industries that were completed after the GACT standard being reviewed in this action (*e.g.,* NESHAP for Aerospace Manufacturing and Rework (40 CFR part 63, subpart GG), NESHAP for Surface Coating of Metal Parts and Products (40 CFR part 63, subpart MMMM), and NESHAP for Surface Coating of Plastic Parts and Products (40 CFR 63, subpart PPPP)). We also reviewed the regulatory requirements and/or technical analyses associated with these regulatory actions to identify any practices, processes, and control technologies considered in these efforts that could be applied to emission sources in the Paint Stripping and Surface Coating source categories, as well as the costs, non-air impacts, and energy implications associated with the use of these technologies. Finally, we reviewed information from other sources, such as state and/or local permitting agency databases and industry-specific market analyses and trade journals, to research advancements in add-on controls and lower HAP technology for coatings. For a more detailed discussion of our methods for performing these technology reviews, refer to the *Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources Technology Review Memo,* available in the docket for this action.

III. Analytical Results and Proposed Decisions

A. What are the results and proposed decisions based on our technology review, and what is the rationale for those decisions?

As described in sections II.C, D, and E of this preamble, our technology review focused on identifying developments in practices, processes, and control technologies for the three source categories. The EPA reviewed various information sources regarding emission sources that are currently

[2] Prepared for the ACA, Washington, DC, by The ChemQuest Group, Inc., Cincinnati, Ohio. 2015.

regulated by the NESHAP to support the technology review. The information sources included the following: The RBLC; state regulations; facility operating permits; other NESHAP-related regulatory actions, including technology reviews for other surface coating NESHAPs promulgated after this NESHAP was finalized in 2008; and industry information. The primary emission sources for the technology review included the following: The spray applied coating operations and paint stripping operations using MeCl containing paint stripping materials.

Based on our review, we did not identify any add-on control technologies, process equipment, management practices or procedures that were not previously considered during development of the 2008 Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP, and we did not identify any new or improved add-on control technologies that would result in additional emission reductions. A brief summary of the EPA's findings in conducting the technology review of Paint Stripping and Surface Coating operations follows. For a detailed discussion of the EPA's findings, refer to the memorandum, *Technology Review for Paint Stripping and Miscellaneous Surface Coating Source Categories,* in the docket for this action.

During the development of the 2008 Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP, management practices were determined for new and existing area sources performing spray applied coating operations using coatings containing the target HAP and for paint stripping operations using MeCl containing materials. The development of the surface coating management practices was based on the following:

- Numerous visits to area source surface coating operations;
- The surface coating industry's use of high efficiency coatings spray equipment, filtered spray booths, and enclosed spray gun cleaners; and
- The EPA's review of available operator training programs.

The paint stripping management practices were based on a detailed study of the paint stripping industry [3] and visits to numerous paint stripping operations.

Paint Stripping Operations

Our search of the RBLC database for improvements in paint stripping technologies provided results for two facilities with permit dates of 2008 or later. Facilities reported the use of VOC emission limits, and work practices in compliance with the Aerospace NESHAP.

We also reviewed the results of the technology review for the Aerospace Manufacturing and Rework Facilities NESHAP (40 CFR part 63, subpart GG). The Aerospace NESHAP regulates emissions from depainting operations (40 CFR 63.746) and limits the amount of organic HAP in chemical strippers used per aircraft, and also has provisions to limit inorganic HAP emissions from non-chemical (*e.g.,* abrasive blasting) depainting operations. As part of that technology review for chemical depainting, the EPA examined Washington State's records of permits for Aerospace Manufacturing and Rework Facilities and identified a 2013 PSD permit amendment that requires the VOC vapor pressure of cleaning solvents and chemical strippers used in depainting operations to be less than 45 mm Hg. It should be noted that the Aerospace NESHAP does not prescribe vapor pressure limits to chemical depainting strippers, but instead has capture and control and volume usage limits for chemical depainting operations that use HAP containing chemical strippers. Otherwise, facilities must use non-HAP chemical strippers. Therefore, the EPA determined that the Aerospace NESHAP was at least as stringent as the Washington State PSD permit requirements. The technology review for the Aerospace NESHAP did not identify any developments in processes or control technologies to reduce organic HAP emissions from chemical depainting operations. (80 FR 8392, February 17, 2015). The Idaho state general permit program for automobile body shops was more restrictive, such that Idaho will not issue a general permit to body shops that are using MeCl as a paint remover.[4] However, the 2008 Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP did consider numerical emission limits but determined that they would not be feasible due to the variability in operational parameters and variety of work being performed. Similar to the Aerospace NESHAP, the 2008 Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP decided to not limit or ban the use of MeCl-based paint strippers, determining instead to set management practices that reduced emissions and encourage the substitution of alternative stripping technologies where they could feasibly be employed. All of these control technologies were in use by the paint stripping industry during development of the NESHAP or already were considered in the development of the NESHAP. In this review, for purposes of these area source GACT standards, we have again determined that these measures could not feasibly be broadly applied to the industry. Therefore, we concluded that the results of the search did not result in any broadly applied improvements in add-on control technology or other equipment.

In conclusion, for the Paint Stripping source category, we did not identify developments in practices, processes, or control technologies broadly applied to the industry during review of the RBLC, the state rules, and subsequent NESHAP that were not already identified and considered during the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP development. We are maintaining our approach of setting widely applicable control technology and management practice standards, while encouraging emissions reductions, such as from product reformulations, where appropriate. The current standards effectively reduce emissions while encouraging sources to further reduce emissions. We identified no improvements broadly applied to the industry or changes in costs. We do not consider the practices we found to be developments for the purposes of this technology review, and continue to determine that they do not warrant revisions to the current emission standards.

Surface Coating Operations

For this technology review, we consulted state rules and operating permits. California has an existing surface coating rule, Airborne Toxic Control Measure for Emissions of Hexavalent Chromium and Cadmium from Motor Vehicle and Mobile Equipment Coatings (ATCM),[5] that prohibits the use, possession, sale,

[3] *Source Reduction and Recycling of Halogenated Solvents in Paint Stripping*—Technical Support Document—A Report on Research Performed by the Source Reduction Research Partnership for the Metropolitan Water District and the Environmental Defense Fund. Prepared By Jacobs Engineering Group Inc. Pasadena, CA. 1990.

[4] Idaho Department of Environmental Quality. *Streamlined air permitting processes for qualifying automotive coating operations.* Revision 6; April 2017. (Accessed June 2021 *https://www2.deq.idaho.gov/admin/LEIA/api/document/download/5194*).

[5] California Air Resources Board. *Automotive Refinishing. https://ww2.arb.ca.gov/our-work/programs/coatings/automotive-refinishing.*

supply, or manufacture for sale in California of any motor vehicle or mobile equipment coating that contains hexavalent chromium or cadmium.[6] While increased compliance costs were expected to raise the prices of coating materials for automotive body paint shops, the California Air Resources Board predicted that these shops would pass the material price increase to consumers, so the impacts to auto body shops would be negligible.[7] In the original NESHAP, the EPA chose not to prohibit the use of coatings that contain any of the heavy metals or target HAP for these source categories. We determined that a nationwide prohibition would impose unreasonable burden on the industry and could force facilities out of business due to a lack of alternative materials that could address the performance criteria (*e.g.,* corrosion protection) that may be used in all environments across the United States.[8] For this technology review, we determined that vendors representing a large market share in the sectors relevant to the NESHAP, specifically coating manufacturers that supply automobile and mobile equipment refinishing coatings, have modified product lines such that non-target HAP products are more readily available. However, in this technology review we still determined that a nationwide prohibition would impose unreasonable burden on the industry, and that other approaches are better suited to reduce emissions. Sources carry out a wide variety of surface coating operations, with different performance criteria, and target HAP-free alternatives would not be viable substitutes for many purposes. Furthermore, as demonstrated by wider adoption of target HAP-free products, the industry is already reducing the usage of target-HAP containing coatings as available, and within their operating requirements, alongside the emission reductions already achieved by implementation of the NESHAP. In addition to the ATCM outlined above, California's South Coast Air Quality Management District (AQMD) adopted a rule for Spraying Operations Using Coatings Containing Chromium (Rule 1469.1) in March 2005.[9] This rule includes requirements for spray transfer efficiency, spray booth operation, housekeeping, monitoring, reporting, and recordkeeping, and in June 2021, South Coast AQMD proposed an amended rule. These amendments aim to further reduce emissions of hexavalent chromium from spraying operations as well as operations such as dried chromate coating removal. They also minimize the accumulation of materials that may contain chromates outside of spray booths that may lead to fugitive emissions.[10] However, these practices were already identified during development of the 2008 Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP, and as stated above, we do not consider the burden imposed by these practices to be warranted for requirements that would apply to these disparate industries and applications. We are maintaining our approach of setting widely applicable control technology and management practice standards, while encouraging emissions reductions, such as from product reformulations, where appropriate. The current standards effectively reduce emissions while encouraging sources to further reduce emissions. Therefore, we do not consider these practices to constitute new or improved add-on control technologies that would result in additional emission reductions.

Under the authority of the Federal Minor Source Review Program (40 CFR 49.151), the EPA issued a permit by rule for new or modified true minor source automobile body repair and miscellaneous surface coating operations in Indian Country (40 CFR 49.162). This permit by rule addresses VOC emissions, but does not address inorganic HAP emissions and does not address paint stripping operations. The permit by rule mirrors the requirements in 40 CFR part 63, subpart HHHHHH, for operator training, spray booths and spray booth filters, and high-efficiency spray guns, but differs in that the exemption for spray guns with a cup capacity less than 3.0 fluid ounces does not apply in serious, severe, and extreme ozone nonattainment areas; instead, in those areas all spray-applied coating operations must be applied with an HVLP spray gun, low volume low pressure (LVLP) spray gun, or air brush spray operation, or with an equivalent spray technology that has been demonstrated by the spray gun manufacturer to achieve a transfer efficiency comparable to that of an HVLP spray gun. The EPA examined 10 state permitting examples for the permit by rule. Three of the 10 state general permit programs for automobile body shops include the requirements of 40 CFR part 63, subpart HHHHHH, but some individual states are more restrictive.[11] These issues were considered during development of the 2008 Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP and do not represent new or improved add-on control technologies that would result in additional emission reductions.

The RBLC database search for improvements in surface coating technologies provided results for 10 facilities with permit dates of 2011 or later (the compliance date for existing sources in 40 CFR part 63, subpart HHHHHH, is January 10, 2011). Facilities reported the use of high-efficiency application methods (*e.g.,* robotic application, electrostatic spray), good work practices, and regenerative thermal oxidizers (RTO) with an established reduction and exhaust gas VOC concentration limits (*i.e.,* 3-hour average of 95 percent removal and 12 parts per million by volume). However, RTO are used to destroy organic compounds and would not be effective at reducing emissions of metal target HAP from spray applied coating operations. All of these control technologies were in use by the surface coating industry during development of the NESHAP and already were considered in the development of the NESHAP. We identified no improvements or changes in costs. Therefore, we concluded that the results of the RBLC search did not result in any improvements in add-on control technology or other equipment.

[6] California Code of Regulations. *Hexavalent Chromium and Cadmium Airborne Toxic Control Measure—Motor Vehicle and Mobile Equipment Coatings.* 17 CCR § 93112. (Accessed April 2021 *https://govt.westlaw.com/calregs/Document/I317A88D0D60811DE88AEDDE29ED1DC0A?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)).*

[7] California Air Resources Board. *Initial Statement of Reasons for Proposed Rulemaking: Airborne Toxic Control Measure for Emissions of Hexavalent Chromium and Cadmium from Motor Vehicle and Mobile Equipment Coatings,* p. V–1. (Accessed April 2021 *https://ww2.arb.ca.gov/sites/default/files/2020-12/ISOR_auto_finish_9-01.pdf*).

[8] US EPA. (September 2007). Proposed rule: *National Emission Standards for Hazardous Air Pollutants: Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources.* 72 FR 52967.

[9] South Coast Air Quality Management District. *Spraying Operations Using Coatings Containing Chromium.* (Accessed June 2021 *http://www.aqmd.gov/docs/default-source/rule-book/reg-xiv/rule-1469-1.pdf*).

[10] South Coast Air Quality Management District. Draft Staff Report: *Proposed Amended Rule 1469.1—Spraying Operations Using Coatings Containing Chromium.* (Accessed June 2021 *http://www.aqmd.gov/docs/default-source/rule-book/Proposed-Rules/1469.1/par1469-1_dsr_040621.pdf?sfvrsn=6*).

[11] U.S. Environmental Protection Agency. (February 2017). *Background Document: Air Quality Permit by Rule for New or Modified True Minor Source Auto Body Repair and Miscellaneous Surface Coating Operations in Indian Country.* (Accessed April 2021 *https://www.epa.gov/sites/production/files/2016-05/documents/autobodybackgrounddocument032315final.pdf*).

We also reviewed the results of the technology review for the Aerospace Manufacturing and Rework Facilities NESHAP (40 CFR part 63, subpart GG). The Aerospace NESHAP regulates emissions of inorganic HAP from the spray application of primers and topcoats (40 CFR 63.745) by requiring the spray application of coatings containing inorganic HAP to be performed in a spray booth or similar enclosure that is exhausted through a filter. The technology review for the Aerospace NESHAP did not identify any developments in processes or control technologies to reduce inorganic HAP emissions from primer and topcoat operations. (80 FR 8392, February 17, 2015)

In conclusion, for the Surface Coating source categories, we did not identify developments in practices, processes, or control technologies during review of the RBLC, the state rules, and subsequent NESHAP that were not already identified and considered during the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP development. We identified no improvements or changes in costs. We do not consider the practices that we found to be developments for the purposes of this technology review, and continue to determine that they do not warrant revisions to the current emission standards.

B. What other actions are we proposing, and what is the rationale for those actions?

1. Electronic Reporting Requirements

The EPA is proposing that owners and operators of paint stripping and surface coating facilities submit electronic copies of initial notifications required in 40 CFR 63.9(b) and 63.11175(a), notifications of compliance status required in 40 CFR 63.9(h) and 63.11175(b), the annual notification of changes report required in 40 CFR 63.11176(a), and the report required in 40 CFR 63.11176(b) through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). For further information regarding the electronic data submission process, please refer to the memorandum titled *Electronic Reporting for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in the docket for this action. No specific form is necessary for the initial notifications required in 40 CFR 63.9(b) and 63.11175(a), notifications of compliance status required in 40 CFR 63.9(h) and 63.11175(b), the annual notification of changes report required in 40 CFR 63.11176(a), and the report required in 40 CFR 63.11176(b). The notifications will be required to be submitted via CEDRI in portable document format (PDF) files.

Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. The situation where an extension may be warranted due to outages of the EPA's CDX or CEDRI which precludes an owner or operator from accessing the system and submitting required reports is addressed in 40 CFR 63.9(b), notifications of compliance status required in 40 CFR 63.9(h), the annual notification of changes report required in 40 CFR 63.11176(a), and the MeCl report required in 40 CFR 63.11176(b). The situation where an extension may be warranted due to a *force majeure* event, which is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents an owner or operator from complying with the requirement to submit a report electronically as required by this rule is addressed in 40 CFR 63.3120(g). Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

The electronic submittal of the reports addressed in this proposed rulemaking has several benefits: Electronic submittal will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. Moreover, electronic reporting is consistent with the EPA's plan [12] to implement Executive Order 13563 and is in keeping with the EPA's agency-wide policy [13] developed in response to the White House's Digital Government Strategy.[14] For more information on the benefits of electronic reporting, see the memorandum *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in the docket for this action, Docket ID No. EPA–OAR–2021–0016.

2. Rule Clarifications and Other Changes, Including Incorporation by Reference

We are proposing plain language clarifications and revisions to better reflect regulatory intent. We also are proposing other changes, including updating references to equivalent test methods, making technical and editorial revisions, incorporation by reference (IBR) of alternative test methods, and simplifying the petition for exemption process. Our analyses and proposed changes related to these issues are discussed in the sections below.

a. Coating HAP Content Definition

The EPA is proposing to clarify that the definition of coatings that do not contain the target HAP is based on the HAP content of the coating as applied, not on the HAP content of the coating components as purchased from the coating supplier. However, coatings that meet the definition of coatings that do not contain the target HAP based on the HAP content as purchased will also meet the definition based on the HAP content as applied.

b. Spray Gun Cup Liners

The EPA is proposing to clarify that the allowance to use spray guns outside

[12] EPA's *Final Plan for Periodic Retrospective Reviews,* August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154.*

[13] *E-Reporting Policy Statement for EPA Regulations,* September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf.*

[14] *Digital Government: Building a 21st Century Platform to Better Serve the American People,* May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html.*

of a spray booth is based on the volume of the spray gun paint cup liner and not the volume of the paint cup, in those spray guns that use a disposable cup liner.

c. Submarines and Tanks Applicability

The EPA is proposing to clarify in this preamble that the surface coating and paint stripping of certain types of military equipment at area sources, such as military submarines (as opposed to those used for scientific research, for example) and military tanks is potentially subject to 40 CFR part 63, subpart HHHHHH, unless the surface coating or paint stripping is performed on site at installations owned or operated by the Armed Forces of the United States (including the Coast Guard and the National Guard of any such state), the National Aeronautics and Space Administration, or the National Nuclear Security Administration. Surface coating of this type of military equipment at original equipment manufacturers or offsite at a contractor's facility would not be covered by the provisions in 40 CFR 63.11169(d)(1), and would be subject to the requirements of 40 CFR part 63, subpart HHHHHH.

d. Circumvention of Paint Cup Capacity Intent

The EPA is proposing to clarify that the exclusion of spray guns with paint cup capacities equal to or less than 3.0 fluid ounces from the definition of spray-applied coatings operations was not intended to constitute an exemption from the NESHAP but was a threshold by which rule applicability for potentially regulated sources may be determined. This was due to the type and scope of operations which were to be regulated under the NESHAP. This clarification is consistent with, and would ensure that the rule clearly reflects, the position provided in a letter issued by the Office of Environmental Compliance and Assurance (OECA) stating that the EPA may find that persons who repeatedly refill and use a three-ounce cup, as a means of avoiding rule applicability, are attempting to circumvent the NESHAP. The EPA accordingly reserves the right to bring enforcement actions against any person whose action equates to rule circumvention.

e. OSHA Carcinogenic Content

The EPA is proposing to remove references to Occupational Safety and Health Administration (OSHA)-defined carcinogens as specified in 29 CFR 1910.1200(d)(4). The reference to OSHA-defined carcinogens as specified in 29 CFR 1910.1200(d)(4) was intended to specify the mass percent threshold above which compounds must be counted in identifying whether coatings are considered ''target HAP containing'' as defined in 40 CFR 63.11180. Target HAP compounds that are carcinogens must be counted if they are present at 0.1 percent by mass or greater and all other target HAP if they are present at 1.0 percent by mass or greater. We are proposing to remove this reference because 29 CFR 1910.1200(d)(4) has been amended and no longer readily defines which compounds are carcinogens. We are proposing to replace these references to OSHA-defined carcinogens and 29 CFR 1910.1200(d)(4) with a list of those target HAP that must be counted if they are present at 0.1 percent by mass or greater. All other target HAP must be counted if they are present at 1.0 percent or greater by mass.

f. Non-HAP Solvent Language

The EPA is proposing to remove the definition of ''non-HAP solvent'' from 40 CFR 63.11180 because there are no requirements to use non-HAP solvents and the definition has no other use in the rule.

g. Filter Test Method

The EPA is proposing to update the spray booth filter test method which was previously incorporated by reference to the most recent American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) method. The rule currently cites ASHRAE Method 52.1, ''Gravimetric and Dust-Spot Procedures for Testing Air-Cleaning Devices Used in General Ventilation for Removing Particulate Matter, June 4, 1992. This method was retired in January 2009, and replaced by ANSI/ASHRAE Standard 52.2–2017 Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size. The EPA is also proposing to include EPA Method 319—Determination of Filtration Efficiency for Paint Overspray Arrestors (Appendix A to 40 CFR part 63), as an alternative to ANSI/ASHRAE Standard 52.2–2017. This is the same method referenced in the NESHAP for Aerospace Manufacturing and Rework (40 CFR part 63, subpart GG) to test paint spray booth filters used to meet the requirements to limit hexavalent chromium emissions. As discussed in section VI.I of this preamble, these methods measure paint booth filter efficiency to measure the capture efficiency of paint overspray arrestors with spray-applied coatings. The ANSI/ASHRAE standard is available from the American Society of Heating, Refrigerating and Air-Conditioning Engineers 1791 Tullie Circle NE, Atlanta, GA 30329. See *http://www.ashrae.org.* The EPA Method standard is available in Appendix A to 40 CFR part 63.

h. Petition for Exemption Process

The EPA is proposing a simplified petition for exemption process for motor vehicle or mobile equipment surface coating operations that do not spray apply any coatings that contain the target HAP. Currently all such sources are subject to the NESHAP, unless they demonstrate to the satisfaction of the Administrator that they do not spray apply any coatings that contain the target HAP. Due to changes in coatings compositions across the industry, and the burden imposed without commensurate environmental benefit, we propose to allow sources to submit notification to the Administrator that they do not spray apply any coatings that contain the target HAP. Such sources would still be required to retain records that describe the coatings that are spray applied, but that information would not need to be reported—to determine whether that has been demonstrated to the satisfaction of the Administrator. The Administrator would maintain the authority to verify records retained on site, including whether the notification of exemption was sufficiently demonstrated. Sources may still petition for exemption using the existing process if they wish for a formal determination.

3. SSM Requirements

a. Elimination of the SSM Exemption

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some section 112 standards apply continuously.

We note that the EPA amended the General Provisions in March 2021 to correct the CFR to reflect the court order

in *Sierra Club* vacating the SSM exemptions.[15]

Consistent with *Sierra Club* v. *EPA,* the standards in this rule apply at all times. We are also proposing a revision to Table 1 to subpart HHHHHH of 40 CFR part 63 (*Applicability of General Provisions to Subpart HHHHHH of Part 63,* hereafter referred to as the ''General Provisions table to subpart HHHHHH''), as explained in more detail below in section III.B.3.b of this preamble.

In proposing these rule amendments, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed alternate standards for those periods. Startups and shutdowns are part of normal operations for the paint stripping and surface coating operations at area sources. Paint stripping and surface coating operations inherently involve frequent startup and shutdown while carrying out normal duties, and the NESHAP's emission standards were developed to control emissions in these situations. We have no data indicating that emissions are different during startup or shutdown than during other normal operations, and the current emission standards adequately control emissions during these startup and shutdown periods.

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead malfunctions are, by definition, sudden, infrequent and not reasonably preventable failures of emissions control, process, or monitoring equipment. (40 CFR 63.2) (definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards. This reading has been upheld as reasonable by the D.C. Circuit in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016).

However, it is unlikely that a malfunction would result in a violation of the standards or significant changes in emissions during paint stripping and surface coating operations at area source facilities. The NESHAP obligates facilities to follow implementation requirements for several stages of GACT or management practices, including application of coatings within a spray booth, using high efficiency spray application equipment, and a variety of other management practices. All facilities must comply with these management practice standards to minimize target HAP emissions from paint stripping and surface coating operations. These standards are not susceptible to malfunctions that would affect emissions, and if such malfunctions were to occur, the multiple layers of protection still reduce the likelihood that any single point of failure would result in a significant increase in emissions.

In the unlikely event that a source fails to comply with the 40 CFR part 63, subpart HHHHHH as a result of a malfunction event, the EPA will determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The annual notification of changes report required in 40 CFR 63.11176(a) already obligates sources to report deviations from relevant requirements in 40 CFR 63.11173. The EPA will also consider whether the source's failure to comply with the standard was, in fact, sudden, infrequent, not reasonably preventable, and was not instead caused, in part, by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the Federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, CAA section 112 is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (D.C. Cir. 2016).

b. Proposed Revisions to the General Provisions Applicability Table

We are proposing to revise the General Provisions table to 40 CFR part 63, subpart HHHHHH (Table 1) entry for 40 CFR 63.6(e)(1)–(2) by changing the ''yes'' in column 3 to a ''no.'' Section 63.6(e)(1)(i) describes the general duty to minimize emissions. Some of the language in that section is not necessary or appropriate in light of the absence of an SSM exemption. We are proposing instead to add general duty regulatory text at 40 CFR 63.11173(h) that reflects the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption. The current language in 40 CFR 63.6(e)(1)(i) characterizes what the general duty entails during periods of SSM. Without an SSM exemption, there is no need to differentiate between normal operations, startup and shutdown, and malfunction events in describing the general duty. Therefore, the language the EPA is proposing for 40 CFR 63.11173(h) does not include that language from 40 CFR 63.6(e)(1)(i). Section 63.6(e)(1)(ii) imposes requirements that are not necessary with the absence of an SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.11173(h). We are also proposing to revise the General Provisions table to 40 CFR part 63, subpart HHHHHH (Table 1) entry for 40 CFR 63.6(f)(1) by changing the ''yes'' in column 3 to a ''no.'' We have added language to the regulatory text at § 63.11173(h) to specify that the standards apply at all times. Although, consistent with *Sierra Club,* the EPA amended 40 CFR 63.6(f)(1) (and also paragraph (h)(1)) on March 11, 2021, to reflect the court order and correct the CFR to remove the SSM exemption and is proposing to revise the description in column 2 of table 1 to clarify that this rule applies at all times, the second sentence of 40 CFR 63.6(f)(1) contains language that is premised on the existence of an exemption and is inapposite in the absence of the exemption. Thus, rather than cross-referencing 63.6(f)(1), we are adding the language of 63.6(f)(1) that requires compliance with standards at all times to the regulatory text at § 63.11173(h).

C. What compliance dates are we proposing, and what is the rationale for the proposed compliance dates?

The EPA is proposing that affected sources must comply with all of the amendments no later than 180 days after the effective date of the final rule. All affected facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart HHHHHH, until the applicable compliance date of the amended rule. The final action is not expected to be a ''major rule'' as defined by 5 U.S.C. 804(2), so the effective date of the final rule will be the promulgation date as specified in CAA section 112(d)(10).

[15] 86 FR 13819, March 11, 2021—Court Vacatur of Exemption From Emission Standards During Periods of SSM.

For existing sources, we are proposing electronic reporting requirements that would impact ongoing compliance requirements for 40 CFR part 63, subpart HHHHHH. We are also acknowledging the change to the requirements for SSM that removed the exemption from the requirements to meet the standard during SSM periods. Our experience with similar industries that are required to employ electronic reporting shows that a time period of a minimum of 90 days, and, more typically, 180 days, is generally necessary to successfully accomplish these revisions. Our experience with similar industries further shows that this sort of regulated facility generally requires a time period of 180 days to read and understand the amended rule requirements; to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; and to update their operation, maintenance, and monitoring plan to reflect the revised requirements. Thus, the EPA is proposing that existing affected sources be in compliance with all regulation's revised requirements within 180 days of the regulation's effective date.

We solicit comment on these proposed compliance periods, and we specifically request submission of information from sources in these source categories regarding specific actions that would need to be undertaken to comply with the proposed amended requirements and the time needed to make the adjustments for compliance with any of the revised requirements. We note that information provided may result in changes to the proposed compliance dates.

IV. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

Currently, we estimate 39,812 area source facilities are subject to the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP and operating in the United States. The affected source under the NESHAP is the collection of all of the items listed in (1) through (6) of this section. Not all affected sources will have all of the items listed in (1) through (6) of this section.

(1) Mixing rooms and equipment;

(2) Spray booths, ventilated prep stations, curing ovens, and associated equipment;

(3) Spray guns and associated equipment;

(4) Spray gun cleaning equipment;

(5) Equipment used for storage, handling, recovery, or recycling of cleaning solvent or waste paint; and

(6) Equipment used for paint stripping at paint stripping facilities using paint strippers containing MeCl.

B. What are the air quality impacts?

Estimated emissions of target HAP and MeCl from the facilities in the Paint Stripping and Surface Coating source categories are not expected to change in any significant way due to this review or its associated amendments.

These proposed amendments acknowledge that all area sources in the source categories must comply with the relevant emission standards at all times, including periods of SSM. We were unable to quantify the emissions that occur during periods of SSM or the specific emissions reductions that would occur as a result of this action.

Indirect or secondary air emissions impacts are impacts that would result from the increased electricity usage associated with the operation of control devices (*e.g.,* increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity and steam needed to operate control devices and other equipment. The proposed amendments would have no effect on the energy needs of the affected paint stripping and surface coating facilities and would, therefore, have no indirect or secondary air emissions impacts.

C. What are the cost impacts?

We estimate that each facility in the source categories will experience costs of approximately $400. These costs are a combination of the estimated reporting and recordkeeping costs (2 technical hours), and the time to read and understand the rule amendments (2 technical hours).[16] Costs associated with adoption of electronic reporting were estimated as part of the reporting and recordkeeping costs and include time for sources to familiarize themselves with electronic record systems.

For further information on the potential costs, see the memorandum titled *Proposal Economic Impact Analysis for the National Emissions Standards of Hazardous Air Pollutants: Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources,* available in the docket for this action.

[16] The labor costs were calculated using the applicable labor rates from the latest version of the Bureau of Labor Statistics (BLS) survey titled National Occupational Employment and Wage Estimates United States located at: *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

D. What are the economic impacts?

The economic impact analysis is designed to inform decision makers about the potential economic consequences of a regulatory action. For the current proposals, the EPA estimated the cost of becoming familiar with the rule, re-evaluating previously developed SSM record systems, and transitioning to electronic reporting. To assess the maximum potential impact, the largest cost expected to be experienced in any one year is compared to the total sales for the ultimate owner of the affected facilities to estimate the total burden for each facility.

For the proposed revisions to the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP, the total cost is estimated to be approximately $400 per facility in the first year of the rule. These costs are not expected to result in a significant market impact, regardless of whether they are passed on to the purchaser or absorbed by the firms.

The EPA also prepared a small business screening assessment to determine whether any of the identified affected entities are small entities, as defined by the U.S. Small Business Administration. Of the facilities potentially affected by the proposed revisions to the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources NESHAP, we estimate that the vast majority are small entities. However, the annualized costs associated with the proposed requirement is from 0.0 to 0.2 percent of annual sales revenue for the ultimate owner of those facilities, well below the 1 percent threshold. Therefore, there are no significant economic impacts on a substantial number of small entities from these proposed amendments.

E. What are the benefits?

As stated above in section IV.B. of this preamble, we were unable to quantify the specific emissions reductions associated with eliminating the SSM exemption.

Because these proposed amendments are not considered economically significant, as defined by Executive Order 12866, we did not monetize the benefits of reducing these emissions. This does not mean that there are no benefits associated with the potential reduction in target HAP and MeCl from this rule.

F. What analysis of environmental justice did we conduct?

Executive Order 12898 directs the EPA to identify the populations of

concern who are most likely to experience unequal burdens from environmental harms; specifically, minority populations, low-income populations, and indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 13985 was signed to advance racial equity and support underserved communities through Federal government actions (86 FR 7009, January 20, 2021). The EPA defines environmental justice (EJ) as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies'' (*https://www.epa.gov/environmentaljustice*). In recognizing that minority and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution. To examine the potential for any EJ issues that might be associated with the source categories, we performed a demographic analysis, which is an assessment of individual demographic groups of the populations living within 5 kilometers (km) and within 50 km of the facilities. The EPA then compared the data from this analysis to the national average for the demographic indicators.

In the analysis, we evaluated the proximity of minority and low-income groups within the populations that live near facilities. Data limitations preclude a complete analysis. This NESHAP applies to sources in many different industries, often operating as small facilities, and limited location data of subject facilities was available. As described in the technology review memo, available in the docket for this action, and section II.C of this preamble, we did conduct searches for available information. However, below results do not account for emission or risk impacts from sources and may not be fully representative of the full distribution of facilities across all locations and populations. This analysis is intended to function as a guide to possible proximity disparities.

Based on the fact that there are over 3,000 facilities in this analysis, and their proximity to urban centers, the source categories' minority demographics are higher than the national average while individual facilities for a large number of sites will significantly exceed the national average demographics for every group due to being located in urban locations. The results of the demographic analysis for populations within 5 km of the facilities within the source categories indicate that the minority population (being the total population minus the white population) is higher when compared to the national percentage (49 percent versus 40 percent). These comparisons also hold true for other demographic groups (African American, Other and Multiracial Groups, Hispanics, and people living in linguistic isolation). The African American demographic group shows the highest difference when compared to the national average (17 percent vs 12 percent). The remaining demographics identified above were above the national average by 2 percent. The methodology and the results of the demographic analysis are presented in a technical report, *Technology Review—Analysis of Demographic Factors for Populations Living Near the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources Source Categories,* available in this docket for this action (Document ID EPA–HQ–OAR–2021–0016). While demographic analysis shows some population categories that are above the national average, this action is not likely to change levels of emissions near facilities. Based on our technology review, we did not identify any add-on control technologies, process equipment, work practices or procedures that were not previously considered during development of the 2008 Paint Stripping and Miscellaneous Surface Coating at Area Sources NESHAP, and we did not identify developments in practices, processes, or control technologies that would result in additional emission reductions.

V. Request for Comments

The EPA requests comment on all aspects of this proposal, including options for reducing emissions that the EPA may not have considered, as well as information that may improve the Agency's understanding of this source category and inform future actions. Among other things, the EPA requests comment on any new add-on control technologies, process equipment, management practices or procedures not previously identified, including information on the availability, costs, feasibility, and efficacy of such measures. The EPA also requests comment on the availability, cost, and applicability of viable substitutes for methylene chloride for automotive refinishing and aerospace parts manufacturing uses. In addition, the EPA requests data or estimates of emissions from facilities in this source category, including information on how emissions, exposures, and potential controls may differ between the different types of sources covered in this rule (such as differences among types or sizes of automotive refinishing sites, and differences between automotive refinishing and aerospace parts manufacturing sites). Section VI of this preamble provides more information on submitting data.

VI. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposal have been submitted for approval to OMB under the PRA.

The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2268.07. You can find a copy of the ICR in the docket for this action (Docket ID No. EPA–HQ–OAR–2021–0016), and it is briefly summarized here.

As part of the technology review for the NESHAP, the EPA is not proposing to revise the emission limit requirements. The EPA is acknowledging revisions to the SSM provisions that previously applied to the NESHAP and is proposing the use of electronic data reporting for future notifications and reports. This information is being collected to assure compliance with 40 CFR part 63, subpart HHHHHH.

Respondents/affected entities: Facilities performing paint stripping and surface coating operations at area sources.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart HHHHHH).

Estimated number of respondents: In the 3 years after the amendments are final, approximately 39,812 respondents per year would be subject to the

NESHAP and no additional respondents are expected to become subject to the NESHAP during that period.

Frequency of response: The total number of responses in year 1 is 76,388. Years 2 and 3 would have no responses.

Total estimated burden: The average annual burden to the paint stripping and surface coating operations at area source facilities over the 3 years if the amendments are finalized is estimated to be 43,900 hours (per year). The average annual burden to the Agency over the 3 years after the amendments are final is estimated to be 0 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The average annual cost to the facilities is $5,200,000 in labor costs for the first 3 years after the amendments are final. The average annual capital and operation and maintenance (O&M) costs is −$27,100. The total average annual Agency cost over the first 3 years after the amendments are final is estimated to be $0.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The economic impact associated with the proposed requirements in this action for the affected small entities is described in section IV.D. above.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

The EPA has determined, based on discussions with state, local, and tribal governments during site visits during the original rule development, that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, the proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Some state, local, or tribal governments have paint stripping and/or surface coating operations (*e.g.,* municipal fleet vehicle maintenance garages) that may be subject to the requirements of this proposed rule. However, we do not believe that any of them are operated by small government entities. Small government entities are expected to contract for refinishing services when these services are needed, rather than doing this work in-house. In addition, total expenditures for all entities to comply with the proposed rule are estimated to be less than $100 million in any year.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. No tribal facilities are known to be engaged in any of the industries that would be affected by this action. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

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

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

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This rulemaking involves technical standards. We are proposing to amend the Paint Stripping and Miscellaneous Surface Coating Operations at Area Source NESHAP in this action to update references to ASHRAE Method 52.1, ''Gravimetric and Dust-Spot Procedures for Testing Air-Cleaning Devices Used in General Ventilation for Removing Particulate Matter, June 4, 1992, with ANSI/ASHRAE Standard 52.2–2017 Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size. Both methods measure paint booth filter efficiency to measure the capture efficiency of paint overspray arrestors with spray-applied coatings. The EPA is also proposing to include EPA Method 319—Determination of Filtration Efficiency for Paint Overspray Arrestors (Appendix A to 40 CFR part 63), as an alternative to ANSI/ASHRAE Standard 52.2–2017.

The ANSI/ASHRAE standard is available from the American Society of Heating, Refrigerating and Air-Conditioning Engineers 1791 Tullie Circle NE, Atlanta, GA 30329. See *www.ashrae.org.*

Under 40 CFR 63.7(f) and 40 CFR 63.8(f) of subpart A of the General Provisions, a source may apply to the EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures in the final rule or any amendments.

The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The methodology and the results of the demographic analysis are presented in a technical report, *Technology Review—Analysis of Demographic Factors for Populations Living Near the Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources Source Categories,* available in this docket for this action (Document ID EPA–HQ–OAR–2021–0016).

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Appendix A, Hazardous substances, Incorporation by reference, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

[FR Doc. 2021–24203 Filed 11–18–21; 8:45 am]

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FEDERAL REGISTER

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No. 221 November 19, 2021

Part IV

The President

Executive Order 14054—Termination of Emergency With Respect to the Situation in Burundi

Federal Register
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Friday, November 19, 2021

Presidential Documents

Title 3—

The President

Executive Order 14054 of November 18, 2021

Termination of Emergency With Respect to the Situation in Burundi

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code,

I, JOSEPH R. BIDEN JR., President of the United States of America, find that the situation that gave rise to the declaration of a national emergency in Executive Order 13712 of November 22, 2015 (Blocking Property of Certain Persons Contributing to the Situation in Burundi), with respect to the situation in Burundi, including the killing of and violence against civilians, unrest, incitement of imminent violence, and significant political repression, which threatened the peace, security, and stability of Burundi, has been significantly altered by events of the past year, including the transfer of power following elections in 2020, significantly decreased violence, and President Ndayishimiye's pursuit of reforms across multiple sectors. Accordingly, I hereby terminate the national emergency declared in Executive Order 13712, and revoke that order, and further order:

Section 1. In light of the revocation of Executive Order 13712, the suspension of entry as immigrants and nonimmigrants of individuals meeting the criteria set forth in section 1(a) of that order will no longer be in effect as of the date of this order and such individuals will no longer be treated as persons covered by Presidential Proclamation 8693 of July 24, 2011 (Suspension of Entry of Aliens Subject to United Nations Security Council Travel Bans and International Emergency Economic Powers Act Sanctions).

Sec. 2. Pursuant to section 202(a) of the NEA (50 U.S.C. 1622(a)), termination of the national emergency declared in Executive Order 13712 shall not affect any action taken or proceeding pending not finally concluded or determined as of the date of this order, any action or proceeding based on any act committed prior to the date of this order, or any rights or duties that matured or penalties that were incurred prior to the date of this order.

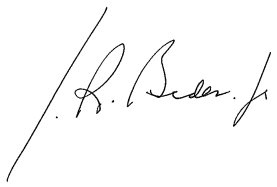
Sec. 3. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
November 18, 2021.

[FR Doc. 2021–25548
Filed 11–18–21; 11:15 am]
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